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	Governance	Data Collection	Data Linkage	Dataset 1 - NHAN Data Sharing	Data Access	Data Use	Data Collection	Data Linkage	Dataset 2 - NSD Data Sharing	DOH Data Access	Data Use	Data Collection	Data Linkage	Dataset 3 - MTF Data Sharing	Data Access	Data Use	Data Collection	Data Linkage	Dataset 4 - AFCA Data Sharing	Data Access	Data Use
1	Authorization/s																				
1.1	Assent	Assent from children authorizes data collection	Assent from children authorize data linkage	Does not s authorize/specify	Does not authorize/specify	Does not authorize/specify	Assent from children authorize data collection	s				Assent from children authorizes data collection	Does not authorize/specify				N/A	N/A	N/A	N/A	N/A
1.2	Consent	Consent from adults authorizes data collection	Consent from adults authorizes data linkage	Does not authorize/specify	Does not authorize/specify	Consent from adults authorizes data use	Consent from adults authorizes data collection					Consent from parents authorizes data collection	Does not authorize/specify			Consent from adults authorizes data use	N/A	N/A	N/A	N/A	N/A
1.3	IRB/equivalent Privacy Board determination	approval authorize	NCHS ERB approva authorizes data linkage	Al NCHS Disclosure Review Board (DRB) authorizes data sharing	N/A	NCHS ERB (IRB) approval authorize data use	RTI (DCC for NSDUH) IRB authorizes data collection					MTF (U-Mich) IRB approval authorizes data collection	Does not authorize/specify	Two IRBs authorize data sharing: 1. ICPSR (U-Mich) IRB 2. MTF (U-Mich) IRB			N/A	N/A	N/A	N/A	N/A
1.4	Local/state/federal law	Four federal laws authorizes data collection: 1. Section 306 of the Public Health Service Act (42 U.S.C. 242k) 2. National Nutrition Monitoring and Related Research Act of 1990 (P.L. 101-445), (October 22, 1990) 3. Food Quality Protection Act of 1996 (P.L. 104-170) 4. Federal Food, Drug, and Cosmetic Act (21 USC 393), Chapter 9)	Confidential Information Protection and Statistical Efficiency Act (CIPSEA) authorizes data sharing through the NCHS RDC	N/A	Designated Agent Agreement (Non- Disclosure CIPSEA Agent Form) authorizes data us	Service Act Section 505 authorizes data collection	n					Does not authorize/specify	Family Educational Rights and Privacy Act (FERPA) authorize data sharing			Social Security Act (Section 479) authorizes data collection by states and Tribal agencies				
1.5	Institutional Certification												Does not authorize/specify				N/A	N/A	N/A	N/A	N/A
1.6	Data originator agreement			Two agreements authorize data sharing from NCHS/NHANES collaborators that are authorized to review pre-release data that they contributed: 1. NCHS non- disclosure affidavit 2. Data Sharing Agreement									Does not authorize/specify	N/A			N/A	N/A	N/A	N/A	N/A

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	Governance			Dataset 1 - NHAN	NES				Dataset 2 - NSD	JH				Dataset 3 - MTF				Dataset 4 - AFCA	RS	
1.7	Repository	Data Collection		Data Sharing	Data Access N/A	Data Use/Access	Data Collection	Data Linkage	Data Sharing	Data Access Two repository	RDC Data Access	Data Collection	Data Linkage Does not	Data Sharing Data Access NAHDAP Restricte		Data Collection	Data Linkage N/A	Data Sharing N/A	Data Access 1. Contractual	Data Use NDACAN Terms of
	agreements/policies					Agreement (Rules of Behavior) authorizes data use				agrements authorize data access: 1. Data Access Agreement (DAA) form 2. For students, the SAMHSA RDC Student Data Use Acknowledgement form signed by th student and their advisor	r t		authorize/specify	Data Use Agreement for Restricted Data in the Virtual Data Enclave (NAHDAP VDE RDUA) authorizes data access	the Virtual Data				agreement between Children's Bureau and NDACAN 2. NDACAN Terms of Use Agreement	Use Agreement authorizes data use
1.8	Other (specify)		DHANES/NHANES approval authorizes data linkage	S	Data Use/Access Agreement (Rules of Behavior) authorizes data access	-								MTF PI authorizes data sharing (through the ICPSR VDE) VDE) VDE)			authorize/specify	Contractual agreement between NDACAN and Children's Bureau authorizes data sharing	Two repository agreements authorize data access: 1. Contractual agreement between Children's Bureau and NDACAN 2. NDACAN Terms of Use Agreement	
2	Applicable Regulation	ons/Policies																		
2.1		N/A		NHANES Protected Data Policy	1. NHANES Protected Data Policy 2. NCHS RDC policy	NCHS RDC policy	SAMHSA recommendation													
2.2	Tribal regulations/policies	N/A	N/A	N/A	N/A	N/A											N/A	N/A	N/A	N/A
2.3	State regulations/policies	N/A									Confidential Information Protection and Statistical Efficiency Act (CIPSEA)									
2.4		 Section 306 of the Public Health Service Act (42 U.S.C. 242k) National Nutrition Monitoring and Related Research Act of 1990 (P.L. 101-445), (October 22, 1990) Food Quality Protection Act of 1996 (P.L. 104-170) Federal Food, Drug, and Cosmetic Act (21 USC 393), Chapter 9)	1. Section 308(d) Public Health Act 2. Confidential Information Protection and Statistical Efficiency Act (CIPSEA)	the Public Health Service Act 2. Confidential Information	Service Act 2. Confidential	f Confidential Information Protection and Statistical Efficiency Act (CIPSEA)		Confidential Information Protection and Statistical Efficiency Act (CIPSEA)	Confidential Information Protection and Statistical Efficiency Act (CIPSEA)				1. Grant of Confidentality from the U.S. Department of Justice 2. Family Educational Rights and Privacy Act (FERPA)	Grant of Confidentality from the U.S. Department of Justice	45 CFR 1355.40 D46				
2.5	International regulations/policies	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A N/A	N/A	N/A	N/A	N/A	N/A	N/A

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								[Legend: Blank		: USE CASE 1 -			firmed to not exist						
	Governance			Dataset 1 - NHAN	ES				Dataset 2 - NSD					Dataset 3 - MT	F				Dataset 4 -
3.5	How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.)	Data Collection Does not authorize/specify	Data Linkage Does not authorize/specify	Data Sharing NHANES Protected Data Policy specifies	Data Access	Does not authorize/specify	Data Collection	Data Linkage	Data Sharing	Data AccessSAMHSA RDCspecifies that fordata access, auser:1. Submit RDCapplication2. Obtain approvalfrom SAMHSA staffon the researchproposed in theRDC application3. Sign andcompleteDesignated AgentForm (DAF)4. Sign andcomplete DataAccess Agreement(DAA) form5. Completeconfidentialitytraining6. Students andtheir advisors musalso sign theSAMHSA RDCStudent Data UserAcknowledgementform7. Access data onlythrough RDC	f t t	Data Collection Does not authorize/specify	Data Linkage Does not authorize/specify	Data SharingICPSR/NAHDAPspecifies that fordata access, a use1. Must executeNAHDAP VDERDUA betweenICPSR (U-Mich) anthe researcher'sinstitution2. Must only accessdata through theICPSR VDE (virtualenclave)	Data AccessICPSR/NAHDAPspecifies that forcdata accessedthrough the ICPSRVDE, a user:1. Must executeNAHDAP VDERDUA betweenICPSR (U-Mich) anthe researcher'sinstitution2. Must only accessdata through theBICPSR VDE (virtualenclave)3. Must obtain IREapproval orexemption fromthe researcher'sinstitution4. Must obtainreview and	d s	Data Collection	Data Linkage	Data Sha
3.6	How data can be used (including data use limitations)	Assent/Consent specifies that the data can be used for statistical reporting and analysis (includes broad research)	Does not authorize/specify	Public Health Service Act specifies that NCHS data containing personal information cannot be used for any purpose other than what was described to survey participants. CIPSEA specifies that	NCHS data containing personal information cannot be used for any purpose other than what was	 308(d) Public Health Service Act [42 U.S.C. 242m(d)], and Confidential Information Protection and Statistical Efficiency Act (CIPSEA) specify that the data can 						be used for broad research	authorize/specify	data can be used	NAHDAP/ICPSR specifies that the data can be used for broad research	RDUA specify that			Does not authorize/sp

- AFCAR	S	
haring	Data Access	Data Use
	Contractural	
	agreement	
	between NDACAN	
	and Children's	
	Bureau specifies	
	that for data accessed:	
	1. User must	
	execute of the	
	NDACAN Terms of	
	Use Agreement	
	2. User must obtain	
	review and	
	approval from NDACAN staff on	
	the proposed	
	research	
	NDACAN Terms of	NDACAN Terms of
specify	Use Agreement	Use Agreement
specify	specifies that the	specifies that the
	data can be used by	
	researchers in	by researchers in
	accordance with	accordance with
	their approved	their approved
	research described	research described
	in Section I.1 of the	in Section I.1 of the
	Terms of Use	Terms of Use
	Agreement	Agreement

								[Legend: Blank				GOVERNANCE /A = information conf	irmed to not exist	:]							
	Governance			Dataset 1 - NHA	NES				Dataset 2 - NSD	DUH				Dataset 3 - M	TF				Dataset 4 - AFCAF	RS	
		Data Collection	Data Linkage	Data Sharing	Data Access	Data Use	Data Collection	Data Linkage	Data Sharing	Data Access	Data Use	Data Collection	Data Linkage	Data Sharing	Data Access	Data Use	Data Collection	Data Linkage	Data Sharing	Data Access	Data Use
3.7	Other (specify)	Does not	Does not	Does not		Does not	SAMHSA														
		authorize/specify	authorize/specify	authorize/specify		authorize/specify	recommends against comparing														
							2020 NSDUH data														
							with prior years due to														
							methodological														
							changes														

Definitions: Limitations are restrictions on data linkage and use (e.g., dataset must only be linked with other disease-relevant data, dataset must be used in a physical enclave, etc.). Controls are processes established to ensure compliance with governance for data sharing, access, and use (e.g., user must access data in a physical enclave, user must sign data use agreement, user must receive data access committee approval, etc.). Authorization gaps exist when there is no explicit authorization or the authorization is not available or found in the information collected by the project team for various data life cycle stages (data collection, linking, sharing, access and use).

	Can the datasets be linked?	What limitations do the linked datasets inherit?	What controls do the linked dataset require?	Wh
NHANES (Dataset	Yes, NHANES and NSDUH can be linked provided:	Researchers/users:	For sharing NHANES, NCHS RDC staff must:	2a. For NSD
1) and NSDUH		1a. Can only link NHANES data to vital statistics, health,	1a. Share NHANES data de-identified of all direct	linkage and
(Dataset 2)	A. NCHS RDC staff:	nutrition, and other related records [NHANES]	identifiers; certain indirect identifiers (geography)	
linkage	1. Shares de-identified data except for certain	1b. Must use NHANES data within the NCHS RDC (on-	may be included [NHANES]	
	indirect identifiers (geography)for NHANES	site enclave) [NHANES]	1b. Perform disclosure review prior to sharing the	
	through the RDC [Control 1a]	1c. Must use NHANES data only for health statistical	NHANES restricted-use data through the RDC	
		reporting and analysis [NHANES]	(NCHS Disclosure Review Board/NCHS	
	Review Board/NCHS Confidentiality Officer prior		Confidentiality Officer) [NHANES]	
	to sharing the NHANES restricted-use data	2a. Must use NSDUH data within the NCHS RDC	1c. Perform disclosure review of the output before	
	through the RDC [Control 1b]	[NSDUH]	releasing it (RDC and DHANES) [NHANES]	
	3. Performs disclosure review of the output by	2b. Must use NSDUH data only for health statistical		
	RDC and DHANES before releasing that output	reporting and analysis [NSDUH]	For accessing NHANES, researchers/users must:	
	[Control 1c]		1d. Obtain approvals from NCHS Confidentiality	
			Officer, NCHS RDC, and DHANES/NHANES on the	
	B. The researcher/user:		proposed research [NHANES]	
	1. Obtains authorization for data linkage and		1e. Execute Data Use/Access Agreement (Rules of	
	sharing for NSDUH [Authorization gap 2a] -		Behavior) [NHANES]	
	Assumption		1f. Sign Designated Agent Agreement [NHANES]	
	2. Links NHANES dataset only to vital statistics,		1g. Complete confidentiality training [NHANES]	
	health, nutrition, and other related records		1h. Access data only within NCHS RDC (on-site	
	[Limitation 1a]		enclave) [NHANES]	
	3. Uses NHANES and NSDUH data within the NCHS			
	RDC [Limitations 1b, 2a, Controls 1h, 2g]		For accessing NSDUH, researchers/users must:	
	4. Uses the linked NHANES and NSDUH data only		2a. Submit RDC application [NSDUH]	
	for health statistical reporting and analysis		2b. Obtain approval from SAMHSA staff on the	
	[Limitations 1c, 2b]		research proposed in the RDC application [NSDUH]	
	5. Submits RDC application [Control 2a]		2c. Sign Designated Agent Form (DAF) [NSDUH]	
	6. Obtains approvals from NCHS Confidentiality		2d. Sign Data Access Agreement (DAA) [NSDUH]	
	Officer, NCHS RDC, DHANES/NHANES, and		2e. Complete confidentiality training [NSDUH]	
	SAMHSA staff on the proposed linkage [Controls		2f. Sign the SAMHSA RDC Student Data User	
	1d, 2b]		Acknowledgement form and obtain advisor's	
	7. Signs the NHANES Data Use/Access Agreement,		signature, if researcher/user is a student [NSDUH]	
	NHANES Designated Agent Agreement, NSDUH		2g. Access data within NCHS RDC [NSDUH]	
	Designated Agent Form, NSDUH Data Access			
	Agreement (DAA); and if the researcher/user is a			
	student, signs the SAMHSA RDC Student Data User			
	Acknowledgement form along with their advisor			
	[Controls 1e, 1f, 2c, 2d, 2f]			
	8. Completes confidentiality training for NHANES			
	and NSDUH data access [Controls 1g, 2e]			

hat authorization gaps exist?

SDUH, information on authorizations for nd sharing is not available/found.

Definitions: Limitations are restrictions on data linkage and use (e.g., dataset must only be linked with other disease-relevant data, dataset must be used in a physical enclave, etc.). Controls are processes established to ensure compliance with governance for data sharing, access, and use (e.g., user must access data in a physical enclave, user must sign data use agreement, user must receive data access committee approval, etc.). Authorization gaps exist when there is no explicit authorization or the authorization is not available or found in the information collected by the project team for various data life cycle stages (data collection, linking, sharing, access and use).

	Can the datasets be linked?	What limitations do the linked datasets inherit?	What controls do the linked dataset require?	Wha
NHANES (Dataset	Yes, NHANES and MTF can be linked provided:	Researchers/users:	For sharing NHANES, NCHS RDC staff must:	3a. For MTF,
1) and MTF		1a. Can only link NHANES data to vital statistics, health,	1a. Share NHANES data de-identified of all direct	linkage is not
(Dataset 3)	A. NCHS RDC staff:	nutrition, and other related records [NHANES]	identifiers; certain indirect identifiers (geography)	
linkage	1. Shares de-identified data except for certain	1b. Must use NHANES data within the NCHS RDC (on-	may be included [NHANES]	
	indirect identifiers (geography)for NHANES through	site enclave) [NHANES]	1b. Perform disclosure review prior to sharing the	
	the RDC [Control 1a]	1c. Must use NHANES data only for health statistical	NHANES restricted-use data through the RDC	
	2. Performs disclosure review by NCHS Disclosure	reporting and analysis [NHANES]	(NCHS Disclosure Review Board/NCHS	
	Review Board/NCHS Confidentiality Officer prior		Confidentiality Officer) [NHANES]	
	to sharing the NHANES restricted-use data	3a. Must use MTF data for broad research or statistical	1c. Perform disclosure review of the output before	
	through the RDC [Control 1b]	purposes [MTF]	releasing it (RDC and DHANES) [NHANES]	
	3. Performs disclosure review of the output by			
	RDC and DHANES before releasing that output		For sharing MTF, ICPSR/NAHDAP staff must:	
	[Control 1c]		3a. Share fully de-identified data (for MTF	
			restricted-use data, this does not include state and	
	B. ICPSR/NAHDAP staff:		zipcode) [MTF]	
	4. Shares fully de-identified data (for MTF		3b. Perform disclosure review prior to sharing	
	restricted-use data, this does not include state and	1	[MTF]	
	zipcode) [Control 3a]		3c. Perform disclosure review of analysis outputs	
	5. Performs disclosure review prior to sharing		prior to removing output data from the VDE [MTF]	
	[Control 3b]			
	6. Performs disclosure review of analysis outputs		For accessing NHANES, researchers/users must:	
	prior to removing output data from the VDE		1d. Obtain approvals from NCHS Confidentiality	
	[Control 3c]		Officer, NCHS RDC, and DHANES/NHANES on the	
			proposed research [NHANES]	
	C. The researcher/user:		1e. Execute Data Use/Access Agreement (Rules of	
	1. Obtains authorization for linking MTF data		Behavior) [NHANES]	
	[Authorization gap 3a] - Assumption		1f. Sign Designated Agent Agreement [NHANES]	

'hat authorization gaps exist?

F, information on authorizations for not available/found.

Definitions: Limitations are restrictions on data linkage and use (e.g., dataset must only be linked with other disease-relevant data, dataset must be used in a physical enclave, etc.). Controls are processes established to ensure compliance with governance for data sharing, access, and use (e.g., user must access data in a physical enclave, user must sign data use agreement, user must receive data access committee approval, etc.). Authorization gaps exist when there is no explicit authorization or the authorization is not available or found in the information collected by the project team for various data life cycle stages (data collection, linking, sharing, access and use).

Can the datasets be linked?	What limitations do the linked datasets inherit?	What controls do the linked dataset require?	Wha
2. Links NHANES dataset only to vital statistics,		1g. Complete confidentiality training [NHANES]	
health, nutrition, and other related records		1h. Access data only within NCHS RDC (on-site	
[Limitation 1a]		enclave) [NHANES]	
3. Uses/access NHANES data within NCHS RDC and			
obtain approval from ICPSR/NAHDAP to export		For accessing MTF, researchers/users must:	
MTF data into NCHS RDC [Limitations 1b, Controls		3d. Execute NAHDAP VDE RDUA between ICPSR (U-	
1h, 3e] - Assumption for MTF		Mich) and the researcher's institution [MTF]	
4. Uses the linked NHANES and MTF data only for		3e. Access data only through the ICPSR VDE	
statistical purposes [Limitations 1c, 3a]		(virtual enclave) [MTF]	
5. Obtains approvals from NCHS Confidentiality		3f. Obtain IRB approval or exemption from the	
Officer, NCHS RDC, DHANES/NHANES, and		researcher's institution for data access [MTF]	
ICPSR/NAHDAP staff on the proposed linkage		3g. Obtain review and approval from NAHDAP on	
[Controls 1d, 3g]		the proposed research [MTF]	
6. Signs the NHANES Data Use/Access Agreement,			
NHANES Designated Agent Agreement, and			
NAHDAP VDE RDUA [Controls 1e, 1f, 3d]			
7. Completes confidentiality training for NHANES			
data access [Control 1g]			
8. Obtains IRB approval or exemption from their			
institution for accessing MTF [Control 3f]			

hat authorization gaps exist?

Definitions: Limitations are restrictions on data linkage and use (e.g., dataset must only be linked with other disease-relevant data, dataset must be used in a physical enclave, etc.). Controls are processes established to ensure compliance with governance for data sharing, access, and use (e.g., user must access data in a physical enclave, user must sign data use agreement, user must receive data access committee approval, etc.). Authorization gaps exist when there is no explicit authorization or the authorization is not available or found in the information collected by the project team for various data life cycle stages (data collection, linking, sharing, access and use).

	Can the datasets be linked?	What limitations do the linked datasets inherit?	What controls do the linked dataset require?	Wha
NHANES (Dataset	Yes, NHANES and AFCARS can be linked provided:	Researchers/users:	For sharing NHANES, NCHS RDC staff must:	4a. For AFCA
1) and AFCARS		1a. Can only link NHANES data to vital statistics, health,	1a. Share NHANES data de-identified of all direct	linkage is no
(Dataset 4)	A. NCHS RDC staff:	nutrition, and other related records [NHANES]	identifiers; certain indirect identifiers (geography)	
linkage	1. Shares de-identified data except for certain	1b. Must use NHANES data within the NCHS RDC (on-	may be included [NHANES]	
	indirect identifiers (geography)for NHANES	site enclave) [NHANES]	1b. Perform disclosure review prior to sharing the	
	through the RDC [Control 1a]	1c. Must use NHANES data only for health statistical	NHANES restricted-use data through the RDC	
	2. Performs disclosure review by NCHS Disclosure	reporting and analysis [NHANES]	(NCHS Disclosure Review Board/NCHS	
	Review Board/NCHS Confidentiality Officer prior		Confidentiality Officer) [NHANES]	
	to sharing the NHANES restricted-use data	4a. Must use AFCARS data in accordance with their	1c. Perform disclosure review of the output before	
	through the RDC [Control 1b]	approved research described in Section I.1 of the	releasing it (RDC and DHANES) [NHANES]	
	3. Performs disclosure review of the output by	NDACAN Terms of Use Agreement [AFCARS]		
	RDC and DHANES before releasing that output		For sharing AFCARS, NDACAN staff must:	
	[Control 1c]		4a. Share AFCARS data de-identified of all 18	
			HIPAA identifiers. [AFCARS]	
	B. NDACAN staff:		4b. Perform disclosure review of data prior to	
	4. Shares AFCARS data de-identified of all 18		sharing (removing county FIPS code with >1,000	
	HIPAA identifiers. [Control 4a]		records, recode DoB to the 15th and adjust all	
	5. Performs disclosure review of data prior to		other dates accordingly). [AFCARS]	
	sharing (removing county FIPS code with >1,000			
	records, recode DoB to the 15th and adjust all		For accessing NHANES, researchers/users must:	
	other dates accordingly). [Control 4b]		1d. Obtain approvals from NCHS Confidentiality	
			Officer, NCHS RDC, and DHANES/NHANES on the	
	C. The researcher/user:		proposed research [NHANES]	
	1. Obtains authorization for linking AFCARS data		1e. Execute Data Use/Access Agreement (Rules of	
	[Authorization gap 4a] - Assumption		Behavior) [NHANES]	
	2. Links NHANES dataset only to vital statistics,		1f. Sign Designated Agent Agreement [NHANES]	
	health, nutrition, and other related records		1g. Complete confidentiality training [NHANES]	

'hat authorization gaps exist?

CARS, information on authorizations for not available/found.

Definitions: Limitations are restrictions on data linkage and use (e.g., dataset must only be linked with other disease-relevant data, dataset must be used in a physical enclave, etc.). Controls are processes established to ensure compliance with governance for data sharing, access, and use (e.g., user must access data in a physical enclave, user must sign data use agreement, user must receive data access committee approval, etc.). Authorization gaps exist when there is no explicit authorization or the authorization is not available or found in the information collected by the project team for various data life cycle stages (data collection, linking, sharing, access and use).

Can the datasets be linked?	What limitations do the linked datasets inherit?	What controls do the linked dataset require?	Wha
[Limitation 1a] 3. Uses/access NHANES and AFCARS data within NCHS RDC [Limitation 1b, Control 1h] 4. Uses the linked NHANES and AFCARS data only for statistical reporting and analysis [Limitations 1c, 4a] 5. Obtains approval from NCHS Confidentiality Officer, NCHS RDC, DHANES/NHANES, and NDACAN staff on the proposed linkage [Controls 1d, 4d] 6. Signs the NHANES Data Use/Access Agreement, NHANES Designated Agent Agreement, NDACAN Terms of Use Agreement [Controls 1e, 1f, 4c] 7. Completes confidentiality training for NHANES data access [Controls 1g]		 1h. Access data only within NCHS RDC (on-site enclave) [NHANES] For accessing AFCARS, researchers/users must: 4c. Execute of the NDACAN Terms of Use Agreement. [AFCARS] 4d. Obtain review and approval from NDACAN staff on the proposed research. [AFCARS] 	

hat authorization gaps exist?

Definitions: Limitations are restrictions on data linkage and use (e.g., dataset must only be linked with other disease-relevant data, dataset must be used in a physical enclave, etc.). **Controls** are processes established to ensure compliance with governance for data sharing, access, and use (e.g., user must access data in a physical enclave, user must sign data use agreement, user must receive data access committee approval, etc.). **Authorization gaps** exist when there is no explicit authorization or the authorization is not available or found in the information collected by the project team for various data life cycle stages (data collection, linking, sharing, access and use).

	Can the datasets be linked?	What limitations do the linked datasets inherit?	What controls do the linked dataset require?
NSDUH (Dataset	Yes, NSDUH and MTF can be linked provided:	Researchers/users:	For sharing MTF, ICPSR/NAHDAP staff must: 2a. For
2) and MTF		2a. Must use NSDUH data within the NCHS RDC	3a. Share fully de-identified data (for MTF linkage
(Dataset 3)	A. ICPSR/NAHDAP staff:	[NSDUH]	restricted-use data, this does not include state and 3a. For
linkage	1. Shares fully de-identified data (for MTF	2b. Must use NSDUH data only for health statistical	zipcode) [MTF] linkage
	restricted-use data, this does not include state and	reporting and analysis [NSDUH]	3b. Perform disclosure review prior to sharing
	zipcode) [Control 3a]		[MTF]
	2. Performs disclosure review prior to sharing	3a. Must use MTF data for broad research or statistical	3c. Perform disclosure review of analysis outputs
	[Control 3b]	purposes [MTF]	prior to removing output data from the VDE [MTF]
	3. Performs disclosure review of analysis outputs		
	prior to removing output data from the VDE		For accessing NSDUH, researchers/users must:
	[Control 3c]		2a. Submit RDC application [NSDUH]
			2b. Obtain approval from SAMHSA staff on the
	B. The researcher/user:		research proposed in the RDC application [NSDUH]
	1. Obtains authorization for data linkage and		2c. Sign Designated Agent Form (DAF) [NSDUH]
	sharing for NSDUH and authorization for linking		2d. Sign Data Access Agreement (DAA) [NSDUH]
	[Authorization gap 2a, 3a] - Assumption		2e. Complete confidentiality training [NSDUH]
	2. Uses NSDUH data within NCHS RDC and obtain		2f. Sign the SAMHSA RDC Student Data User
	approval from ICPSR/NAHDAP to export MTF data		Acknowledgement form and obtain advisor's
	into NCHS RDC [Limitations 2a, Controls 2g, 3e] -		signature, if researcher/user is a student [NSDUH]
	Assumption for MTF		2g. Access data within the NCHS RDC [NSDUH]
	3. Uses the linked NSDUH and MTF data only for		
	statistical purposes [Limitations 2b, 3a]		For accessing MTF, researchers/users must:
	5. Submits RDC application [Control 2a]		3d. Execute NAHDAP VDE RDUA between ICPSR (U-
	6. Obtains approvals from SAMHSA staff and		Mich) and the researcher's institution [MTF]
	NAHDAP staff on the proposed linkage [Controls		3e. Access data only through the ICPSR VDE
	2b, 3g]		(virtual enclave) [MTF]
	7. Signs the NSDUH Designated Agent Form,		3f. Obtain IRB approval or exemption from the
	NSDUH Data Access Agreement (DAA); and if the		researcher's institution [MTF]
	researcher/user is a student, signs the SAMHSA		3g. Obtain review and approval from NAHDAP on
	RDC Student Data User Acknowledgement form		the proposed research [MTF]
	along with their advisors; and signs NAHDAP VDE		
	RDUA [Controls 2c, 2d, 2f, 3d]		
	8. Completes confidentiality training for NSDUH		
	data access [Controls 2e]		
	9. Obtains IRB approval or exemption from their		
	institution for accessing MTF [Control 3f]		

/hat authorization gaps exist?

SDUH, information on authorizations for nd sharing is not available/found. TF, information on authorizations for not available/found.

Definitions: Limitations are restrictions on data linkage and use (e.g., dataset must only be linked with other disease-relevant data, dataset must be used in a physical enclave, etc.). **Controls** are processes established to ensure compliance with governance for data sharing, access, and use (e.g., user must access data in a physical enclave, user must sign data use agreement, user must receive data access committee approval, etc.). **Authorization gaps** exist when there is no explicit authorization or the authorization is not available or found in the information collected by the project team for various data life cycle stages (data collection, linking, sharing, access and use).

		Can the datasets be linked?	What limitations do the linked datasets inherit?	What controls do the linked dataset require?	What
5	NSDUH (Dataset	Yes, NSDUH and AFCARS can be linked provided:	Researchers/users:	For sharing AFCARS, NDACAN staff must: 22	a. For NSDL
	2) and AFCARS		2a. Must use NSDUH data within the NCHS RDC	4a. Share AFCARS data de-identified of all 18	nkage and s
	(Dataset 4)	A. NDACAN staff:	[NSDUH]	HIPAA identifiers. [AFCARS] 4a	a. For AFCA
	linkage	1. Shares AFCARS data de-identified of all 18	2b. Must use NSDUH data only for health statistical	4b. Perform disclosure review of data prior to	nkage is no
		HIPAA identifiers. [Control 4a]	reporting and analysis [NSDUH]	sharing (removing county FIPS code with >1,000	
		2. Performs disclosure review of data prior to		records, recode DoB to the 15th and adjust all	
		sharing (removing county FIPS code with >1,000	4a. Must use AFCARS data in accordance with their	other dates accordingly). [AFCARS]	
		records, recode DoB to the 15th and adjust all	approved research described in Section I.1 of the		
		other dates accordingly). [Control 4b]	NDACAN Terms of Use Agreement [AFCARS]	For accessing NSDUH, researchers/users must:	
				2a. Submit RDC application [NSDUH]	
		B. The researcher/user:		2b. Obtain approval from SAMHSA staff on the	
		1. Obtains authorization for data linkage and		research proposed in the RDC application [NSDUH]	
		sharing for NSDUH and obtains authorization for		2c. Sign Designated Agent Form (DAF) [NSDUH]	
		linking AFCARS [Authorization gaps 2a, 4a] -		2d. Sign Data Access Agreement (DAA) [NSDUH]	
		Assumption		2e. Complete confidentiality training [NSDUH]	
		2. Uses the NSDUH and AFCARS data within NCHS		2f. Sign the SAMHSA RDC Student Data User	
		RDC [Limitation 2a, Control 2g]		Acknowledgement form and obtain advisor's	
		3. Uses the linked NSDUH and AFCARS data only		signature, if researcher/user is a student [NSDUH]	
		for health statistical reporting and analysis		2g. Access data within NCHS RDC [NSDUH]	
		[Limitations 2b, 4a]			
		5. Submits RDC application [Control 2a]		For accessing AFCARS, researchers/users must:	
		6. Obtains approvals from SAMHSA staff and		4c. Execute of the NDACAN Terms of Use	
		NDACAN staff on the proposed linkage [Controls		Agreement. [AFCARS]	
		2b, 4d]		4d. Obtain review and approval from NDACAN	
		7. Signs the NSDUH Designated Agent Form,		staff on the proposed research. [AFCARS]	
		NSDUH Data Access Agreement (DAA); and if the			
		researcher/user is a student, signs the SAMHSA			
		RDC Student Data User Acknowledgement form			
		along with their advisors; and signs NDACAN			
		Terms of Use Agreement [Controls 2c, 2d, 2f, 4c]			
		8. Completes confidentiality training for NSDUH			
		data access [Control 2e]			

hat authorization gaps exist?

SDUH, information on authorizations for nd sharing is not available/found. CARS, information on authorizations for not available/found.

Definitions: Limitations are restrictions on data linkage and use (e.g., dataset must only be linked with other disease-relevant data, dataset must be used in a physical enclave, etc.). **Controls** are processes established to ensure compliance with governance for data sharing, access, and use (e.g., user must access data in a physical enclave, user must sign data use agreement, user must receive data access committee approval, etc.). **Authorization gaps** exist when there is no explicit authorization or the authorization is not available or found in the information collected by the project team for various data life cycle stages (data collection, linking, sharing, access and use).

		Can the datasets be linked?	What limitations do the linked datasets inherit?	What controls do the linked dataset require?	Wha
6	MTF (Dataset 3)	Yes, MTF and AFCARS can be linked provided:	Researchers/users:	For sharing MTF, ICPSR/NAHDAP staff must:	3a. For MTF,
	and AFCARS		3a. Must use MTF data for broad research or statistical	3a. Share fully de-identified data (for MTF	linkage is not
	(Dataset 4)	A. ICPSR/NAHDAP staff must:	purposes [MTF]	restricted-use data, this does not include state and	4a. For AFCA
	linkage	1. Shares fully de-identified data (for MTF		zipcode) [MTF]	linkage is not
		restricted-use data, this does not include state and	4a. Must use AFCARS data in accordance with their	3b. Perform disclosure review prior to sharing	
		zipcode) [Control 3a]	approved research described in Section I.1 of the	[MTF]	
		2. Performs disclosure review prior to sharing	NDACAN Terms of Use Agreement [AFCARS]	3c. Perform disclosure review of analysis outputs	
		[Control 3b]		prior to removing output data from the VDE [MTF]	
		3. Performs disclosure review of analysis outputs			
		prior to removing output data from the VDE		For sharing AFCARS, NDACAN staff must:	
		[Control 3c]		4a. Share AFCARS data de-identified of all 18	
				HIPAA identifiers. [AFCARS]	
		B. NDACAN staff:		4b. Perform disclosure review of data prior to	
		4. Shares AFCARS data de-identified of all 18		sharing (removing county FIPS code with >1,000	
		HIPAA identifiers. [Control 4a]		records, recode DoB to the 15th and adjust all	
		5. Performs disclosure review of data prior to		other dates accordingly). [AFCARS]	
		sharing (removing county FIPS code with >1,000			
		records, recode DoB to the 15th and adjust all		For accessing MTF, researchers/users must:	
		other dates accordingly). [Control 4b]		3d. Execute NAHDAP VDE RDUA between ICPSR (U-	-
		C. The researcher/user:		Mich) and the researcher's institution [MTF]	
		1. Obtains authorization for linking MTF and		3e. Access data only through the ICPSR VDE (virtual enclave) [MTF]	
		AFCARS data [Authorization gaps 3a, 4a] -		3f. Obtain IRB approval or exemption from the	
		Assumption		researcher's institution [MTF]	
		2. Uses the linked data for broad research or		3g. Obtain review and approval from NAHDAP on	
		statistical purposes [Limitation 3a]		the proposed research [MTF]	
		3. Obtain approvals from ICPSR/NAHDAP and			
		NDACAN staff on the proposed linkages		For accessing AFCARS, researchers/users must:	
		[Limitation 4a, Controls 3g, 4d]		4c. Execute of the NDACAN Terms of Use	
		4. Uses/accesses the MTF and AFCARS data in the		Agreement. [AFCARS]	
		ICPSR VDE [Control 3e]		4d. Obtain review and approval from NDACAN	
		5. Signs NAHDAP VDE RDUA and NDACAN Terms of		staff on the proposed research. [AFCARS]	
		Use Agreement [Controls 3d and 4c]			
		6. Obtains IRB approval or exemption from their			
		institution for accessing MTF [Control 3f]			

'hat authorization gaps exist?

TF, information on authorizations for not available/found. CARS, information on authorizations for not available/found.

Definitions: Limitations are restrictions on data linkage and use (e.g., dataset must only be linked with other disease-relevant data, dataset must be used in a physical enclave, etc.). **Controls** are processes established to ensure compliance with governance for data sharing, access, and use (e.g., user must access data in a physical enclave, user must sign data use agreement, user must receive data access committee approval, etc.). **Authorization gaps e**xist when there is no explicit authorization or the authorization is not available or found in the information collected by the project team for various data life cycle stages (data collection, linking, sharing, access and use).

Can the datasets be linked? What limitations do the linked datasets inherit? What controls do the linked dataset require? All datasets Yes, NHANES, NSDUH, MTF, and AFCARS can be **Researchers/users:** For sharing NHANES, NCHS RDC staff must: linked provided: 1a. Can only link NHANES data to vital statistics, health, 1a. Share NHANES data de-identified of all direct nutrition, and other related records [NHANES] identifiers; certain indirect identifiers (geography) NCHS RDC/ICPSR-NAHDAP/NDACAN staff: 1b. Must use NHANES data within the NCHS RDC (onmay be included [NHANES] 1. Shares NHANES, MTF and AFCARS data desite enclave) [NHANES] 1b. Perform disclosure review prior to sharing the identified of all direct identifiers 1c. Must use NHANES data only for health statistical NHANES restricted-use data through the RDC for NHANES, certain indirect identifiers reporting and analysis [NHANES] (NCHS Disclosure Review Board/NCHS Confidentiality Officer) [NHANES] (geography) may be included 2a. Must use NSDUH data within the NCHS RDC 1c. Perform disclosure review of the output before for MTF, state and zipcode may be included [NSDUH] releasing it (RDC and DHANES) [NHANES] [Controls 1a, 3a, 4a] 2. Performs disclosure review prior to sharing of 2b. Must use NSDUH data only for health statistical (a) NHANES data by NCHS Disclosure Review For sharing MTF, ICPSR/NAHDAP staff must: reporting and analysis [NSDUH] Board/NCHS Confidentiality Officer, (b) MTF 3a. Share fully de-identified data (for MTF data, and (c) AFCARS data (removing county FIPS 3a. Must use MTF data for broad research or statistical restricted-use data, this does not include state and code with >1,000 records, recode DoB to the 15th zipcode) [MTF] purposes [MTF] and adjust all other dates accordingly) [Controls 3b. Perform disclosure review prior to sharing 1b, 3b, 4b] 4a. Must use AFCARS data in accordance with their [MTF] approved research described in Section I.1 of the 3. Reaches agreement with NHANES and MTF 3c. Perform disclosure review of analysis outputs data sources on an approach to perform NDACAN Terms of Use Agreement [AFCARS] prior to removing output data from the VDE [MTF] disclosure review that meets each data sources' requirements and appropriately addresses any For sharing AFCARS, NDACAN staff must: increased re-identifiability risk introduced by 4a. Share AFCARS data de-identified of all 18 linking these datasets [Controls 1c, 3c] HIPAA identifiers. [AFCARS] 4b. Perform disclosure review of data prior to sharing (removing county FIPS code with >1,000 The researcher/user: 1. Obtains authorizations for linkage and sharing records, recode DoB to the 15th and adjust all for NSDUH and obtains authorization for linking other dates accordingly). [AFCARS]

What authorization gaps exist?

2a. For NSDUH, information on authorizations for linkage and sharing is not available/found.
3a. For MTF, information on authorizations for linkage is not available/found.
4a. For AFCARS, information on authorizations for linkage is not available/found.

Definitions: Limitations are restrictions on data linkage and use (e.g., dataset must only be linked with other disease-relevant data, dataset must be used in a physical enclave, etc.). Controls are processes established to ensure compliance with governance for data sharing, access, and use (e.g., user must access data in a physical enclave, user must sign data use agreement, user must receive data access committee approval, etc.). Authorization gaps exist when there is no explicit authorization or the authorization is not available or found in the information collected by the project team for various data life cycle stages (data collection, linking, sharing, access and use).

Can the datasets be linked?	What limitations do the linked datasets inherit?	What controls do the linked dataset require?	Wha
for MTF and AFCARS [Authorization gaps 2a, 3a,			
4a] - Assumption		For accessing NHANES, researchers/users must:	
2. Ensures that NSDUH, MTF and AFCARS data		1d. Obtain approvals from NCHS Confidentiality	
used for linking to NHANES data must be either		Officer, NCHS RDC, and DHANES/NHANES on the	
vital statistics, health, nutrition, or other related		proposed research [NHANES]	
records [Limitation 1a]		1e. Execute Data Use/Access Agreement (Rules of	
3. Uses NHANES, NSDUH, MTF (after obtaining		Behavior) [NHANES]	
permission from ICPSR/NAHDAP staff) and AFCARS		1f. Sign Designated Agent Agreement [NHANES]	
data within NCHS RDC [Limitations 1b, 2a, Controls		1g. Complete confidentiality training [NHANES]	
1h, 2g, 3e] - Assumption for MTF		1h. Access data within NCHS RDC (on-site enclave)	
4. Uses linked NHANES, NSDUH, MTF, and AFCARS		[NHANES]	
data for statistical purposes only [Limitation 1c,			
2b, 3a]		For accessing NSDUH, researchers/users must:	
5. Submit RDC application for accessing NSDUH		2a. Submit RDC application [NSDUH]	
[Control 2a]		2b. Obtain approval from SAMHSA staff on the	
6. Obtains approval from NCHS Confidentiality		research proposed in the RDC application [NSDUH]	
Officer, NCHS RDC, and DHANES/NHANES,		2c. Sign Designated Agent Form (DAF) [NSDUH]	
SAMHSA staff, NAHDAP staff, and NDACAN staff		2d. Sign Data Access Agreement (DAA) [NSDUH]	
on the proposed linkage [Controls 1d, 2b, 3g, 4d]		2e. Complete confidentiality training [NSDUH]	
7. Signs and completes the NHANES Data		2f. Sign the SAMHSA RDC Student Data User	
Use/Access Agreement, NHANES Designated Agent		Acknowledgement form and obtain advisor's	
Agreement, NSDUH Designated Agent Form,		signature, if researcher/user is a student [NSDUH]	
NSDUH Data Access Agreement (DAA), NAHDAP		2g. Access data within the NCHS RDC [NSDUH]	
VDE RDUA, NDACAN Terms of Use Agreement			
[Controls 1e, 1f, 2c, 2d, 2f, 3d, 4c]		For accessing MTF, researchers/users must:	
8. Completes confidentiality training for NHANES		3d. Execute NAHDAP VDE RDUA between ICPSR (U-	
and NSDUH data access [Controls 1g, 2e]		Mich) and the researcher's institution [MTF]	

/hat authorization gaps exist?

Definitions: Limitations are restrictions on data linkage and use (e.g., dataset must only be linked with other disease-relevant data, dataset must be used in a physical enclave, etc.). Controls are processes established to ensure compliance with governance for data sharing, access, and use (e.g., user must access data in a physical enclave, user must sign data use agreement, user must receive data access committee approval, etc.). Authorization gaps exist when there is no explicit authorization or the authorization is not available or found in the information collected by the project team for various data life cycle stages (data collection, linking, sharing, access and use).

	Can the datasets be linked?	What limitations do the linked datasets inherit?	What controls do the linked dataset require?	Wha
	9. Obtains IRB approval or exemption from their		3e. Access data only through the ICPSR VDE	
	institution for accessing MTF [Control 3f]		(virtual enclave) [MTF]	
			3f. Obtain IRB approval or exemption from the	
			researcher's institution [MTF]	
			3g. Obtain review and approval from NAHDAP on	
			the proposed research [MTF]	
			For accessing AFCARS, researchers/users must:	
			4c. Execute of the NDACAN Terms of Use	
			Agreement. [AFCARS]	
			4d. Obtain review and approval from NDACAN	
			staff on the proposed research. [AFCARS]	
L				

hat authorization gaps exist?

	-	mental health of children. Are COVID-19 pandemic related mental health o	utcomes more severe for children in foster
Dataset 1	- NHANES 'Mental Health - Depre	ession Screener – Youth' dataset (2017-2020, limited)	
	Dataset Source	National Health and Nutrition Examination Survey (NHANES)	
	Dataset Source Agency	CDC	
	Dataset Type (Clinical, EHR, Survey, SDOH, etc.)	Survey/Clinical	
	Information Sources	Website; NCHS, DHANES, and RDC staff; NHANES linkage info document	
Dataset 1			
	- NHANES	Raw Language	Interpretation
1	Data Collection		interpretation
1.1	Authorizations and Applicable		
	Regulations/Policies		
1.1.1 1.1.1.1	Authorizations	Example 'Child Assent Form':	 Assent from children Consent from adults NCHS ERB (IRB) Approval Section 306 of the Public Health Service Act (42 U.S.C. 242k) National Nutrition Monitoring and Related Research Act of 1990 (P.L. 101-445), (October 1990) Food Quality Protection Act of 1996 (P.L. 10 170) Federal Food, Drug, and Cosmetic Act (21 U 393), Chapter 9 Assent from children authorizes data collection
		"Your parents say that you can take part in this special survey. You have just read about the survey in this book. The survey tells us about the health of people. We will ask you to have an exam at our vans that are here in your town. This exam is a little like going to the doctor. Other kids and their families will be at the center. You do not have to do this if you do not want to. You can also stop at any time and you do not have to do any tests that you do not want to. If you take part, you will learn some things about yourself. You will help us learn a lot about other kids in the United States." [1]	
1.1.1.2	Consent	Template for Home Interview Consent: You have been chosen to take part in the National Health and Nutrition Examination Survey (NHANES), conducted by the National Center for Health Statistics, part of the Centers for Disease Control and Prevention (CDC). This research tells us about the health and nutrition of people in the United States. It combines an interview with a health exam. You may take part in this survey or not. The choice is yours. You will not lose any benefits if you say no. If you choose to take part, you don't have to answer every question and you can stop the interview at any time. [1]	Consent from adults authorizes data collectior

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ion	[1]
	https://wwwn.cdc.gov/nchs/data/nhanes/
	2019-2020/documents/2016-Child-Assent- 7-11-Form-508.pdf (Accessed: 4/17/23)
	<u>7-11-rom-508.pur</u> (Accessed: 4/17/25)
on	[1]
	https://wwwn.cdc.gov/nchs/data/nhanes/
	2019-2020/documents/2019-Home- Interview-Consent-English-508.pdf
	(Accessed: 4/17/23)

Dataset 1 - I	NHANES			
		Raw Language	Interpretation	Source
1.1.1.3	IRB/equivalent Privacy Board determination	NCHS Ethics Review Board (ERB) Approvals of NCHS Protocols: NHANES 2021-2022 Protocol #2021-05 NHANES 2019-2020 Protocol #2018-01 NHANES 2017-2018 Protocol #2018-01 (Effective beginning October 26, 2017) Continuation of Protocol #2011-17 (Effective through October 26, 2017). [1] PoCs stated that NCHS ERB approval ensures data collection is consistent with assent/consent [2]		 [1] <u>https://www.cdc.gov/nchs/nhanes/irba98</u> <u>.htm</u> (Accessed: 4/17/23) [2] NCHS and DHANES Meeting
1.1.1.4	Local/state/federal law	- The National Nutrition Monitoring and Related Research Act of 1990 (P.L. 101-445), (October 22, 1990), which specifies that NHANES be maintained as	Four federal laws authorizes data collection: 1. Section 306 of the Public Health Service Act (42 U.S.C. 242k) 2. National Nutrition Monitoring and Related Research Act of 1990 (P.L. 101-445), (October 22, 1990) 3. Food Quality Protection Act of 1996 (P.L. 104- 170) 4. Federal Food, Drug, and Cosmetic Act (21 USC 393), Chapter 9	[1] NHANES Linkage Info doc from NCHS staff
1.1.1.5	Institutional Certification	Information not available/found	Information not available/found	
1.1.1.6	Data originator agreement	Information not available/found	Information not available/found	
1.1.1.7	Repository agreements/policies	Information not available/found	Information not available/found	
1.1.1.8	Other (specify)	Information not available/found	Information not available/found	
1.1.2	Applicable Regulations/Policies			
1.1.2.1	Local regulations/policies	N/A - PoCs are not aware of any specific policies that apply. [1]	N/A	[1] NCHS and DHANES Meeting
1.1.2.2	Tribal regulations/policies	N/A - Tribal or local areas are not specifically targeted, so no specific agreements. [1]	N/A	[1] NCHS and DHANES Meeting
1.1.2.3	State regulations/policies	N/A - PoCs are not aware of any specific policies that apply. [1]	N/A	[1] NCHS and DHANES Meeting

Dataset 1 -	NHANES		
		Raw Language	Interpretation
1.1.2.4	Federal regulations/policies	Four public laws authorize or necessitate the collection of information about the health of the American people. These are: - Section 306 of the Public Health Service Act (42 U.S.C. 242k), which directs NCHS to collect statistics on subjects, such as the extent and nature of illness and disability of the population; environmental, social and other health hazards; determinants of health; health resources; and utilization of health care; - The National Nutrition Monitoring and Related Research Act of 1990 (P.L. 101-445), (October 22, 1990), which specifies that NHANES be maintained as a component of the comprehensive nutrition monitoring plan with continuous coverage of dietary and nutritional status for the population and high-risk subgroups; - The Food Quality Protection Act of 1996 (P.L. 104-170), which requires the	1. Section 306 of the Public Health Service Ac (42 U.S.C. 242k) 2. National Nutrition Monitoring and Related Research Act of 1990 (P.L. 101-445), (October 1990) 3. Food Quality Protection Act of 1996 (P.L. 10 170) 4. Federal Food, Drug, and Cosmetic Act (21 U 393), Chapter 9
		 implementation of surveys to collect data on food consumption patterns of infants and children and data on dietary exposure to pesticides among infants and children; and The Federal Food, Drug, and Cosmetic Act (21 USC 393), Chapter 9, which authorizes the collection of information to support the Food and Drug Administration's objective to obtain current, timely, and policy-relevant consumer information to carry out its statutory functions. [1] 	
1.1.2.5	International regulations/policies	N/A - The National Health and Nutrition Examination Survey (NHANES) is a program of studies designed to assess the health and nutritional status of adults and children in the United States. The sample for the survey is selected to represent the U.S. population of all ages. [1]	N/A
1.1.2.6	Contractual obligations	N/A - PoCs are not aware of any specific policies that apply. [1]	N/A
1.1.2.7	Repository policies		N/A
1.2 1.2.1	Governance for data linkage, sharing, access, and use based on data collection authorization or applicable regulations/policies (i.e., the origin of the governance) Whether the data can be linked	Child proxies 0-15 years – The parent/guardian of the child consents verbally	Assent/Consent specifies that the data can be
		as a proxy respondent for the child. Ages 16 and 17 years – Multiple consents/assents are required for this age group since children 16 – 17 years of age respond to their own interview. First, the parent/guardian verbally provides permission to the audio recording, interview administration, and linkage. If the parent/guardian grants permission (consent), then the child is asked to assent to the recording, interview, and linkage. [1]	linked
1.2.2	With what other data can it be linked or can it not be linked (scope of linkage)	Consent template for 'Home Interview Consent': Health research using NHANES can be enhanced by combining your survey records with other data sources. The data gathered are used to link your answers to vital statistics, health, nutrition, and other related records. "We can do additional health research by linking the interview and exam data of everyone listed under "SP NAME" in the gray box below to vital statistics, health, nutrition, and other related records. May we try to link these survey records with other records? Yes, No, N/A." [1]	Assent/Consent specifies that the data can be linked to vital statistics, health, nutrition, and other related records
	Whether data can be shared	Does not authorize/specify	Does not authorize/specify
1.2.3	How data can be shared (de-	Does not authorize/specify	Does not authorize/specify

	Source
ct	[1] NHANES Linkage Info doc from NCHS staff
d er 22,	
L04-	
USC	
	 [1] https://www.cdc.gov/nchs/nhanes/about nhanes.htm (Accessed: 4/17/23)
	[1] NCHS and DHANES Meeting
e	[1] NHANES Linkage Info doc from NCHS staff
e id	 [1] https://wwwn.cdc.gov/nchs/data/nhanes/ 2019-2020/documents/2019-Home- Interview-Consent-English-508.pdf (Accessed: 4/17/23)

Dataset 1 - I	NHANES			
		Raw Language	Interpretation	Source
1.2.5	How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.)	Does not authorize/specify	Does not authorize/specify	
1.2.6	How data can be used (data use limitations)	Consent template for 'Home Interview Consent': "Data gathered in this survey are used to study many health issues. We are required by law to use your information for statistical research only and to keep it confidential." [1] While the consent states that data may only be used for statistical purposes, PoC stated that this is a broad definition and the data may be used for general research purposes. [2]	Assent/Consent specifies that the data can be used for statistical reporting and analysis (includes broad research)	 [1] <u>https://wwwn.cdc.gov/nchs/data/nhanes</u> <u>2019-2020/documents/2019-Home-</u> <u>Interview-Consent-English-508.pdf</u> (Accessed: 4/17/23) [2] NCHS and DHANES Meeting
1.2.7	Other (specify)	Does not authorize/specify	Does not authorize/specify	
2	Data Linkage			
2.1	Authorizations and Applicable Regulations/Policies			
2.1.1	Authorizations		 Assent from children Consent from adults NCHS ERB (IRB) approval DHANES/NHANES approval 	
2.1.1.1	Assent	 Child proxies 0-15 years – The parent/guardian of the child consents verbally as a proxy respondent for the child. Ages 16 and 17 years – Multiple consents/assents are required for this age group since children 16 – 17 years of age respond to their own interview. First, the parent/guardian verbally provides permission to the audio recording, interview administration, and linkage. If the parent/guardian grants permission (consent), then the child is asked to assent to the recording, interview, and linkage. [1] 	Assent from children authorizes data linkage	[1] NHANES Linkage Info doc from NCHS staff
2.1.1.2	Consent	Consent template for 'Home Interview Consent': Health research using NHANES can be enhanced by combining your survey records with other data sources. The data gathered are used to link your answers to vital statistics, health, nutrition, and other related records. "We can do additional health research by linking the interview and exam data of everyone listed under "SP NAME" in the gray box below to vital statistics, health, nutrition, and other related records. May we try to link these survey records with other records? Yes, No, N/A." [1]	Consent from adults authorizes data linkage	[1] https://wwwn.cdc.gov/nchs/data/nhanes, 2019-2020/documents/2019-Home- Interview-Consent-English-508.pdf (Accessed: 4/17/23)
2.1.1.3	IRB/equivalent Privacy Board determination	Individual level linkage (1:1 linkage) requires IRB approval. [1]	NCHS ERB approval authorizes data linkage	[1] NCHS and DHANES Meeting
2.1.1.4	Local/state/federal laws	Information not available/found	Information not available/found	
2.1.1.5	Institutional Certification	Information not available/found	Information not available/found	
2.1.1.6	Data originator agreement	Information not available/found	Information not available/found	
2.1.1.7	Repository agreements/policies	Information not available/found	Information not available/found	
2.1.1.8	Other (specify)	RDC is not the owner of NHANES data. When RDC receives an application to link data with an external dataset, it is sent to the data owner (DHANES/NHANES) for their review and approval. [1]	DHANES/NHANES approval authorizes data linkage	[1] NCHS RDC Meeting
2.1.2	Applicable Regulations/Policies			
2.1.2.1	Local regulations/policies	Information not available/found	Information not available/found	
2.1.2.2	Tribal regulations/policies	N/A - Tribal or local areas are not specifically targeted, so no specific agreements. [1]	N/A	[1] NCHS and DHANES Meeting

ataset 1 -				
- <i>i</i> -		Raw Language	Interpretation	Source
2.1.2.3	State regulations/policies	Information not available/found	Information not available/found	
2.1.2.4	Federal regulations/policies	Information not available/found	Information not available/found	
2.1.2.5	International regulations/policies	N/A - The National Health and Nutrition Examination Survey (NHANES) is a program of studies designed to assess the health and nutritional status of adults and children in the United States. The sample for the survey is selected to represent the U.S. population of all ages. [1]	N/A	[1] https://www.cdc.gov/nchs/nhanes/abo nhanes.htm (Accessed: 4/17/23)
2.1.2.6	Contractual obligations	Information not available/found	Information not available/found	
2.1.2.7	Repository policies	Information not available/found	Information not available/found	
2.2	Governance for data linkage, sharing, access, and use based on data linkage authorization or applicable regulations/ policies (i.e., the origin of the governance)			
2.2.1	Whether the data can be linked	Child proxies 0-15 years – The parent/guardian of the child consents verbally as a proxy respondent for the child. Ages 16 and 17 years – Multiple consents/assents are required for this age group since children 16 – 17 years of age respond to their own interview. First, the parent/guardian verbally provides permission to the audio recording, interview administration, and linkage. If the parent/guardian grants permission (consent), then the child is asked to assent to the recording, interview, and linkage. [1] Individual level linkage (1:1 linkage) requires IRB approval. [2] RDC is not the owner of NHANES data. When RDC receives an application to link data with an external dataset, it is sent to the data owner	Assent/Consent, NCHS ERB approval, and DHANES/HANES approval specify that the data can be linked	 [1] NHANES Linkage Info doc from NCHS staff [2] NCHS and DHANES Meeting [3] NCHS RDC Meeting
2.2.2	With what other data can it be linked or	(DHANES/NHANES) for their review and approval. [3] Consent template for 'Home Interview Consent':	Assent/Consent specifies that the data can be	[1]
2.2.2	can it not be linked (scope of linkage)	Health research using NHANES can be enhanced by combining your survey records with other data sources. The data gathered are used to link your answers to vital statistics, health, nutrition, and other related records. "We can do additional health research by linking the interview and exam data of everyone listed under "SP NAME" in the gray box below to vital statistics, health, nutrition, and other related records. May we try to link these survey records with other records? Yes, No, N/A." [1]	linked to vital statistics, health, nutrition, and other related records	https://wwwn.cdc.gov/nchs/data/nhane 2019-2020/documents/2019-Home- Interview-Consent-English-508.pdf (Accessed: 4/17/23)
2.2.3	Whether data can be shared	Does not authorize/specify	Does not authorize/specify	
2.2.4	How data can be shared (de- identification status, disclosure review)	Does not authorize/specify	Does not authorize/specify	
2.2.5	How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.)	Does not authorize/specify	Does not authorize/specify	
2.2.6	How data can be used (data use limitations)	Does not authorize/specify	Does not authorize/specify	
2.2.7	Other (specify)	Does not authorize/specify	Does not authorize/specify	
3	Data Sharing			
3.1	Authorizations and Applicable Regulations/Policies			

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		Raw Language	Interpretation	
3.1.1	Authorizations		 NCHS Disclosure Review Board (DRB) Confidential Information Protection and Statistical Efficiency Act (CIPSEA) NCHS non-disclosure affidavit (for 	
			NCHS/NHANES collaborators) 4. Data Sharing Agreement (for NCHS/NHANES collaborators)	
3.1.1.1	Assent	Does not authorize/specify	Does not authorize/specify	
3.1.1.2	Consent	Does not authorize/specify	Does not authorize/specify	
3.1.1.3	IRB/equivalent Privacy Board determination	IRB/equivalent Privacy Board determination: NCHS has a Disclosure Review Board (DRB) which helps determine NCHS data sharing policy and public data sharing approvals. [1]	NCHS Disclosure Review Board (DRB) authorizes data sharing	[1] N
3.1.1.4	Local/state/federal laws	RDC is the data dissemination arm for NCHS restricted use data. NHANES collects their data under CIPSEA which authorizes NCHS to share the data with vetted/approved researchers (who then become agents of CIPSEA to use the restricted use data). Data collected under CIPSEA has a statement/promise of confidentiality to participants that the RDC will not release any data that could be used to reidentify the person or entity that provided the data. [1]	Confidential Information Protection and Statistical Efficiency Act (CIPSEA) authorizes data sharing through the NCHS RDC	[1] N
3.1.1.5	Institutional Certification	Information not available/found	Information not available/found	
3.1.1.6	Data originator agreement	Additionally, all NCHS/NHANES collaborators (i.e., FDA, NIH, USDA, etc.) are	Two agreements authorize data sharing from	[1] N
		given the minimal amount of data pre-public release required to assess quality	NCHS/NHANES collaborators that are authorized	staff
		control for their contributed data collections. As a condition for sharing	to review pre-release data that they contributed:	
		confidential data, the collaborator must also sign the NCHS non-disclosure	1. NCHS non-disclosure affidavit	
		affidavit and data are shared through a Data Sharing Agreement. [1]	2. Data Sharing Agreement	
3.1.1.7	Repository agreements/policies	Information not available/found	Information not available/found	
3.1.1.8	Other	Information not available/found	Information not available/found	
3.1.2	Applicable Regulations/Policies			
3.1.2.1	Local regulations/policies	Several NHANES datasets are not released to the public. However, secure,	NHANES Protected Data Policy	[1]
		controlled access is granted through the NCHS Research Data Center (RDC) to		http
		guarantee confidentiality of the survey participants. A comprehensive list of		NHA
		the NHANES data files available through the RDC is available at,		<u>2022</u>
		http://wwwn.cdc.gov/Nchs/Nhanes/Search/DataPage.aspx?Component=NonP		
		ublic. The NHANES data files released only through the RDC fall into two		
		general categories: 1) the data file could possibly disclose participation in the		
		survey (e.g., due to small sample sizes or rare combination of characteristics)		
		or 2) the data file contains sensitive information (e.g., sexual behavior) and		
		have been deemed to be NHANES Protected Data. A list of NHANES Protected		
		Data Files from the 1999-2020 data collection cycles is included in the Appendix. [1]		
3.1.2.2	Tribal regulations/policies	N/A - Tribal or local areas are not specifically targeted, so no specific agreements. [1]	N/A	[1] N
· · · · · · · · · · · · · · · · · · ·	State regulations/policies	Information not available/found	Information not available/found	

	Source
s) and	
NHANES	
outhorizes	[1] NCHS RDC Email Communication
nd orizes data	[1] NCHS RDC Meeting
g from authorized ontributed:	[1] NHANES Linkage Info doc from NCHS staff
	[1] https://www.cdc.gov/nchs/data/nhanes/ NHANES-Protected-Data-Policy-Aug- 2022.pdf (Accessed: 4/17/23)
	[1] NCHS and DHANES Meeting

Dataset 1 -	NHANES		
		Raw Language	Interpretation
3.1.2.4	Federal regulations/policies	RDC is the data dissemination arm for NCHS restricted use data. NHANES	1. Section 308(d) Public Health Act
		collects their data under CIPSEA which authorizes NCHS to share the data with	
		vetted/approved researchers (who then become agents of CIPSEA to use the	Statistical Efficiency Act (CIPSEA)
		restricted use data). Data collected under CIPSEA has a statement/promise of	
		confidentiality to participants that the RDC will not release any data that	
		could be used to reidentify the person or entity that provided the data. [1]	
		There are two laws that govern the NCHS RDC: Section 308(d) of the Public	
		Health	
		Service Act and the Confidential Information Protection and Statistical Efficiency Act	
		(CIPSEA). The Public Health Service Act protects confidentiality and states that	
		the only people who can access confidential data are NCHS staff and	
		Designated Agents. Therefore, researchers wishing to access confidential data	
		must become Designated Agents. CIPSEA stipulates that the penalty for	
		willfully violating confidentiality is a class E felony with up to 5 years in prison	
		or a \$250,000 fine or both. The Freedom of Information Act does not apply to	
		data collected under CIPSEA. [2]	
3.1.2.5	International regulations/policies	N/A - The National Health and Nutrition Examination Survey (NHANES) is a	N/A
		program of studies designed to assess the health and nutritional status of	
		adults and children in the United States. The sample for the survey is selected	
		to represent the U.S. population of all ages. [1]	
3.1.2.6	Contractual obligations	N/A	N/A
3.1.2.7	Repository policies	Information not available/found	Information not available/found
3.2	Governance for data linkage, sharing,	,	
	access, and use based on data		
	sharing authorization or applicable		
	regulations/policies (i.e., the origin		
	of the governance)		
3.2.1	Whether the data can be linked	Does not authorize/specify	Does not authorize/specify
3.2.2	With what other data can it be linked or	Does not authorize/specify	
	can it not be linked (scope of linkage)		
			Does not authorize/specify
3.2.3	Whether data can be shared	RDC is the data dissemination arm for NCHS restricted use data. NHANES	Confidential Information Protection and
		collects their data under CIPSEA which authorizes NCHS to share the data with	Statistical Efficiency Act (CIPSEA) specifies that
		vetted/approved researchers (who then become agents of CIPSEA to use the	data can be shared through NCHS RDC
		restricted use data). Data collected under CIPSEA has a statement/promise of	(authorized by CIPSEA to share the data)
		confidentiality to participants that the RDC will not release any data that	
		could be used to reidentify the person or entity that provided the data. [1]	

_	Source
	[1] NCHS RDC Meeting[2]
	https://www.cdc.gov/rdc/data/b4/Disclos
	ure-Manual-v2.5.pdf (Accessed: 4/17/23)
	[4]
	[1] https://www.cdc.gov/nchs/nhanes/about
	<u>nhanes.htm</u> (Accessed: 4/17/23)
	[1] NCHS RDC Meeting

		Raw Language	Interpretation	Source
3.2.4	How data can be shared (de- identification status, disclosure review)	Direct identifiers (name, social security number, address) cannot be accessed through the RDC. Indirect Identifiers (geography) may be available through the RDC. • All geography below the national level is restricted for continuous NHANES, prior to that all geography below the regional level is restricted. • The exact date of interview and exam are restricted for all years. NHANES does not provide a variable name for exact date of interview and exam in the limited access documentation. [1] Deductive disclosure performed by the NCHS Disclosure Review Board/NCHS Confidentiality Officer before the data are released. [2] Researchers that wish to access data in the RDC must submit an application where they specify what data they need, what their research questions are, and their desired output. This application is reviewed and approved by the NCHS confidentiality officer (who chairs the NCHS DRB). If application is approved, the RDC and data owners (DHANES/NHANES) will then jointly review the output to ensure it conforms to their approved application and cannot reidentify an individual (as per CIPSEA) before that output is allowed to leave the RDC. [3]	NCHS RDC specifies that data shared through RDC: 1. Must be de-identified of all direct identifiers and certain indirect identifiers (geography) may be included 2. Must undergo disclosure review by NCHS Disclosure Review Board/NCHS Confidentiality Officer prior to sharing the restricted-use data through the RDC, and then the RDC and DHANES reviews the output before releasing that output	 [1] "National Health and Examination Survey (NH/ Variables" webpage: <u>https://www.cdc.gov/rdd</u> <u>1222.htm</u> (Accessed: 4/1 [2] NCHS and DHANES M [3] NCHS RDC Meeting
3.2.5	How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.)	Several NHANES datasets are not released to the public. However, secure, controlled access is granted through the NCHS Research Data Center (RDC) to guarantee confidentiality of the survey participants. A comprehensive list of the NHANES data files available through the RDC is available at, http://wwwn.cdc.gov/Nchs/Nhanes/Search/DataPage.aspx?Component=NonPublic . The NHANES data files released only through the RDC fall into two general categories: 1) the data file could possibly disclose participation in the survey (e.g., due to small sample sizes or rare combination of characteristics) or 2) the data file contains sensitive information (e.g., sexual behavior) and have been deemed to be NHANES Protected Data. A list of NHANES Protected Data Files from the 1999-2020 data collection cycles is included in the Appendix. [1]	NHANES Protected Data Policy specifies that the restricted use data must be accessed through the NCHS RDC (on-site enclave)	[1] https://www.cdc.gov/nc HANES-Protected-Data-F 2022.pdf (Accessed: 4/1)
3.2.6	How data can be used (data use limitations)	Section 308(d) of the Public Health Service Act (42 U.S.C. 242m(d)) includes NCHS's authority to collect information and prohibits anyone from using any personal information for any purpose other than what was described to survey participants. [1] In general, NCHS data can only be used for statistical purposes and research purposes as per CIPSEA and used for the purpose it was collected for as per Section 308(d) of the Public Health Service Act. [2]	Section 308(d) of the Public Health Service Act specifies that NCHS data containing personal information cannot be used for any purpose other than what was described to survey participants. CIPSEA specifies that NCHS data can only be used for statistical and research purposes.	 [1] <u>https://www.cdc.gov/rdd</u> <u>n308.pdf</u> (Accessed: 4/1) [2] NCHS RDC Email Com
3.2.7	Other (specify)	Does not authorize/specify	Does not authorize/specify	
4	Data Access			
4.1	Authorizations and Applicable Regulations/Policies			
4.1.1	Authorizations		1. Data Use/Access Agreement (Rules of Behavior)	
4.1.1.1	Assent	Does not authorize/specify	Does not authorize/specify	
4.1.1.2	Consent	Does not authorize/specify	Does not authorize/specify	
4.1.1.3	IRB/equivalent Privacy Board determination	N/A	N/A	

etation	Source
data shared through	[1] "National Health and Nutrition
	Examination Survey (NHANES) Restricted
of all direct identifiers	Variables" webpage:
tifiers (geography) may	https://www.cdc.gov/rdc/b1datatype/Dt
	1222.htm (Accessed: 4/17/23)
are review by NCHS /NCHS Confidentiality	[2] NCHS and DHANES Meeting
he restricted-use data	[3] NCHS RDC Meeting
en the RDC and DHANES	
re releasing that output	
Policy specifies that the	[1] https://www.cdc.gov/nchs/data/nhane/N
be accessed through nclave)	HANES-Protected-Data-Policy-Aug-
neiavej	<u>2022.pdf</u> (Accessed: 4/17/23)
	[4]
blic Health Service Act	[1] https://www.cdc.gov/rdc/Data/b4/coctio
containing personal sed for any purpose	https://www.cdc.gov/rdc/Data/b4/sectio n308.pdf (Accessed: 4/17/23)
cribed to survey	<u>11000.pur</u> (ACC235Cu. 4 /17/23)
	[2] NCHS RDC Email Communication
HS data can only be	
esearch purposes.	
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ement (Rules of	
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ataset 1 -	NHANES		
		Raw Language	Interpretation
4.1.1.4	Local/state/federal laws	N/A	N/A
4.1.1.5	Institutional Certification	Information not available/found	Information not available/found
4.1.1.6	Data originator agreement	Information not available/found	Information not available/found
4.1.1.7	Repository agreements/policies	N/A	N/A
4.1.1.8	Other (specify)	Researchers that wish to access data in the RDC must submit an application where they specify what data they need, what their research questions are, and their desired output. This application is reviewed and approved by the NCHS confidentiality officer (who chairs the NCHS Disclosure Review Board). If application is approved, the RDC and data owners (DHANES/NHANES) will then jointly review the output to ensure it conforms to their approved application and cannot reidentify an individual (as per CIPSEA) before that output is allowed to leave the RDC. Once application is approved, researchers must also undergo confidentially training, data use/access agreement (similar to a Rules of Behavior form), sign a non-disclosure CIPSEA agent form, which makes them agents under the statue and legally liable for proper use of the data and the RDC can prosecute researchers under CIPSEA if the data is misused. [1]	
4.1.2	Applicable Regulations/Policies		
4.1.2.1	Local regulations/policies	Several NHANES datasets are not released to the public. However, secure, controlled access is granted through the NCHS Research Data Center (RDC) to guarantee confidentiality of the survey participants. A comprehensive list of the NHANES data files available through the RDC is available at, <u>http://wwwn.cdc.gov/Nchs/Nhanes/Search/DataPage.aspx?Component=Non Public</u> . The NHANES data files released only through the RDC fall into two general categories: 1) the data file could possibly disclose participation in the survey (e.g., due to small sample sizes or rare combination of characteristics) or 2) the data file contains sensitive information (e.g., sexual behavior) and have been deemed to be NHANES Protected Data. A list of NHANES Protected Data Files from the 1999-2020 data collection cycles is included in the	
4.1.2.2	Tribal regulations/policies	Appendix. [1] N/A - Tribal or local areas are not specifically targeted, so no specific	N/A
		agreements. [1]	
4.1.2.3	State regulations/policies	Information not available/found	Information not available/found

	Source
	N/A
or)	[1] NCHS RDC Meeting
	[1]
	https://www.cdc.gov/nchs/data/nhanes/ NHANES-Protected-Data-Policy-Aug-
	<u>2022.pdf</u> (Accessed: 4/17/23)
	[1] NCHS and DHANES Meeting

Dataset 1 -	NHANES			
		Raw Language	Interpretation	Source
4.1.2.4	Federal regulations/policies	There are two laws that govern the NCHS RDC: Section 308(d) of the Public Health Service Act and the Confidential Information Protection and Statistical Efficiency Act (CIPSEA). The Public Health Service Act protects confidentiality and states that the only people who can access confidential data are NCHS staff and Designated Agents. Therefore, researchers wishing to access confidential data must become Designated Agents. CIPSEA stipulates that the penalty for willfully violating confidentiality is a class E felony with up to 5 years in prison or a \$250,000 fine or both. The Freedom of Information Act does not apply to data collected under CIPSEA. [1]	 Section 308(d) of the Public Health Service Act Confidential Information Protection and Statistical Efficiency Act (CIPSEA) 	 [1] <u>https://www.cdc.gov/rdc/data/b4/Disclo</u> <u>sure-Manual-v2.5.pdf</u> (Accessed: 4/17/23) [2] <u>https://www.cdc.gov/rdc/data/b4/Design</u> <u>atedAgent-321.pdf</u> (Accessed: 4/17/23)
		Designated Agent Agreement – NCHS Research Data Center (RDC) I, (name), do solemnly swear (or affirm) I will observe all policies and procedures that protect the confidential data I access from unauthorized disclosures. The data that I will access in the RDC is described in my RDC proposal. I will not disclose this confidential data, either while as an agent or after project conclusion, whether in data files, lists, or reports created using the confidential data, as specified under section 308 (d) of the Public Health Service Act and under penalties* set forth in §3572(f) of the Confidential Information Protection and Statistical Efficiency Act of 2018 (44 USC 3561 – 3583). [2]		
4.1.2.5	International regulations/policies	N/A - The National Health and Nutrition Examination Survey (NHANES) is a program of studies designed to assess the health and nutritional status of adults and children in the United States. The sample for the survey is selected to represent the U.S. population of all ages. [1]	N/A	[1] https://www.cdc.gov/nchs/nhanes/about nhanes.htm (Accessed: 4/17/23)
4.1.2.6	Contractual obligations	Information not available/found	Information not available/found	
4.1.2.7	Repository policies	N/A - the RDC does not have a repository agreement with NHANES. The RDC has a data use agreement with NHANES. The RDC does not archive NHANES data nor is the RDC a repository for NHANES data.	N/A	[1] NCHS RDC Email Communication
4.2	Governance for data linkage, sharing, access, and use based on data access authorization or applicable regulations/policies (i.e., the origin of the governance)			
4.2.1	Whether the data can be linked	Does not authorize/specify	Does not authorize/specify	
4.2.2	With what other data can it be linked or can it not be linked (scope of linkage)	Does not authorize/specify	Does not authorize/specify	
4.2.3	Whether data can be shared	Does not authorize/specify	Does not authorize/specify	

Dataset 1 -	NHANES			
		Raw Language	Interpretation	Source
4.2.4	How data can be shared (de- identification status, disclosure review)	Direct identifiers (name, social security number, address) cannot be accessed through the RDC. Indirect Identifiers (geography) may be available through the RDC. • All geography below the national level is restricted for continuous NHANES, prior to that all geography below the regional level is restricted. • The exact date of interview and exam are restricted for all years. NHANES does not provide a variable name for exact date of interview and exam in the limited access documentation. [1] Deductive disclosure performed by the NCHS Disclosure Review Board/NCHS Confidentiality Officer before the data are released. [2] Researchers that wish to access data in the RDC must submit an application where they specify what data they need, what their research questions are, and their desired output. This application is reviewed and approved by the NCHS confidentiality officer (who chairs the NCHS DRB). If application is approved, the RDC and data owners (DHANES/NHANES) will then jointly review the output to ensure it conforms to their approved application and cannot reidentify an individual (as per CIPSEA) before that output is allowed to leave the RDC. [3]	NCHS RDC specifies that data shared through RDC: 1. Must be de-identified of all direct identifiers and certain indirect identifiers (geography) may be included 2. Must undergo disclosure review by NCHS Disclosure Review Board/NCHS Confidentiality Officer prior to sharing the restricted-use data through the RDC, and then the RDC and DHANES reviews the output before releasing that output	 [1] "National Health and Nutrition Examination Survey (NHANES) Restricted Variables" webpage: <u>https://www.cdc.gov/rdc/b1datatype/Dt</u> <u>1222.htm</u> (Accessed: 4/17/23) [2] NCHS and DHANES Meeting [3] NCHS RDC Meeting
4.2.5	How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.)		 Must execute Data Use/Access Agreement (Rules of Behavior) Must sign Designated Agent Agreement (Non- Disclosure CIPSEA Agent Form) 	[1] NCHS RDC Meeting
4.2.6	How data can be used (data use limitations)	Section 308(d) of the Public Health Service Act (42 U.S.C. 242m(d)) includes NCHS's authority to collect information and prohibits anyone from using any personal information for any purpose other than what was described to survey participants. [1] In general, NCHS data can only be used for statistical purposes and research purposes as per CIPSEA and used for the purpose it was collect for as per Section 308(d) of the Public Health Service Act. [2]	Section 308(d) of the Public Health Service Act specifies that NCHS data containing personal information cannot be used for any purpose other than what was described to survey participants. CIPSEA specifies that NCHS data can only be used for statistical and research purposes.	 [1] <u>https://www.cdc.gov/rdc/Data/b4/sectio</u> <u>n308.pdf</u> (Accessed: 4/17/23) [2] NCHS RDC Email Communication
4.2.7	Other (specify)	Information not available/found		
5	Data Use			
5.1	Authorizations and Applicable Regulations/Policies			
5.1.1	Authorizations		 Consent from adults NCHS ERB (IRB) approval Designated Agent Agreement (Non-Disclosure CIPSEA Agent Form) Data Use/Access Agreement (Rules of Behavior) 	
		1	Does not authorize/specify	

	NHANES			
		Raw Language	Interpretation	Source
5.1.1.2	Consent	Consent template for 'Home Interview Consent': "Data gathered in this survey are used to study many health issues. We are required by law to use your information for statistical research only and to keep it confidential." [1] While the consent states that data may only be used for statistical purposes, PoC stated that this is a broad definition and the data may be used for general	Consent from adults authorizes data use	 [1] <u>https://wwwn.cdc.gov/nchs/data/nhane/2019-2020/documents/2019-Home-Interview-Consent-English-508.pdf</u> (Accessed: 4/17/23) [2] NCHS and DHANES Meeting
		research purposes. [2]		
5.1.1.3	IRB/equivalent Privacy Board determination	ERB impacts/authorizes how the data can be used, for example, providing authorization for the addition of the linkage question to the NHANES consent forms. [1]	NCHS ERB (IRB) approval authorizes data use	[1] NCHS and DHANES Meeting
5.1.1.4	Local/state/federal laws	Researchers that wish to access data in the RDC must submit an application where they specify what data they need, what their research questions are, and their desired output. This application is reviewed and approved by the NCHS confidentiality officer (who chairs the NCHS Disclosure Review Board). If application is approved, the RDC and data owners (DHANES/NHANES) will then jointly review the output to ensure it conforms to their approved application and cannot reidentify an individual (as per CIPSEA) before that output is allowed to leave the RDC. Once application is approved, researchers must also undergo confidentially training, data use/access agreement (similar to a Rules of Behavior form), sign a non-disclosure CIPSEA agent form, which makes them agents under the statue and legally liable for proper use of the data and the RDC can prosecute researchers under CIPSEA if the data is misused. [1]	Designated Agent Agreement (Non-Disclosure CIPSEA Agent Form) authorizes data use	[1] NCHS RDC Meeting
5.1.1.5	Institutional Certification	Information not available/found	Information not available/found	
5.1.1.6	Data originator agreement	Information not available/found	Information not available/found	
5.1.1.7	Repository agreements/policies	N/A - the RDC does not have a repository agreement with NHANES. The RDC has a data use agreement with NHANES. The RDC does not archive NHANES data nor is the RDC a repository for NHANES data.	N/A	[1] NCHS RDC Email Communication
5.1.1.8	Other (specify)	Researchers that wish to access data in the RDC must submit an application where they specify what data they need, what their research questions are, and their desired output. This application is reviewed and approved by the NCHS confidentiality officer (who chairs the NCHS Disclosure Review Board). If application is approved, the RDC and data owners (DHANES/NHANES) will then jointly review the output to ensure it conforms to their approved application and cannot reidentify an individual (as per CIPSEA) before that output is allowed to leave the RDC. Once application is approved, researchers must also undergo confidentially training, data use/access agreement (similar to a Rules of Behavior form), sign a non-disclosure CIPSEA agent form, which makes them agents under the statue and legally liable for proper use of the data and the RDC can prosecute researchers under CIPSEA if the data is misused. [1]	Data Use/Access Agreement (Rules of Behavior) authorizes data use	[1] NCHS RDC Meeting
5.1.2	Applicable Regulations/Policies			

ataset 1 -	NHANES			
		Raw Language	Interpretation	Source
5.1.2.1	Local regulations/policies	Researchers that wish to access data in the RDC must submit an application where they specify what data they need, what their research questions are, and their desired output. This application is reviewed and approved by the NCHS confidentiality officer (who chairs the NCHS Disclosure Review Board). If application is approved, the RDC and data owners (DHANES/NHANES) will then jointly review the output to ensure it conforms to their approved application and cannot reidentify an individual (as per CIPSEA) before that output is allowed to leave the RDC. Once application is approved, researchers	NCHS RDC policy	[1] NCHS RDC Meeting
5.1.2.2	Tribal regulations/policies	must also undergo confidentially training, data use/access agreement (similar to a Rules of Behavior form), sign a non-disclosure CIPSEA agent form, which makes them agents under the statue and legally liable for proper use of the data and the RDC can prosecute researchers under CIPSEA if the data is misused. [1]	N/A	[1] NCUS and DUANES Mosting
5.1.2.2	The regulations/policies	N/A - Tribal or local areas are not specifically targeted, so no specific agreements. [1]	N/A	[1] NCHS and DHANES Meeting
5.1.2.3	State regulations/policies	Information not available/found	Information not available/found	
5.1.2.4	Federal regulations/policies	NCHS survey data are protected by Federal confidentiality laws including Section 308(d) Public Health Service Act [42 U.S.C. 242m(d)] and the Confidential Information Protection and Statistical Efficiency Act or CIPSEA [Pub. L. No. 115-435, 132 Stat. 5529 § 302]. These confidentiality laws state the data collected by NCHS may be used only for statistical reporting and analysis. [1]	 Section 308(d) of the Public Health Service Act Confidential Information Protection and Statistical Efficiency Act (CIPSEA) 	[1] https://www.cdc.gov/nchs/data_acces estrictions.htm (Accessed: 4/17/23)
5.1.2.5	International regulations/policies	N/A - The National Health and Nutrition Examination Survey (NHANES) is a program of studies designed to assess the health and nutritional status of adults and children in the United States. The sample for the survey is selected to represent the U.S. population of all ages. [1]	N/A	[1] https://www.cdc.gov/nchs/nhanes/ab nhanes.htm (Accessed: 4/17/23)
5.1.2.6	Contractual obligations	Information not available/found	Information not available/found	
5.1.2.7	Repository policies	N/A - the RDC does not have a repository agreement with NHANES. The RDC has a data use agreement with NHANES. The RDC does not archive NHANES data nor is the RDC a repository for NHANES data.	N/A	[1] NCHS RDC Email Communication
5.2	Governance for data linkage, sharing, access, and use based on data access authorization or applicable regulations/policies (i.e., the origin of the governance)			
5.2.1	Whether the data can be linked	Does not authorize/specify	Does not authorize/specify	
5.2.2	With what other data can it be linked or can it not be linked (scope of linkage)	Does not authorize/specify	Does not authorize/specify	
5.2.3	Whether data can be shared	Does not authorize/specify	Does not authorize/specify	
5.2.4	How data can be shared (de- identification status, disclosure review)	Does not authorize/specify	Does not authorize/specify	
5.2.5	How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD,			
	etc.)	Does not authorize/specify	Does not authorize/specify	

Dataset 1 -	NHANES			
		Raw Language	Interpretation	Source
5.2.6	How data can be used (data use limitations)	Consent template for 'Home Interview Consent': "Data gathered in this survey are used to study many health issues. We are required by law to use your information for statistical research only and to keep it confidential." [1] NCHS survey data are protected by Federal confidentiality laws including Section 308(d) Public Health Service Act [42 U.S.C. 242m(d)] and the Confidential Information Protection and Statistical Efficiency Act or CIPSEA [Pub. L. No. 115-435, 132 Stat. 5529 § 302]. These confidentiality laws state the data collected by NCHS may be used only for statistical reporting and analysis. [2] RDC Data Use Agreement: These data were collected with the assurance that they will be used only for health statistical reporting and analysis. [3]	 Consent, Section 308(d) Public Health Service Act [42 U.S.C. 242m(d)], and Confidential Information Protection and Statistical Efficiency Act (CIPSEA) specify that the data can only be used for statistical reporting and analysis (includes broad research). RDC DUA specifies that the data were collected with the assurance that they will be used only for health statistical reporting and analysis. 	 [1] https://wwwn.cdc.gov/nchs/data/nhane /2019-2020/documents/2019-Home- Interview-Consent-English-508.pdf (Accessed: 4/17/23) [2] https://www.cdc.gov/nchs/data_access/ estrictions.htm (Accessed: 4/17/23) [3] https://www.cdc.gov/rdc/data/b4/rd data-b4-accessagreement.pdf (Accessed 4/17/23)
5.2.7	Other (specify)	Does not authorize/specify	Does not authorize/specify	
6	PII Elements			•
6.1	PII elements collected	Interviewer Procedures Manual refers to collecting last name, middle name, first name, SSN, DOB, sex at birth, gender, address. [1]	Last name, middle name, first name, SSN, DOB, sex at birth, gender, and address are collected from participants	[1] https://wwwn.cdc.gov/nchs/data/nhanes /2021-2023/manuals/2022-Interviewer- Procedures-508.pdf (Accessed: 4/17/23)
6.2	PII elements holder (i.e., party that holds the PII)	PII is stripped before coming to the RDC and resides with the data collector (DHANES/NHANES). [1] What types of confidential variables can I access through the RDC? Direct identifiers (name, social security number, address) cannot be accessed through the RDC. Indirect Identifiers (geography) may be available through the RDC. [2]	Data collector (DHANES/NHANES)	 [1] NCHS RDC Meeting [2] <u>https://www.cdc.gov/rdc/b1datatype/Dt</u> <u>100.htm</u> (Accessed: 4/17/23)
6.3	Use of common data model, if any, for data collection	N/A	N/A	
7	Prior Data Linkages			1
7.1	Dataset linked with other datasets			
7.1.1	Name of other linked dataset	NCHS is currently linking various NCHS surveys with administrative data from the following: National Death Index (NDI) Centers for Medicare and Medicaid Services (CMS) Medicare Medicaid/CHIP United States Renal Data System (USRDS) Social Security Administration (SSA) Department of Housing and Urban Development (HUD) Department of Veterans Affairs (VA). [1]	NCHS is currently linking NHANES with the following: National Death Index (NDI) Centers for Medicare and Medicaid Services (CMS) Medicare Medicaid/CHIP United States Renal Data System (USRDS) Social Security Administration (SSA) Department of Housing and Urban Development (HUD) Department of Veterans Affairs (VA)	[1] <u>https://www.cdc.gov/nchs/data-</u> linkage/index.htm (Accessed: 4/17/23)

Dataset 1 -	NHANES		
		Raw Language	Interpretation
7.1.2	Other dataset type (clinical, EHR, survey, claims, SDOH, etc.)	NCHS is currently linking various NCHS surveys with administrative data from the following: National Death Index (NDI) Centers for Medicare and Medicaid Services (CMS) Medicare Medicaid/CHIP United States Renal Data System (USRDS) Social Security Administration (SSA) Department of Housing and Urban Development (HUD) Department of Veterans Affairs (VA). [1]	Administrative
7.1.3	Other dataset source(s)	NCHS is currently linking various NCHS surveys with administrative data from the following: National Death Index (NDI) Centers for Medicare and Medicaid Services (CMS) Medicare Medicaid/CHIP United States Renal Data System (USRDS) Social Security Administration (SSA) Department of Housing and Urban Development (HUD) Department of Veterans Affairs (VA). [1]	Sources of data for NHANES linkages: CDC, CM USRDS, SSA, HUD and VA
7.1.4	Linking methodology (PPRL or non- PPRL); linkage technology	Method for NHANES-NDI linkage: The linkage between the NCHS survey data and the NDI was based on both deterministic and probabilistic approaches. The probabilistic approach performs weighting and link adjudication following the Fellegi-Sunter method (9). The Fellegi-Sunter method is the foundational methodology used for record linkage. It estimates the likelihood that each pair is a match before selecting the most probable match between a survey record and NDI record. Following these approaches, a selection process was implemented with the goal of selecting pairs believed to represent the same individual between the data sources. The three main steps taken to link the NCHS survey data to the NDI are as follows: 1. Deterministic linkage was conducted, joining on exact SSN, and validated by comparison of other identifying fields. 2. Probabilistic linkage was conducted, identifying likely matches, or links, between all records. All deterministic matched pairs (from Step 1) were assigned a probabilistic match probability of 1; other records were linked and scored as follows (note that SSN is excluded from the analysis for this step): a. Pairs were formed via blocking. b. Potential matches were scored based on the concurrence of first name, middle initial, last name or father's surname, year of birth, month of birth, day of birth, state of birth, state of residence, race, and sex. c. Match probabilities were estimated through a model which assigned the estimated probability that pairs are matches.	

Source				
[1] <u>https://www.cdc.gov/nchs/data-</u> <u>linkage/index.htm</u> (Accessed: 4/17/23)				
[1] https://www.cdc.gov/nchs/data-				
<u>linkage/index.htm</u> (Accessed: 4/17/23)				
[1] https://www.cdc.gov/nchs/data/datalink age/2019NDI-Linkage-Methods-and- Analytic-Considerations-508.pdf (Accessed: 4/17/23)				

ataset 1	- NHANES			
		Raw Language	Interpretation	Source
		3. Pairs were selected which were believed to represent the same individual between the data sources. The pair having the highest estimated match probability was kept as long as it was above the linkage cut-off (see Appendix		
		 I). The linkage algorithm was developed with custom code (using SAS 9.4) and was tailored to perform these specific linkages, in order to produce high- quality matches with a low degree of linkage error. More detailed descriptions of the linkage methodology can be found in Appendix I of this report. [1] 		
7.1.5	PII elements used for the linkage	For linkage with NDI: The primary identifiers used in the linkages were: SSN9 or SSN4 (depending on the survey year or cycle of the survey), first name, middle initial, last name or father's surname, month of birth, day of birth, year of birth, state of birth, state of residence, race, and sex. [1]	For linkage with NDI, the following PIIs were used: -SSN9 or SSN4 (depending on the survey year or cycle of the survey) - first name - middle initial - last name or father's surname - month of birth - day of birth - year of birth - state of birth - state of residence - race - sex	[1] https://www.cdc.gov/nchs/data/datalinl age/2019NDI-Linkage-Methods-and- Analytic-Considerations-508.pdf (Accessed: 4/17/23)
7.1.6	Entity resolver (data originator or data linker or third party)	NCHS performed the entity resolution	NCHS performed the entity resolution	[1] https://www.cdc.gov/nchs/data/datalin age/2019NDI-Linkage-Methods-and- Analytic-Considerations-508.pdf (Accessed: 4/17/23)
7.1.7	Party performing the linkages	NCHS performed the data linkage	NCHS performed the data linkage	 [1] <u>https://www.cdc.gov/nchs/data/datalin</u> <u>age/2019NDI-Linkage-Methods-and-</u> <u>Analytic-Considerations-508.pdf</u> (Accessed: 4/17/23)
7.1.8	Linkage quality assessment	An external data source was used to assess the quality of the 2015 LMF and 2019 LMF. Based on the analysis, the 2019 LMF shows a slightly higher concordance with the external benchmark than the 2015 LMF, especially during the years when only SSN4 was collected. These analyses show that the new algorithm has improved linkage accuracy. [1]	An external data source was used to assess the quality of the 2015 LMF and 2019 LMF.	 [1] <u>https://www.cdc.gov/nchs/data/datalinlage/2019NDI-Linkage-Methods-and-Analytic-Considerations-508.pdf</u> (Accessed: 4/17/23)
7.1.9	Linked data sharing method (linkage maps or pre-linked dataset)	Additionally, the linked data files are made available in secure facilities for approved research projects. Researchers who want to access the restricted-use 2019 LMF must submit a research proposal to the NCHS Research Data Center (RDC) to obtain permission to access the restricted use files. [1]	Pre-linked data is made available through RDC	[1] https://www.cdc.gov/nchs/data/datalinl age/2019NDI-Linkage-Methods-and- Analytic-Considerations-508.pdf (Accessed: 4/17/23)

GOVERNANCE INFORMATION			
Effects of the COVID-19 pandemic	on mental health of children. Are COVID-19 pandemic related	I mental health outcomes more sev	vere for children in foster care?
National Survey on Drug Use	and Health (NSDUH)		
Dataset Source	National Survey on Drug Use and Health (NSDUH)		
Dataset Source Agency	SAMHSA		
Dataset Type (Clinical, EHR, Survey,	Survey (2017-2020)		
SDOH, etc.)			
Information Sources	Meeting with SAMHSA staff; Website		
National Survey on Drug Use	and Health (NSDUH)		
, ,	Raw Language	Interpretation	Source
Data Collection			
Authorizations and Applicable Regulations/Policies			
Authorizations			
Assent	You must always obtain informed consent from a respondent (and	Assent from children authorizes data	[1]
	gain permission from a parent/guardian before speaking to a	collection	https://www.samhsa.gov/data/sites/
	youth respondent aged 12-17 about the study, then obtain		default/files/reports/rpt23074/NSDU
	informed consent from the parent and youth to participate in the		HmrbFIManual2019.pdf (Accessed:
	study) by reading the Introduction and Informed Consent script		4/20/23)
	verbatim and providing the Study Description. [1]		
Consent	You must always obtain informed consent from a respondent (and	Consent from adults authorizes data	[1]
	gain permission from a parent/guardian before speaking to a	collection	https://www.samhsa.gov/data/sites/
	youth respondent aged 12-17 about the study, then obtain		default/files/reports/rpt23074/NSDU
	informed consent from the parent and youth to participate in the		HmrbFIManual2019.pdf (Accessed:
	study) by reading the Introduction and Informed Consent script		4/20/23)
	verbatim and providing the Study Description. [1]		
IBB/equivalent Privacy Board	RTI International takes great precautions to ensure all its surveys	BTI (DCC for NSDIIH) IBB authorizes	[1]
			https://nsduhweb.rti.org/respweb/c
			onfidentiality.html (Accessed:
			4/20/23)
			,
	guidelines from the U.S. Department of Health and Human		
	Service's Office for Human Research Protections.		
Local/state/federal law	The National Survey on Drug Use and Health (NSDLIH) provides	Public Health Service Act Section 505	[1]
			https://nsduhweb.rti.org/respweb/f
			aq.html (Accessed: 4/20/23)
			(
	currently conducted on an annual basis. NSDUH is authorized by		
	Section 505 of the Public Health Service Act, which requires		
	annual surveys to collect data on the level and patterns of		
	substance use.		
Institutional Certification	Information not available/found	Information not available/found	
	iffects of the COVID-19 pandemic National Survey on Drug Use Dataset Source Agency Dataset Type (Clinical, EHR, Survey, SDOH, etc.) nformation Sources National Survey on Drug Use Data Collection Authorizations and Applicable Regulations/Policies Authorizations	Effects of the COVID-19 pandemic on mental health of children. Are COVID-19 pandemic related National Survey on Drug Use and Health (NSDUH) Dataset Source National Survey on Drug Use and Health (NSDUH) Dataset Source Agency SAMHSA Dataset Source Network SAMHSA Dataset Type (Clinical, EHR, Survey, Survey (2017-2020) Survey (2017-2020) Notional Survey on Drug Use and Health (NSDUH) Raw Language Data Collection Raw Language Nathorizations and Applicable Raw Language Regulations/Policies You must always obtain informed consent from a respondent (and gain permission from a parent/guardian before speaking to a youth respondent aged 12-17 about the study, then obtain informed consent from the parent and youth to participate in the study) by reading the Introduction and Informed Consent script verbatim and providing the Study Description. [1] Consent You must always obtain informed consent from a respondent (and gain permission from a parent/guardian before speaking to a youth respondent aged 12-17 about the study, then obtain informed consent from the garent and youth to participate in the study) by reading the Introduction and Informed Consent script verbatim and providing the Study Description. [1] Consent You must always obtain informed consent from a respondent (and gain permission from a parent/guardian before speaking to a youth respondent aged 12-17 about the study, then obtain informed consent script verbatim and providing the Study Description. [1]	iffects of the COVID-19 pandemic on mental health of children. Are COVID-19 pandemic related mental health outcomes more set National Survey on Drug Use and Health (NSDUH) Dataset Source Mational Survey on Drug Use and Health (NSDUH) SAMHSA Dataset Source Agency SAMHSA Dataset Source Agency SAMHSA Dataset Type (Clinical, EHR, Survey, Information Sources Meeting with SAMHSA staff; Website Information Sources Meeting with SAMHSA staff; Website National Survey on Drug Use and Health (NSDUH) Interpretation Data Collection Raw Language Interpretation Authorizations and Applicable Regulations/Policies Vou must always obtain informed consent from a respondent (and gain permission from a paret/guardian before speaking to a youth respondent aged 12-17 about the study, then obtain informed consent from the parent and youth to participate in the study by preading the introduction and Informed Consent script werbatim and providing the Study Description. [1] Consent from adults authorizes data collection IRB/equivalent Privacy Board determination RTI International takes great precautions to ensure all its surveys, were conducted. The IRB reviews the study's protocio following guidelines from the US. Department of Health and Human Service'S Office for Human Research Protections. RTI (DCC for NSDUH) iBB authorizes data collection IRB/equivalent Privacy Board determination The National Survey on Drug Use and Health (NSDUH) provides national and state-level data on the use

		Raw Language	Interpretation	Source
1.1.1.7	Repository agreements/policies	Information not available/found	Information not available/found	
1.1.1.8	Other (specify)	Information not available/found	Information not available/found	
.1.2	Applicable Regulations/Policies			
1.1.2.1	Local regulations/policies	Because of the coronavirus disease 2019 (COVID-19) pandemic,	SAMHSA recommendation	[1]
		major changes were made to the methods used in data collection		https://www.samhsa.gov/data/fa
		in 2020. There is no way to separate out the true changes in		oncerns-about-trend-
		behavior from the changes due to the new methodology.		comparability/why-does-samhsa-
				caution-against-comparing-2020-
		The main methodological changes were:		estimates-estimates-prior-years
				(Accessed: 9/12/23)
		Almost no data collection from mid-March through September		
		2020, Introduction of web data collection in October 2020 with		
		very limited in-person data collection, and		
		Additions to the questionnaire beginning in October 2020.		
		The 2020 NSDUH is missing two quarters of data. Tests of data		
		from before 2020 show that estimates based on just quarters 1		
		and 4 are not comparable to estimates based on the entire year.		
		This indicates that 2020 estimates should not be compared to		
		previous years. Repeated analyses have showed that web		
		responses are not comparable to in-person responses, and that		
		the comparability is not consistent in a way that we can fully		
		account for. For these reasons, it is not recommended to compare		
		any estimates from 2020 to estimates from 2019 or earlier. [1]		
1.1.2.2	Tribal regulations/policies	Information not available/found	Information not available/found	
1.1.2.3	State regulations/policies	Information not available/found	Information not available/found	
1.1.2.4	Federal regulations/policies	NSDUH collects highly-sensitive information from individual	Confidential Information Protection	[1]
		respondents, including data on substance use and mental health	and Statistical Efficiency Act (CIPSEA)	https://www.datafiles.samhsa.g
		concerns. Ensuring respondent confidentiality is crucial to		et-help/public-vs-restricted-
		encouraging participation in the survey and responses are		use/what-difference-between-ns
		protected under the Confidential Information Protection and		public-and-restricted-use-data
		Statistical Efficiency Act (CIPSEA). [1]		(Accessed: 4/20/23)
1.1.2.5	International regulations/policies	N/A - The National Survey on Drug Use and Health (NSDUH),	N/A	[1]
		conducted annually by the Substance Abuse and Mental Health		https://www.samhsa.gov/data/
		Services Administration (SAMHSA), provides nationally		we-collect/nsduh-national-surve
		representative data on the use of tobacco, alcohol, and illicit		drug-use-and-health (Accessed:
		drugs; substance use disorders; receipt of substance use		4/20/23)
		treatment; mental health issues; and the use of mental health		
		services among the civilian, noninstitutionalized population aged		
		12 or older in the United States. [1]		
1.1.2.6	Contractual obligations	Information not available/found	Information not available/found	
1.1.2.7	Repository policies	Information not available/found	Information not available/found	

	, ,	and Health (NSDUH)		
		Raw Language	Interpretation	Source
1.2.1	Whether the data can be linked	Does not authorize/specify - linkage is not specified in any authorization. [1]	Does not authorize/specify	[1] NDACAN Meeting
1.2.2	With what other data can it be linked or can it not be linked (scope of linkage)	Does not authorize/specify - linkage is not specified in any authorization. [1]	Does not authorize/specify	[1] NDACAN Meeting
1.2.3	Whether data can be shared	Information not available/found	Information not available/found	
1.2.4	How data can be shared (de- identification status, disclosure review)	Information not available/found	Information not available/found	
1.2.5	How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.)	Information not available/found	Information not available/found	
1.2.6	How data can be used (data use limitations)	Information not available/found	Information not available/found	
1.2.7	Other (specify)	Because of the coronavirus disease 2019 (COVID-19) pandemic, major changes were made to the methods used in data collection in 2020. There is no way to separate out the true changes in behavior from the changes due to the new methodology. The main methodological changes were: Almost no data collection from mid-March through September 2020, Introduction of web data collection in October 2020 with very limited in-person data collection, and Additions to the questionnaire beginning in October 2020. The 2020 NSDUH is missing two quarters of data. Tests of data from before 2020 show that estimates based on just quarters 1 and 4 are not comparable to estimates based on the entire year. This indicates that 2020 estimates should not be compared to previous years. Repeated analyses have showed that web responses are not comparable to in-person responses, and that the comparability is not consistent in a way that we can fully account for. For these reasons, it is not recommended to compare any estimates from 2020 to estimates from 2019 or earlier. [1]	SAMHSA recommends against comparing 2020 NSDUH data with prior years due to methodological changes	[1] https://www.samhsa.gov/data/fa oncerns-about-trend- comparability/why-does-samhsa- caution-against-comparing-2020- estimates-estimates-prior-years (Accessed: 9/12/23)
<u>)</u>	Data Linkage		1	
2.1	Authorizations and Applicable Regulations/Policies			
2.1.1	Authorizations			
2.1.1.1	Assent	Information not available/found	Information not available/found	
2.1.1.1	Consent	Information not available/found	Information not available/found	

ataset 2	- National Survey on Drug Use	and Health (NSDUH)		
		Raw Language	Interpretation	Source
2.1.1.3	IRB/equivalent Privacy Board determination	Information not available/found	Information not available/found	
2.1.1.4	Local/state/federal laws	Information not available/found	Information not available/found	
2.1.1.5	Institutional Certification	Information not available/found	Information not available/found	
2.1.1.6	Data originator agreement	Information not available/found	Information not available/found	
2.1.1.7	Repository agreements/policies	Information not available/found	Information not available/found	
2.1.1.8	Other (specify)	Information not available/found	Information not available/found	
2.1.2	Applicable Regulations/Policies			
2.1.2.1	Local regulations/policies	Information not available/found	Information not available/found	
2.1.2.2	Tribal regulations/policies	Information not available/found	Information not available/found	
2.1.2.3	State regulations/policies	Information not available/found	Information not available/found	
2.1.2.4	Federal regulations/policies	Information not available/found	Information not available/found	
2.1.2.5	International regulations/policies	N/A - The National Survey on Drug Use and Health (NSDUH),	N/A	[1]
		conducted annually by the Substance Abuse and Mental Health		https://www.samhsa.gov/data/da
		Services Administration (SAMHSA), provides nationally		we-collect/nsduh-national-survey-
		representative data on the use of tobacco, alcohol, and illicit		drug-use-and-health (Accessed:
		drugs; substance use disorders; receipt of substance use		4/20/23)
		treatment; mental health issues; and the use of mental health		
		services among the civilian, noninstitutionalized population aged		
		12 or older in the United States. [1]		
2.1.2.6	Contractual obligations	Information not available/found	Information not available/found	
2.1.2.7	Repository policies	Information not available/found	Information not available/found	
2.2	Governance for data linkage, shari	ng, access, and use based on data linkage authorization or ap	oplicable regulations/policies (i.e.,	the origin of the governance)
2.2.1	Whether the data can be linked	Information not available/found	Information not available/found	
2.2.2	With what other data can it be	Information not available/found	Information not available/found	
	linked or can it not be linked (scope of linkage)			
2.2.3	Whether data can be shared	Information not available/found	Information not available/found	
2.2.4	How data can be shared (de-	Information not available/found	Information not available/found	
	identification status, disclosure review)			
2.2.5	How data can be accessed (access	Information not available/found	Information not available/found	
	type, data use agreement, data			
	access committee/group approval,			
	IRB LOD, etc.)			
2.2.6	How data can be used (data use	Information not available/found	Information not available/found	
2.2.0	limitations)			
2.2.7	Other (specify)	Information not available/found	Information not available/found	
3	Data Sharing			
3.1	Authorizations and Applicable			
	Regulations/Policies			

		Raw Language	Interpretation	Source
3.1.1.1	Assent	Information not available/found	Information not available/found	
3.1.1.2	Consent	Information not available/found	Information not available/found	
3.1.1.3		Information not available/found	Information not available/found	
	determination			
3.1.1.4	Local/state/federal laws	Information not available/found	Information not available/found	
3.1.1.5	Institutional Certification	Information not available/found	Information not available/found	
3.1.1.6	Data originator agreement	Information not available/found	Information not available/found	
3.1.1.7	Repository agreements/policies	Information not available/found	Information not available/found	
3.1.1.8	Other	Information not available/found	Information not available/found	
3.1.2	Applicable Regulations/Policies			
3.1.2.1	Local regulations/policies	Information not available/found	Information not available/found	
3.1.2.2	Tribal regulations/policies	Information not available/found	Information not available/found	
3.1.2.3	State regulations/policies	Information not available/found	Information not available/found	
3.1.2.4	Federal regulations/policies	NSDUH collects highly-sensitive information from individual	Confidential Information Protection	[1]
		respondents, including data on substance use and mental health	and Statistical Efficiency Act (CIPSEA)	https://www.datafiles.samhsa.gov
		concerns. Ensuring respondent confidentiality is crucial to		et-help/public-vs-restricted-
		encouraging participation in the survey and responses are		use/what-difference-between-nsd
		protected under the Confidential Information Protection and		public-and-restricted-use-data
		Statistical Efficiency Act (CIPSEA). [1]		(Accessed: 4/20/23)
3.1.2.5	International regulations/policies	N/A - The National Survey on Drug Use and Health (NSDUH),	N/A	[1]
		conducted annually by the Substance Abuse and Mental Health		https://www.samhsa.gov/data/dat
		Services Administration (SAMHSA), provides nationally		we-collect/nsduh-national-survey-
		representative data on the use of tobacco, alcohol, and illicit		drug-use-and-health (Accessed:
		drugs; substance use disorders; receipt of substance use		4/20/23)
		treatment; mental health issues; and the use of mental health		
		services among the civilian, noninstitutionalized population aged		
		12 or older in the United States. [1]		
3.1.2.6	Contractual obligations	Information not available/found	Information not available/found	
3.1.2.7	Repository policies	Information not available/found	Information not available/found	
3.2	Governance for data linkage, shari	ng, access, and use based on data sharing authorization or a	oplicable regulations/policies (i.e.,	the origin of the governance)
3.2.1	Whether the data can be linked	Information not available/found	Information not available/found	
3.2.2	With what other data can it be	Information not available/found	Information not available/found	
	linked or can it not be linked			
	(scope of linkage)			
3.2.3	Whether data can be shared	Information not available/found	Information not available/found	
3.2.4	How data can be shared (de-	Information not available/found	Information not available/found	
	identification status, disclosure			
	review)			
3.2.5	How data can be accessed (access	Information not available/found	Information not available/found	
	type, data use agreement, data			
	access committee/group approval,			
	IRB LOD, etc.)			

		Raw Language	Interpretation	Source
3.2.6	How data can be used (data use limitations)	Information not available/found	Information not available/found	
3.2.7	Other (specify)	Information not available/found	Information not available/found	
4	Data Access			
4.1	Authorizations and Applicable			
	Regulations/Policies			
4.1.1	Authorizations			
4.1.1.1	Assent	Information not available/found	Information not available/found	
4.1.1.2	Consent	Information not available/found	Information not available/found	
4.1.1.3	IRB/equivalent Privacy Board	Information not available/found	Information not available/found	
	determination			
4.1.1.4	Local/state/federal laws	Information not available/found	Information not available/found	
4.1.1.5	Institutional Certification	Information not available/found	Information not available/found	
4.1.1.6	Data originator agreement	Information not available/found	Information not available/found	
1.1.1.7	Repository agreements/policies	All analysts entering the RDC must sign the DAA (Data Access	Two repository agrements authorize	[1]
		Agreement) form. For students wanting to access NSDUH RUF,	data access:	https://www.samhsa.gov/data/data
		both students and their advisors must also sign the SAMHSA RDC	1. Data Access Agreement (DAA) form	we-collect/samhsa-rdc (Accessed:
		Student Data User Acknowledgement form. [1]	2. For students, the SAMHSA RDC	4/20/23)
			Student Data User Acknowledgement	
			form signed by the student and their	
			advisor	
4.1.1.8	Other (specify)	Information not available/found	Information not available/found	
4.1.2	Applicable Regulations/Policies			
4.1.2.1	Local regulations/policies	Information not available/found	Information not available/found	
4.1.2.2	Tribal regulations/policies	Information not available/found	Information not available/found	
4.1.2.3	State regulations/policies	Information not available/found	Information not available/found	
4.1.2.4	Federal regulations/policies	All researchers on the project must complete confidentiality	Confidential Information Protection	[1]
		training and sign and complete the Designated Agent Form (DAF)	and Statistical Efficiency Act (CIPSEA)	https://www.samhsa.gov/data/data
		with a notary signature. Signing the DAF allows researchers to		we-collect/samhsa-rdc (Accessed:
		become designated agents to access CIPSEA protected data. In		4/20/23)
		addition, all analysts entering the RDC must sign the DAA (Data		
		Access Agreement) form. The training certificate and signed DAA		
		and DAF must be submitted to be considered a complete package.		
		For students wanting to access NSDUH RUF, both students and		
		their advisors must also sign the SAMHSA RDC Student Data User		
		Acknowledgement form. [1]		

		Raw Language	Interpretation	Source
4.1.2.5	International regulations/policies	N/A - The National Survey on Drug Use and Health (NSDUH), conducted annually by the Substance Abuse and Mental Health Services Administration (SAMHSA), provides nationally representative data on the use of tobacco, alcohol, and illicit drugs; substance use disorders; receipt of substance use treatment; mental health issues; and the use of mental health services among the civilian, noninstitutionalized population aged 12 or older in the United States. [1]	N/A	[1] https://www.samhsa.gov/data/data we-collect/nsduh-national-survey- drug-use-and-health (Accessed: 4/20/23)
4.1.2.6	Contractual obligations	Information not available/found	Information not available/found	
4.1.2.7	Repository policies	Prospective researchers must submit an RDC application, also known as an RDC proposal, that will be reviewed by the SAMHSA RDC team. The proposal must be approved before any other procedures can happen. [1] All researchers on the project must complete confidentiality training and sign and complete the Designated Agent Form (DAF) with a notary signature. Signing the DAF allows researchers to become designated agents to access CIPSEA protected data. In addition, all analysts entering the RDC must sign the DAA (Data Access Agreement) form. The training certificate and signed DAA and DAF must be submitted to be considered a complete package. For students wanting to access NSDUH RUF, both students and their advisors must also sign the SAMHSA RDC Student Data User Acknowledgement form. [1]	SAMHSA RDC policy	[1] <u>https://www.samhsa.gov/data/data</u> <u>we-collect/samhsa-rdc</u> (Accessed: 4/20/23)
4.2	_	ing, access, and use based on data access authorization or ap		the origin of the governance)
4.2.1	Whether the data can be linked	Information not available/found	Information not available/found	
4.2.2	With what other data can it be linked or can it not be linked (scope of linkage)	Information not available/found	Information not available/found	
4.2.3	Whether data can be shared	Information not available/found	Information not available/found	
4.2.4	How data can be shared (de- identification status, disclosure review)	Information not available/found	Information not available/found	

Dataset 2 -	National Survey on Drug Use	and Health (NSDUH)		
		Raw Language	Interpretation	Source
4.2.5	How data can be accessed (access	Prospective researchers must submit an RDC application, also	SAMHSA RDC specifies that for data	[1]
	type, data use agreement, data	known as an RDC proposal, that will be reviewed by the SAMHSA	access, a user:	https://www.samhsa.gov/data/data-
	access committee/group approval,	RDC team. The proposal must be approved before any other	1. Submit RDC application	we-collect/samhsa-rdc (Accessed:
	IRB LOD, etc.)	procedures can happen. SAMHSA review is to make sure that all	2. Obtain approval from SAMHSA	4/20/23)
		requirements as specified in "Guidelines for SAMHSA RDC Data	staff on the research proposed in the	
		Users" and "RDC sample proposal" are carefully followed. In	RDC application	
		addition to the format and completeness, the following two	3. Sign and complete Designated	
		aspects are of particular importance for the application to pass	Agent Form (DAF)	
		SAMHSA review:	4. Sign and complete Data Access	
		The feasibility of existing data to the project, that is, whether it is	Agreement (DAA) form	
		possible for the research to be conducted with the available	5. Complete confidentiality training	
		information. On occasion, it is clear from the outset that the	6. Students and their advisors must	
		sample will not support the intended analysis. For instance,	also sign the SAMHSA RDC Student	
		NSDUH does not allow for individual-level record linkage.	Data User Acknowledgement form	
		The risk of disclosure of restricted information, that is, whether	7. Access data only through RDC	
		the analysis can be conducted without compromising the		
		confidentiality promised to all respondents (children, adults,		
		households, neighborhoods).		
		We may ask the researchers or the data users to provide		
		additional clarifications and revisions if it is deemed necessary.		
		The application will be approved if all requirements are met.		
		Approval of the proposal does not constitute endorsement by		
		SAMHSA of the substantive, methodological, theoretical, policy		
		relevance, or scientific aspects of the proposed research. [1]		
		All researchers on the project must complete confidentiality		
		training and sign and complete the Designated Agent Form (DAF)		
		with a notary signature. Signing the DAF allows researchers to		

Dataset 2	 National Survey on Drug Use 	and Health (NSDUH)		
		Raw Language	Interpretation	Source
		become designated agents to access CIPSEA protected data. In		
		addition, all analysts entering the RDC must sign the DAA (Data		
		Access Agreement) form. The training certificate and signed DAA		
		and DAF must be submitted to be considered a complete package.		
		For students wanting to access NSDUH RUF, both students and		
		their advisors must also sign the SAMHSA RDC Student Data User		
		Acknowledgement form. [1]		
		The research data center (RDC) program provides a mechanism		
		for data users to access NSDUH restricted-use data files in a		
		secure, confidentiality-compliant manner. SAMHSA RDC does not		
		have our own RDC sites. SAMHSA RDC collaborates with the		
		National Center for Health Statistics (NCHS) RDC and the Federal		
		Statistical Research Data Centers (FSRDC) to carry out the NSDUH		
		RDC program. All SAMHSA RDC users should carefully read		
		"Guidelines for SAMHSA RDC Data Users" before accessing RUF		
		data. [1]		
4.2.6	How data can be used (data use limitations)	Information not available/found	Information not available/found	
4.2.7	Other (specify)	Information not available/found	Information not available/found	
5	Data Use			
5.1	Authorizations and Applicable			
	Regulations/Policies			
5.1.1	Authorizations			
5.1.1.1	Assent	Information not available/found	Information not available/found	
5.1.1.2	Consent	Information not available/found	Information not available/found	
5.1.1.3	IRB/equivalent Privacy Board	Information not available/found	Information not available/found	
	determination			
5.1.1.4	Local/state/federal laws	Information not available/found	Information not available/found	
5.1.1.5	Institutional Certification	Information not available/found	Information not available/found	
5.1.1.6	Data originator agreement	Information not available/found	Information not available/found	
5.1.1.7	Repository agreements/policies	All analysts entering the RDC must sign the DAA (Data Access	RDC Data Access Agreement (DAA)	[1]
		Agreement) form. [1]	form authorizes data use	https://www.samhsa.gov/data/dat
				we-collect/samhsa-rdc (Accessed:
				4/20/23)
5.1.1.8	Other (specify)	Information not available/found	Information not available/found	
5.1.2	Applicable Regulations/Policies			
5.1.2.1	Local regulations/policies	Information not available/found	Information not available/found	
5.1.2.2	Tribal regulations/policies	Information not available/found	Information not available/found	

Dataset Z	- National Survey on Drug Use			-
		Raw Language	Interpretation	Source
5.1.2.3	State regulations/policies	 Study description: This study, sponsored by the U.S. Department of Health and Human Services, collects information for research and program planning by asking about: tobacco, alcohol, and drug use or non-use, knowledge and attitudes about drugs, mental health, and other health issues. You cannot be identified through any information you give us. Your name and address will never be connected to your answers. Also, federal law requires us to keep all of your answers confidential. Any data that you provide will only be used by authorized personnel for statistical purposes according to the Confidential Information Protection and Statistical Efficiency Act of 2002. [1] 	Confidential Information Protection and Statistical Efficiency Act (CIPSEA)	[1] https://www.samhsa.gov/data/sites default/files/reports/rpt23074/NSDI HmrbFIManual2019.pdf (Accessed: 4/20/23)
5.1.2.4	Federal regulations/policies	Information not available/found	Information not available/found	
5.1.2.5	International regulations/policies	N/A - The National Survey on Drug Use and Health (NSDUH), conducted annually by the Substance Abuse and Mental Health Services Administration (SAMHSA), provides nationally representative data on the use of tobacco, alcohol, and illicit drugs; substance use disorders; receipt of substance use treatment; mental health issues; and the use of mental health services among the civilian, noninstitutionalized population aged 12 or older in the United States. [1]	N/A	 [1] <u>https://www.samhsa.gov/data/data-we-collect/nsduh-national-survey-drug-use-and-health</u> (Accessed: 4/20/23)
5.1.2.6	Contractual obligations	Information not available/found	Information not available/found	
5.1.2.7	Repository policies	The Substance Abuse and Mental Health Data Archive (SAMHDA) provides a public web portal that allows people to review and download public-use and restricted-use data files and documentation. SAMHSA has partnered with the National Center for Health Statistics (NCHS) to host restricted-use NSDUH data at its Federal Statistical Research Data Centers (RDCs). RDCs are secure facilities that provide access to a range of restricted-use microdata for statistical purposes. SAMHSA is the most recent federal partner to work with NCHS in making NSDUH restricted-use microdata available to approved researchers at RDC sites. Eligible researchers may now apply for access to these data through SAMHSA's RDC website.		[1] <u>https://www.datafiles.samhsa.gov/a</u> <u>bout-us/policies</u> (Accessed: 4/20/23)
5.2	Governance for data linkage shari	ing, access, and use based on data access authorization or ap	 nlicable regulations/nolicies (i.e., th	ne origin of the governance)

		and Health (NSDUH)		•
		Raw Language	Interpretation	Source
5.2.2	With what other data can it be linked or can it not be linked (scope of linkage)	Information not available/found	Information not available/found	
5.2.3	Whether data can be shared	Information not available/found	Information not available/found	
5.2.4	How data can be shared (de- identification status, disclosure review)	Information not available/found	Information not available/found	
5.2.5	How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.)	Information not available/found	Information not available/found	
5.2.6	How data can be used (data use	RDC Data Access Agreement (DAA):	RDC DAA specifies that the data were	[1]
	limitations)	These data were collected with the assurance that they will be	collected with the assurance that	https://www.samhsa.gov/data/sites
		used only for health statistical reporting and analysis.	they will be used only for health	default/files/2021-11/Access-
			statistical reporting and analysis	Agreement-20211101-Fillable.pdf
				(Accessed: 4/20/23)
5.2.7	Other (specify)	Information not available/found	Information not available/found	
6	PII Elements			
6.1	PII elements collected	Information not available/found	Information not available/found	
6.2	PII elements holder (i.e., party that holds the PII)	Information not available/found	Information not available/found	
6.3	Use of common data model, if any, for data collection	Information not available/found	Information not available/found	
7	Prior Data Linkages			
7.1	Dataset linked with other datasets			
7.1.1	Name of other linked dataset	Information not available/found	Information not available/found	
7.1.2	Other dataset type (clinical, EHR, survey, claims, SDOH, etc.)	Information not available/found	Information not available/found	
7.1.3	Other dataset source(s)	Information not available/found	Information not available/found	
7.1.4	Linking methodology (PPRL or non- PPRL); linkage technology	Information not available/found	Information not available/found	
7.1.5	PII elements used for the linkage	Information not available/found	Information not available/found	
7.1.6	Entity resolver (data originator or data linker or third party)	Information not available/found	Information not available/found	
7.1.7	Party performing the linkages	Information not available/found	Information not available/found	
7.1.8	Linkage quality assessment	Information not available/found	Information not available/found	
7.1.9	Linked data sharing method (linkage maps or pre-linked	Information not available/found	Information not available/found	
	dataset)			

USE CASE 1	- GOVERNANCE INFORMATION			
	-	al health of children. Are COVID-19 pandemic related me		r children in foster care?
Jataset 3		ntinuing Study of American Youth (Restricted-Use)	
	Dataset Source	National Addiction and HIV Data Archive Program (NAHDAP)		
	Dataset Source Agency	Funded by NIDA, conducted by Survey Research Center in the		
		Institute for Social Research at the University of Michigan		
	Dataset Type (Clinical, EHR, Survey, SDOH, etc.)	Survey (2017-2021)		
	Information Sources	U-Mich Legal meeting, NAHDAP staff meeting; MTF team		
		email communication; website		
)ataset 3	- Monitoring the Future (MTF)			
		Raw Language	Interpretation	Source
1	Data Collection		•	l
1.1	Authorizations and Applicable			
	Regulations/Policies			
1.1.1	Authorizations		1. Assent from children	
			2. Consent from parents	
			3. MTF (U-Mich) IRB approval	
1.1.1.1	Assent	MTF is an ongoing study; MTF obtains assent from children,	Assent from children authorizes data	[1] U-Mich Legal Meeting
		but also has a consent process with the parents for data	collection	
		collection. [1]		
1.1.1.2	Consent	Consent forms are sent to the parents of the targeted	Consent from parents authorizes data	[1] NAHDAP Meeting
		respondents 3 weeks prior to the targeted survey dates; this	collection	[2]
		survey is sent to school administrators, which are then sent to		https://monitoringthefuture.org/w
		the parents who elicit the consent forms. [1]		content/uploads/2022/12/mtf2022
				<u>df</u> (Accessed: 4/18/23)
		Informed consent (active or passive, per school policy) is		
		obtained from parents of students younger than 18 years and		
		from students aged 18 years or older. About three weeks prior		
		to the questionnaire administration date, parents of the		
		target respondents are sent a letter by first-class mail, usually		
		from the principal, announcing and describing the MTF study		
		and providing parents with an opportunity to decline		
		participation of their child if they wish. [2]		
1.1.1.3	IRB/equivalent Privacy Board determination	The MTF PIs needed approval from their IRB to collect the	MTF (U-Mich) IRB approval authorizes	[1] NAHDAP Meeting
		data. [1]	data collection	
1.1.1.4	Local/state/federal law	Information not available/found	Information not available/found	
1.1.1.5	Institutional Certification	Information not available/found	Information not available/found	
1.1.1.6	Data originator agreement	Information not available/found	Information not available/found	
1.1.1.7	Repository agreements/policies	Information not available/found	Information not available/found	
1.1.1.8		Information not available/found	Information not available/found	
1.1.2	Applicable Regulations/Policies			
1.1.2.1	Local regulations/policies	Information not available/found	Information not available/found	
1.1.2.2	Tribal regulations/policies	Information not available/found	Information not available/found	

	- Monitoring the Future (MTF)	Raw Language	Interpretation	Source
1.1.2.3	State regulations/policies	Information not available/found	Information not available/found	Source
1.1.2.4	Federal regulations/policies	Information not available/found	Information not available/found	
1.1.2.4		N/A - Since 1975 the MTF survey has measured drug and	N/A	[1] <u>https://nida.nih.gov/research-</u>
1.1.2.5			N/A	
		alcohol use and related attitudes among adolescent students		topics/trends-statistics/monitorin
		nationwide. [1]		future (Accessed: 4/18/23)
1.1.2.6		Information not available/found	Information not available/found	
1.1.2.7		Information not available/found	Information not available/found	
		s, and use based on data collection authorization or app		
1.2.1		Does not authorize/specify - U-Mich Legal is unaware of any previous linkage of the MTF data; the consent/assent does not have any language that pertains to linkage. [1]	Does not authorize/specify	[1] U-Mich Legal Meeting
1.2.2	With what other data can it be linked or can	Does not authorize/specify - U-Mich Legal is unaware of any	Does not authorize/specify	[1] U-Mich Legal Meeting
	it not be linked (scope of linkage)	previous linkage of the MTF data; the consent/assent does		
		not have any language that pertains to linkage. [1]		
1.2.3	Whether data can be shared	Information not available/found - The consent references the	Information not available/found	[1] U-Mich Legal Meeting
		Grant of confidentiality from the U.S. Department of Justice,	,	
		and may also include language about sharing de-identified		
		data. [1]		
1.2.4	-	Information not available/found	Information not available/found	
	status, disclosure review)			
1.2.5	How data can be accessed (access type,	Does not authorize/specify	Does not authorize/specify	
	data use agreement, data access			
	committee/group approval, IRB LOD, etc.)			
1.2.6	How data can be used (data use limitations)	The consent specifies that the data can be used for broad	Consent specifies that the data can be	[1] U-Mich Legal Meeting
		research. [1]	used for broad research	
1.2.7		Information not available/found	Information not available/found	
2	Data Linkage			1
	-			
2.1	Authorizations and Applicable			
	Regulations/Policies		1	
2.1.1	Authorizations			
2.1.1.1	Assent	Does not authorize/specify - U-Mich Legal is unaware of any	Does not authorize/specify	[1] U-Mich Legal Meeting
		previous linkage of the MTF data; the consent/assent does		
		not have any language that pertains to linkage. [1]		
2.1.1.2	Consent	Does not authorize/specify - U-Mich Legal is unaware of any	Does not authorize/specify	[1] U-Mich Legal Meeting
		previous linkage of the MTF data; the consent/assent does		
		not have any language that pertains to linkage. [1]		
2.1.1.3	IRB/equivalent Privacy Board determination		Does not authorize/specify	
		Does not authorize/specify	Does not authorize/specify	
		Does not authorize/specify	Does not authorize/specify	
2.1.1.4			Does not authorize/specify	
2.1.1.5			Doos not authorizo/specify	
2.1.1.5 2.1.1.6	Data originator agreement	Does not authorize/specify	Does not authorize/specify	
2.1.1.5	Data originator agreement Repository agreements/policies		Does not authorize/specify Does not authorize/specify Information not available/found	

Dataset 3	- Monitoring the Future (MTF)			
		Raw Language	Interpretation	Source
2.1.2.1	Local regulations/policies	Information not available/found	Information not available/found	
2.1.2.2	Tribal regulations/policies	Information not available/found	Information not available/found	
2.1.2.3	State regulations/policies	Information not available/found	Information not available/found	
2.1.2.4	Federal regulations/policies	Information not available/found	Information not available/found	
2.1.2.5	International regulations/policies	N/A - Since 1975 the MTF survey has measured drug and	N/A	[1] https://nida.nih.gov/research-
		alcohol use and related attitudes among adolescent students		topics/trends-statistics/monitoring-
		nationwide. [1]		future (Accessed: 4/18/23)
2.1.2.6	Contractual obligations	Information not available/found	Information not available/found	
2.1.2.7	Repository policies	Information not available/found	Information not available/found	
2.2	Governance for data linkage, sharing, acces	s, and use based on data linkage authorization or applic	able regulations/policies (i.e., the ori	gin of the governance)
2.2.1	Whether the data can be linked	Does not authorize/specify	Does not authorize/specify	
2.2.2	With what other data can it be linked or can		Does not authorize/specify	
	it not be linked (scope of linkage)			
2.2.3	Whether data can be shared	Does not authorize/specify	Does not authorize/specify	
2.2.4	How data can be shared (de-identification	Does not authorize/specify	Does not authorize/specify	
	status, disclosure review)			
2.2.5	How data can be accessed (access type,	Does not authorize/specify	Does not authorize/specify	
	data use agreement, data access			
	committee/group approval, IRB LOD, etc.)			
2.2.6	How data can be used (data use limitations)	Does not authorize/specify	Does not authorize/specify	
2.2.7	Other (specify)	Information not available/found	Information not available/found	
3	Data Sharing			
3.1	Authorizations and Applicable			
	Regulations/Policies			
3.1.1	Authorizations		1. ICPSR (U-Mich) IRB approval	
0.1.1			2. MTF (U-Mich) IRB approval	
			3. MTF PI determination (for	
			sharing/accessing data through ICPSR	
			VDE)	
			4. Family Educational Rights and Privacy	,
			Act (FERPA)	
3.1.1.1	Assent	Information not available/found - The consent references the		[1] U-Mich Legal Meeting
5.1.1.1		Grant of confidentiality from the U.S. Department of Justice,		
		and <u>may</u> also include language about sharing de-identified		
		data. [1]		
3.1.1.2	Consent	Information not available/found - The consent references the	Information not available/found	[1] U-Mich Legal Meeting
5.1.1.2		Grant of confidentiality from the U.S. Department of Justice,		
		and <u>may</u> also include language about sharing de-identified		
		data. [1]		

	Monitoring the Future (MTF)	Raw Language	Interpretation	Source
2442		Raw Language	•	
3.1.1.3		For MTF, the RUDDDA was not executed since the data originating organization is also within U-Mich, and the practice at the time MTF was deposited; the current practice is to execute a memorandum of understanding for studies within U Mich to deposit data (however, MTF also does not have a memorandum of understanding in place). In lieu of these documents (RUDDDA and MoU), MTF did have IRB oversight of ICPSR taking over the dissemination of the restricted-use data; the IRB number of the MTF study is linked to ICPSR's reference number (for ICPSR's IRB) U-Mich authorized NAHDAP to share the MTF data; IRB oversight was provided and authorization from the MTF PI. [1]	Two IRBs authorize data sharing: 1. ICPSR (U-Mich) IRB 2. MTF (U-Mich) IRB	[1] NAHDAP Meeting [2] https://www.icpsr.umich.edu/wel ages/datamanagement/confident y/ (Accessed: 4/18/23)
		conditions consistent with the informed consent of the study participants and the relevant <u>Institutional Review Board (IRB)</u> approval. [2]		
3.1.1.4		Generally, schools must have written permission from the parent or eligible student in order to release any information from a student's education record. However, FERPA allows schools to disclose those records, without consent, to the following parties or under the following conditions (34 CFR § 99.31): -School officials with legitimate educational interest; -Other schools to which a student is transferring; -Specified officials for audit or evaluation purposes; -Appropriate parties in connection with financial aid to a student; -Organizations conducting certain studies for or on behalf of the school; -Accrediting organizations; -To comply with a judicial order or lawfully issued subpoena; -Appropriate officials in cases of health and safety emergencies; and -State and local authorities, within a juvenile justice system, pursuant to specific State law. [1]	Family Educational Rights and Privacy Act (FERPA) authorize data sharing	[1] https://www2.ed.gov/policy/gen/ d/fpco/ferpa/index.html (Accesse 4/25/23)
3.1.1.5	Institutional Certification	Information not available/found	Information not available/found	
3.1.1.6	Data originator agreement	N/A - For MTF, the RUDDDA was not executed since the data originating organization is also within U-Mich, and the practice at the time MTF was deposited; the current practice is to execute a memorandum of understanding for studies within U	N/A	[1] NAHDAP Meeting
		Mich to deposit data (however, MTF also does not have a memorandum of understanding in place). [1]		

Other	Raw Language The determination for sharing data through the VDE is made	Interpretation MTF PI authorizes data sharing (through	Source
Other	The determination for sharing data through the VDE is made	MTE PL authorizes data sharing (through	
	by the NADHAP staff based on the level of disclosure risk and/or discussion with the data originator. For MTF, the PI requested that the restricted-use MTF data be shared/accessed through VDE. [1]	the ICPSR VDE)	[1] NAHDAP meeting
Applicable Regulations/Policies			
	Information not available/found	Information not available/found	
- · ·	· · · · · · · · · · · · · · · · · · ·		
Federal regulations/policies	MTF also has a grant of confidentality from the U.S. Department of Justice (which is different from the usual NIH grant of confidentality) In brief, the primary regulations are all IRB related, plus any/all applicable federal agency-specific policies (NIH data sharing, FERPA, etc). [1]	 Grant of Confidentality from the U.S. Department of Justice Family Educational Rights and Privacy Act (FERPA) 	 [1] MTF Email Communication [2] U-Mich Legal Meeting [3] <u>https://www2.ed.gov/policy/gen/gu</u> <u>d/fpco/ferpa/index.html</u> (Accessed: 4/25/23)
	Generally, schools must have written permission from the parent or eligible student in order to release any information from a student's education record. However, FERPA allows schools to disclose those records, without consent, to the following parties or under the following conditions (34 CFR § 99.31): -School officials with legitimate educational interest; -Other schools to which a student is transferring; -Specified officials for audit or evaluation purposes; -Appropriate parties in connection with financial aid to a student; -Organizations conducting certain studies for or on behalf of the school; -Accrediting organizations; -To comply with a judicial order or lawfully issued subpoena; -Appropriate officials in cases of health and safety emergencies; and		
	Applicable Regulations/Policies Local regulations/policies Tribal regulations/policies State regulations/policies Federal regulations/policies	Applicable Regulations/Policies Information not available/found Tribal regulations/policies Information not available/found State regulations/policies Information not available/found Federal regulations/policies MTF also has a grant of confidentality from the U.S. Department of Justice (which is different from the usual NIH grant of confidentiality) In brief, the primary regulations are all IRB related, plus any/all applicable federal agency-specific policies (NIH data sharing, FERPA, etc). [1] Grant of confidentiality from the U.S. Department of Justice is different from a certificate of confidentiality because it comes from the authority to issue this is for drugs and other controlled substance research; the grant of confidentiality specifies that researchers cannot reidentify participants, and its purpose is to protect participant confidentiality. [2] Generally, schools must have written permission from the parent or eligible student in order to release any information from a student's education record. However, FERPA allows schools to disclose those records, without consent, to the following parties or under the following conditions (34 CFR § 99.31): -School officials with legitimate educational interest; -Other schools to which a student is transferring; -Specified officials with legitimate education purposes; -Appropriate parties in connection with financial aid to a student; -Organizations conducting	Applicable Regulations/Policies Information not available/found Information not available/found Tribal regulations/policies Information not available/found Information not available/found State regulations/policies Information not available/found Information not available/found Federal regulations/policies Information not available/found Information not available/found Bepartment of Justice (which is different from the usual NH grant of confidentiality) In brief, the primary regulations are all IRB related, plus any/all applicable federal agency-specific policies (NIH data sharing, FERPA, etc). [1] Crant of Confidentiality from the U.S. Department of Justice is different from a certificate of confidentiality because it comes from the authority to issue this is for drugs and other controlled substance research; the grant of confidentiality. [2] Generally, schools must have written permission from the parent or eligible student in order to release any information from a student's education record. However, FERPA allows schools to disclose those records, without consent, to the following parties or under the following conditions (34 CFR § 9.9.31); -School officials with legitimate educational interest; -Other schools to which a student is transferring; -Specified officials for audit or evaluation purposes; -Appropriate parties in connection with financial aid to a student; -Organizations conducting certain studies for or on behalf of the school; -Accrediting organizations; -To comply with a judicial order or lawfully issued subpoena; -Appropriate officials in cases of health and safety emergencies; and

		Deve la constant	Internet of the	C
		Raw Language	Interpretation	Source
3.1.2.5	International regulations/policies	N/A - Since 1975 the MTF survey has measured drug and	N/A	[1] <u>https://nida.nih.gov/research-</u>
		alcohol use and related attitudes among adolescent students		topics/trends-statistics/monitoring
		nationwide. [1]		future (Accessed: 4/18/23)
3.1.2.6	Contractual obligations	Information not available/found	Information not available/found	
3.1.2.7	Repository policies	Information not available/found	Information not available/found	
3.2	Governance for data linkage, sharing, acces	ss, and use based on data sharing authorization or applica	ble regulations/policies (i.e., the ori	gin of the governance)
3.2.1		Does not authorize/specify	Does not authorize/specify	
3.2.2	With what other data can it be linked or can		Does not authorize/specify	
	it not be linked (scope of linkage)			
3.2.3	Whether data can be shared	In lieu of these documents (RUDDDA and MoU), MTF did have	ICPSR (U-Mich) IRB and MTF (U-Mich)	[1] NAHDAP Meeting
		IRB oversight of ICPSR taking over the dissemination of the	IRB approval specify that data can be	
		restricted-use data; the IRB number of the MTF study is linked	shared through ICPSR/NAHDAP	
		to ICPSR's reference number (for ICPSR's IRB) U-Mich		
		authorized NAHDAP to share the MTF data; IRB oversight was		
		provided and authorization from the MTF PI. [1]		
3.2.4	How data can be shared (de-identification	The MTF data is fully de-identified survey data For MTF	FERPA and ICPSR/NAHDAP specify that	[1] NAHDAP Meeting
5.2.1	status, disclosure review)		data shared through ICPSR VDE:	[2]
		are restrictions for the type of analysis at the state or lower	1. Must be fully de-identified (for MTF	https://www.icpsr.umich.edu/web
		geographic-level. [1]	restricted-use data, this does not	ages/datamanagement/confidentia
		8	include state and zipcode)	y/ (Accessed: 4/18/23)
		There is another document for MTF that is provided to data	2. Must undergo disclosure review by	[3] U-Mich Legal Meeting
		users which specifies the risk / disclosure review procedures	ICPSR/NAHDAP staff prior to sharing,	
		for output data generated from the use of MTF data in the	and disclosure review of analysis	
		VDE – the output cannot be removed from the VDE until it has		
		been reviewed by NAHDAP/ICPSR staff. [1]	output data from the VDE	
		With the exception of deposits placed in openICPSR , our		
		public data-sharing service, ICPSR reviews all datasets to		
		assess disclosure risk. ICPSR trains data curators to apply		
		specified procedures to protect respondent confidentiality in		
		all of the data ICPSR curates, archives, and distributes. For		
		example, ICPSR checks each study for identifiers present in		
		the data. [2]		
		FERPA states that if you have collected personally identifying		
		information on a student, you are not allowed to share that		
		information without consent unless you meet one of the		
		FERPA conditions (one of those being, that the data is fully de-		
		identified). [3]		

	- Monitoring the Future (MTF)			
		Raw Language	Interpretation	Source
3.2.5	How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.)	The National Addiction & HIV Data Archive Program (NAHDAP), funded by the National Institute on Drug Abuse (NIDA), is hosted at the Inter-university Consortium for Political and Social Research (ICPSR). NAHDAP data in the ICPSR Virtual Data Enclave (VDE) are restricted from general dissemination to protect the confidentiality of the individuals and/or organizations represented in the data. To access data in the VDE, a Restricted Data Use Agreement (RDUA) must be established between the University of Michigan and the researcher's institution. [1] Please note that many of NAHDAP's studies contain confidential data and are not available for Web download. Instructions on how to obtain those datasets are provided at the top of the study home page under "Access Notes." You will be required to provide Institutional Review Board (IRB) approval or exemption for your project. [2] Yes, IRB approval is required to access the MTF data. [3] NADHAP staff will review all requests to access data, including review of the research proposal: - Research proposals are abstract length and include research questions, why they need access to the data, specifically, why they need access to the restricted-use data - NAHDAP staff review these requests for the ability to use the data to answer the proposed research questions - For MTF restricted-use data (that contains state and zipcode), there are restrictions for the type of analysis at the state or lower geographic-level There is no data use committee specific to MTF that reviews, but ICPSR has a data stewardship committee to assist with reviewing requests if NADHAP staff need advice. This	ICPSR/NAHDAP specifies that for data access, a user: 1. Must execute NAHDAP VDE RDUA between ICPSR (U-Mich) and the researcher's institution 2. Must only access data through the ICPSR VDE (virtual enclave) 3. Must obtain IRB approval or exemption from the researcher's institution 4. Must obtain review and approval from NAHDAP on the proposed research	[1] https://www.icpsr.umich.edu/web/ ages/NAHDAP/vde/index.html (Accessed: 4/18/23) [2] https://www.icpsr.umich.edu/web/ ages/NAHDAP/data/index.html (Accessed: 4/18/23) [3] NAHDAP Meeting
		committee does not typically review – usually NAHDAP staff will reach out to the Directors of NAHDAP (Joy/Amy), and as needed, the MTF Team to address any questions. [3]		
3.2.6	How data can be used (data use limitations)	The MTF data can be used for general research which entails broad research, NAHDAP/ICPSR reviews the proposed research (but not for scientific merit). [1]	NAHDAP/ICPSR specifies that the data can be used for broad research	[1] NAHDAP Meeting
3.2.7	Other (specify)	Information not available/found	Information not available/found	
	Data Access			
.1	Authorizations and Applicable			
	Regulations/Policies			

		Raw Language	Interpretation	Source
4.1.1	Authorizations		1. MTF PI determination (for	
			sharing/accessing data through ICPSR	
			VDE)	
4.1.1.1	Assent	Information not available/found	Information not available/found	
4.1.1.2	Consent	Information not available/found	Information not available/found	
4.1.1.3	IRB/equivalent Privacy Board determination	Information not available/found	Information not available/found	
4.1.1.4	Local/state/federal laws	Information not available/found	Information not available/found	
4.1.1.5	Institutional Certification	Information not available/found	Information not available/found	
4.1.1.6	Data originator agreement	Information not available/found	Information not available/found	
4.1.1.7	Repository agreements/policies	There is a NAHDAP-specific RDUA that is used for MTF, which	NAHDAP Restricted Data Use	[1] NAHDAP Meeting
		is tailored for accessing data through the VDE; this RDUA also	Agreement for Restricted Data in the	
		includes data use specifications. [1]	Virtual Data Enclave (NAHDAP VDE	
			RDUA) authorizes data access	
4.1.1.8	Other (specify)	The determination for sharing data through the VDE is made	MTF PI authorizes data access (through	[1] NAHDAP Meeting
		by the NADHAP staff based on the level of disclosure risk	the ICPSR VDE)	
		and/or discussion with the data originator. For MTF, the PI		
		requested that the restricted-use MTF data be		
		shared/accessed through VDE. [1]		
4.1.2	Applicable Regulations/Policies			
4.1.2.1	Local regulations/policies	Information not available/found	Information not available/found	
4.1.2.2	Tribal regulations/policies	Information not available/found	Information not available/found	
4.1.2.3	State regulations/policies	Information not available/found	Information not available/found	
4.1.2.4	Federal regulations/policies	Information not available/found	Information not available/found	
4.1.2.5	International regulations/policies	N/A - Since 1975 the MTF survey has measured drug and	N/A	[1] <u>https://nida.nih.gov/research-</u>
		alcohol use and related attitudes among adolescent students		topics/trends-statistics/monitoring-
		nationwide. [1]		future (Accessed: 4/18/23)
4.1.2.6	Contractual obligations	Information not available/found	Information not available/found	

ataset 3 -	 Monitoring the Future (MTF) 			
		Raw Language	Interpretation	Source
4.1.2.7	Repository policies	The National Addiction & HIV Data Archive Program (NAHDAP), funded by the National Institute on Drug Abuse (NIDA), is hosted at the Inter-university Consortium for Political and Social Research (ICPSR). NAHDAP data in the ICPSR Virtual Data Enclave (VDE) are restricted from general dissemination to protect the confidentiality of the individuals and/or organizations represented in the data. To access data in the VDE, a Restricted Data Use Agreement (RDUA) must be established between the University of Michigan and the researcher's institution. [1] Please note that many of NAHDAP's studies contain confidential data and are not available for Web download. Instructions on how to obtain those datasets are provided at the top of the study home page under "Access Notes." You will be required to provide Institutional Review Board (IRB) approval or exemption for your project. [2] Yes, IRB approval is required to access the MTF data. [3] NADHAP staff will review all requests to access data, including review of the research proposal: - Research proposals are abstract length and include research questions, why they need access to the data, specifically, why they need access to the restricted-use data - NAHDAP staff review these requests for the ability to use the data to answer the proposed research questions - For MTF restricted-use data (that contains state and zipcode), there are restrictions for the type of analysis at the state or lower geographic-level	NAHDAP/ICPSR VDE policy	Source [1] https://www.icpsr.umich.edu/web/jages/NAHDAP/vde/index.html (Accessed: 4/18/23) [2] https://www.icpsr.umich.edu/web/jages/NAHDAP/data/index.html (Accessed: 4/18/23) [3] NAHDAP Meeting
		There is no data use committee specific to MTF that reviews, but ICPSR has a data stewardship committee to assist with reviewing requests if NADHAP staff need advice. This committee does not typically review – usually NAHDAP staff will reach out to the Directors of NAHDAP (Joy/Amy), and as needed, the MTF Team to address any questions. [3]		
4.2	Governance for data linkage, sharing, acces	s, and use based on data access authorization or applica	ble regulations/policies (i.e., the orig	in of the governance)
4.2.1	Whether the data can be linked	Does not authorize/specify	Does not authorize/specify	
4.2.2	With what other data can it be linked or can it not be linked (scope of linkage)	Does not authorize/specify	Does not authorize/specify	
4.2.3	Whether data can be shared	Does not authorize/specify	Does not authorize/specify	
4.2.4	How data can be shared (de-identification status, disclosure review)	There is another document for MTF that is provided to data users which specifies the risk / disclosure review procedures for output data generated from the use of MTF data in the VDE – the output cannot be removed from the VDE until it has been reviewed by NAHDAP/ICPSR staff. [1]	ICPSR/NAHDAP specifies that disclosure review of analysis outputs is required prior to removing output data from the VDE.	[1] NAHDAP Meeting

Dataset 3	- Monitoring the Future (MTF)			
		Raw Language	Interpretation	Source
4.2.5	How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.)	The National Addiction & HIV Data Archive Program (NAHDAP), funded by the National Institute on Drug Abuse (NIDA), is hosted at the Inter-university Consortium for Political and Social Research (ICPSR). NAHDAP data in the ICPSR Virtual Data Enclave (VDE) are restricted from general dissemination to protect the confidentiality of the individuals and/or organizations represented in the data. To access data in the VDE, a Restricted Data Use Agreement (RDUA) must be established between the University of Michigan and the researcher's institution. [1] Please note that many of NAHDAP's studies contain confidential data and are not available for Web download. Instructions on how to obtain those datasets are provided at the top of the study home page under "Access Notes." You will be required to provide Institutional Review Board (IRB) approval or exemption for your project. [2] Yes, IRB approval is required to access the MTF data. [3] NADHAP staff will review all requests to access data, including review of the research proposal: - Research proposals are abstract length and include research questions, why they need access to the data, specifically, why they need access to the restricted-use data - NAHDAP staff review these requests for the ability to use the data to answer the proposed research questions - For MTF restricted-use data (that contains state and zipcode), there are restrictions for the type of analysis at the state or lower geographic-level There is no data use committee specific to MTF that reviews, but ICPSR has a data stewardship committee to assist with reviewing requests if NADHAP staff need advice. This committee does not typically review – usually NAHDAP staff will reach out to the Directors of NAHDAP (Joy/Amy), and as needed, the MTF Team to address any questions. [3]	ICPSR/NAHDAP specifies that for data accessed through the ICPSR VDE, a user: 1. Must execute NAHDAP VDE RDUA between ICPSR (U-Mich) and the researcher's institution 2. Must only access data through the ICPSR VDE (virtual enclave) 3. Must obtain IRB approval or exemption from the researcher's institution 4. Must obtain review and approval from NAHDAP on the proposed research	[1] https://www.icpsr.umich.edu/web/p ages/NAHDAP/vde/index.html (Accessed: 4/18/23) [2] https://www.icpsr.umich.edu/web/p ages/NAHDAP/data/index.html (Accessed: 4/18/23) [3] NAHDAP Meeting
4.2.6	How data can be used (data use limitations)	The MTF data can be used for general research which entails broad research, NAHDAP/ICPSR reviews the proposed	NAHDAP/ICPSR specifies that the data can be used for broad research	[1] NAHDAP Meeting
4.2.7	Other (specify)	research (but not for scientific merit). [1] Information not available/found	Information not available/found	
4.2.7 5	Data Use			
	Authorizations and Applicable Regulations/Policies			1
_	Authorizations		1. Consent from adults	
5.1.1.1	Assent	Information not available/found	Information not available/found	

	Monitoring the Future (MTF)	Raw Language	Interpretation	Source
5.1.1.2	Concept	Raw Language The consent specifies that the data can be used for broad	Consent from adults authorizes data	[1] U-Mich Legal Meeting
5.1.1.2	Consent	research. [1]	use	[1] O-Mich Legal Meeting
5.1.1.3	IRB/equivalent Privacy Board determination	Information not available/found	Information not available/found	
5.1.1.4	Local/state/federal laws	Information not available/found	Information not available/found	
5.1.1.5	Institutional Certification		Information not available/found	
5.1.1.6	Data originator agreement	Information not available/found	Information not available/found	
5.1.1.7	Repository agreements/policies	There is a NAHDAP-specific RDUA that is used for MTF, which	NAHDAP Restricted Data Use	[1] NAHDAP Meeting
		is tailored for accessing data through the VDE; this RDUA also	Agreement for Restricted Data in the	
		includes data use specifications. [1]	Virtual Data Enclave (NAHDAP VDE	
			RDUA) authorizes data use	
5.1.1.8	Other (specify)	Information not available/found	Information not available/found	
5.1.2	Applicable Regulations/Policies		Information not available/found	
5.1.2.1	Local regulations/policies	Information not available/found	Information not available/found	
5.1.2.2	Tribal regulations/policies	Information not available/found	Information not available/found	
5.1.2.3	State regulations/policies	Information not available/found	Information not available/found	
5.1.2.4	Federal regulations/policies	MTF also has a grant of confidentality from the U.S.	Grant of Confidentality from the U.S.	[1] MTF Email Communication
		Department of Justice (which is different from the usual NIH	Department of Justice	[2] U-Mich Legal Meeting
		grant of confidentality) In brief, the primary regulations are		
		all IRB related, plus any/all applicable federal agency-specific		
		policies (NIH data sharing, FERPA, etc). [1]		
		Grant of confidentiality from the U.S. Department of Justice is		
		different from a certificate of confidentiality because it comes		
		from the authority to issue this is for drugs and other		
		controlled substance research; the grant of confidentiality		
		specifies that researchers cannot reidentify participants, and		
		its purpose is to protect participant confidentiality. [2]		
5.1.2.5	International regulations/policies	N/A - Since 1975 the MTF survey has measured drug and	N/A	[1] <u>https://nida.nih.gov/research</u>
		alcohol use and related attitudes among adolescent students		topics/trends-statistics/monitori
		<u>nationwide</u> . [1]		future (Accessed: 4/18/23)
5.1.2.6	Contractual obligations		N/A	
5.1.2.7	Repository policies	There is a NAHDAP-specific RDUA that is used for MTF, which	NAHDAP/ICPSR VDE policy	[1] NAHDAP Meeting
		is tailored for accessing data through the VDE; this RDUA also		
		includes data use specifications. [1]		
5.2 0		s, and use based on data access authorization or applica		gin of the governance)
5.2.1		Does not authorize/specify	Does not authorize/specify	
5.2.2	With what other data can it be linked or can it not be linked (scope of linkage)	Does not authorize/specify	Does not authorize/specify	
5.2.3	Whether data can be shared	Does not authorize/specify	Does not authorize/specify	
5.2.4	How data can be shared (de-identification status, disclosure review)	Does not authorize/specify	Does not authorize/specify	
5.2.5	How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.)	Does not authorize/specify	Does not authorize/specify	

Dataset 3	- Monitoring the Future (MTF)			
		Raw Language	Interpretation	Source
5.2.6	How data can be used (data use limitations)	The consent specifies that the data can be used for broad research. [1] NAHDAP/ICPSR RDUA: That the Confidential Data will be used solely for research or statistical purposes relative to the research project identified in the online application to obtain confidential data incorporated into this Agreement, and for no other purpose whatsoever without the prior consent of NAHDAP/ICPSR. [2]	Consent and the NAHDAP/ICPSR RDUA specify that the data be used solely for research or statistical purposes	 [1] U-Mich Legal Meeting [2] <u>https://www.icpsr.umich.edu/files/N</u> <u>AHDAP/NAHDAPGenericVDERDUA.pd</u> <u>f</u>
5.2.7	Other (specify)	Information not available/found	Information not available/found	
6	PII Elements			
6.1	PII elements collected	We collect name, email, address, cell phone #. [1]	Name, email, address, and cell phone number are collected from participants	[1] MTF Email Communication
6.2	PII elements holder (i.e., party that holds the PII)	We hold the PII in Ann Arbor and we are covered by the Grant of Confidentality in regards to holding the PII vested at UM. [1]	Data collector (MTF / U-Mich, Ann Arbor).	[1] MTF Email Communication
6.3	Use of common data model, if any, for data collection	N/A - MTF does not use a common data model; however, MTF adheres to a metadata schema at the study and variable level – based on the data documentation initiative (DDI), which is used commonly across social science domain repositories. [1]	N/A	[1] NAHDAP Meeting
7	Prior Data Linkages			
7.1	Dataset linked with other datasets			
7.1.1	Name of other dataset linked to this dataset	N/A - The MTF data is fully de-identified survey data, so there have not been any data users that have linked the MTF data at the individual-level; however, NAHDAP may approve research projects that propose to link the MTF with other aggregate data. [1]	N/A	[1] NAHDAP Meeting
7.1.2	Other dataset type (clinical, EHR, survey, claims, SDOH, etc.)	N/A	N/A	N/A
7.1.3	Other dataset source(s)	N/A	N/A	N/A
7.1.4	Linking methodology (PPRL or non-PPRL); linkage technology	N/A	N/A	N/A
7.1.5	PII elements used for the linkage	N/A	N/A	N/A
7.1.6	Entity resolver (data originator or data linker or third party)	N/A	N/A	N/A
7.1.7	Party performing the linkages	N/A	N/A	N/A
7.1.8	Linkage quality assessment	N/A	N/A	N/A
7.1.9	Linked data sharing method (linkage maps or pre-linked dataset)	N/A	N/A	N/A

USF CASF 1 -	GOVERNANCE INFORMATION			
		nental health of children. Are COVID-19 pandemic related mental health ou	tcomes more severe for children	in foste
	AFCARS (Foster Care Files, 2017-			
	Dataset Source	Adoption and Foster Care Analysis and Reporting System (AFCARS)		
	Dataset Source Agency	Administration for Children and Families (ACF)		
	Dataset Type (Clinical, EHR, Survey, SDC			
	Information Sources	Website, interview with NDACAN Team (archive for AFCARS data)		
Dataset 4 -	AFCARS		1	1
		Raw Language	Interpretation	
1	Data Collection		-	
1.1	Authorizations and Applicable			
	Regulations/Policies			
1.1.1	Authorizations		1. Social Security Act (Section 479)	
			2. 45 CFR § 1355.40 D46	
1.1.1.1	Assent	N/A	N/A	
1.1.1.2	Consent	N/A	N/A	
1.1.1.3	IRB/equivalent Privacy Board	N/A - No IRB approval is necessary for the states to collect information, or	N/A	[1] ND/
	determination	to forward the data to the Children's Bureau. [1]		
1.1.1.4	Local/state/federal law	The Adoption and Foster Care Analysis and Reporting System (AFCARS) is a	Social Security Act (Section 479)	[1]
		federally mandated data collection system intended to provide case	authorizes data collection by states	s <u>https:/</u>
		specific information on all children covered by the protections of Title IV-	and Tribal agencies	details
		B/E of the Social Security Act (Section 427). Under the final AFCARS' rule,		
		states are required to collect data on all adopted children who are placed		[2]
		by the state's child welfare agency or by private agencies under contract		https:/
		with the public child welfare agency. States are encouraged to report othe	r	05/12/
		private adoptions not involving the public welfare agency that are finalized	1	analysi
		in the state as well. In addition, states are required to collect data on all		
		children in foster care for whom the state child welfare agency has		[3] ND/
		responsibility for placement, care, or supervision. [1]		
				[4] <u>htt</u>
		AFCARS is a data collection system for national adoption and foster care		<u>afcars</u>
		data authorized under section 479 of the Social Security Act (the Act).		
		Section 479(c)(3)(A) of the Act requires the collection of comprehensive		
		national information with respect to the demographic characteristics of		
		children in foster care and those who are adopted with state involvement		
		and their biological, foster, and adoptive parents. Section 474(f) of the Act		
		requires HHS to impose penalties for non-compliant AFCARS data. Section		
		1102 of the Act instructs the Secretary to promulgate regulations necessar	y	
		for the effective administration of the functions for which HHS is		
		responsible under the Act. [2]		
		Social Security Act (Section 479) authorizes data collection. Renewals and		
		extensions of AFCARS data collection are published in the Federal Register	.	
		and can affect Tribal areas (e.g. [FR-2023-05427 Notice AFCARS data	,	
		collection renewal for 3 years] "State and tribal title IV—E agencies are		

ster care?
Source
IDACAN Team Meeting
s://www.ndacan.acf.hhs.gov/datasets/dataset-
ils.cfm?ID=255 (Accessed: 4/19/23)
s://www.federalregister.gov/documents/2020/
2/2020-09817/adoption-and-foster-care-
<pre>ysis-and-reporting-system (Accessed: 4/19/23)</pre>
IDACAN Email Communication
ttps://www.acf.hhs.gov/cb/fact-sheet/about-
rs
13

		Raw Language	Interpretation	Source
		required to report AFCARS case-level information on all children in foster		
		care and children who have been adopted or placed in a guardianship with		
		title IV—E agency involvement.") [3 & 4]		
		[3] Comment on data collection at the source: "Information in case records		
		are kept confidential, but because the child is in the placement and care of		
		the title IV-E agency, information on the child's case must be disclosed to		
		courts and providers under specific circumstances, to assist the child and		
		family." [3]		
1.1.1.5	Institutional Certification	N/A	N/A	
1.1.1.6	Data originator agreement	N/A	N/A	
1.1.1.7	Repository agreements/policies	Information not available/found	Information not available/found	
1.1.1.8	Other (specify)	Information not available/found	Information not available/found	
1.1.2	Applicable Regulations/Policies			
1.1.2.1	Local regulations/policies	Information not available/found	Information not available/found	
1.1.2.2	Tribal regulations/policies	Information not available/found	Information not available/found	
1.1.2.3	State regulations/policies	Information not available/found	Information not available/found	
1.1.2.4	Federal regulations/policies	AFCARS data collection is done by the states in accordance with 45 CFR	45 CFR 1355.40 D46	[1] NDACAN Team Meeting
		1355.40, which defines the policies around data collection and provision of		
		data to the AFCARS system. Each state forwards their data to the		[2]
		Children's Bureau, where the data are gathered and tested for		https://www.ndacan.acf.hh
		completeness, consistency, and validity. Once a year, the data are		details.cfm?ID=255 (Accesse
		compiled into an annual file and forwarded to NDACAN for archiving and		、
		distribution to qualified applicants. No IRB approval is necessary for the		
		states to collect information, or to forward the data to the Children's		
		Bureau. [1]		
1.1.2.5	International regulations/policies	N/A	N/A	
1.1.2.6		N/A	N/A	
1.1.2.7		N/A	N/A	
1.2		ess, and use based on data collection authorization or applicable regul		the governance)
1.2.1	Whether the data can be linked	Does not authorize/specify - linkage (with external data) is not specified in		[1] NDACAN Team Meeting
1.2.1	Whether the data can be linked	any authorization. [1]		
1.2.2	With what other data can it be linked or	Does not authorize/specify - linkage (with external data) is not specified in	Does not authorize/specify	[1] NDACAN Team Meeting
1.2.2	can it not be linked (scope of linkage)	any authorization. [1]		
	carrie not be inited (scope of initede)		Information not available /found	
1 2 3	Whether data can be shared	Information not available/found	Information not available/toling	
1.2.3	Whether data can be shared	Information not available/found	Information not available/found	
1.2.3 1.2.4	How data can be shared (de-identification	Information not available/found Information not available/found	Information not available/found	
1.2.4	How data can be shared (de-identification status, disclosure review)	Information not available/found	Information not available/found	
	How data can be shared (de-identification status, disclosure review) How data can be accessed (access type,			
1.2.4	 How data can be shared (de-identification status, disclosure review) How data can be accessed (access type, data use agreement, data access 	Information not available/found	Information not available/found	
1.2.4	How data can be shared (de-identification status, disclosure review) How data can be accessed (access type,	Information not available/found	Information not available/found	
1.2.4	 How data can be shared (de-identification status, disclosure review) How data can be accessed (access type, data use agreement, data access 	Information not available/found	Information not available/found	
1.2.4 1.2.5 1.2.6	 How data can be shared (de-identification status, disclosure review) How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.) How data can be used (data use limitations) 	Information not available/found Information not available/found Information not available/found	Information not available/found Information not available/found Information not available/found	
1.2.4 1.2.5 1.2.6 1.2.7	 How data can be shared (de-identification status, disclosure review) How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.) How data can be used (data use limitations) Other (specify) 	Information not available/found Information not available/found	Information not available/found Information not available/found	
1.2.4 1.2.5 1.2.6 1.2.7 2	 How data can be shared (de-identification status, disclosure review) How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.) How data can be used (data use limitations) Other (specify) Data Linkage 	Information not available/found Information not available/found Information not available/found	Information not available/found Information not available/found Information not available/found	
1.2.4 1.2.5 1.2.6 1.2.7	How data can be shared (de-identification status, disclosure review) How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.) How data can be used (data use limitations) Other (specify) Data Linkage Authorizations and Applicable	Information not available/found Information not available/found Information not available/found	Information not available/found Information not available/found Information not available/found	
1.2.4 1.2.5 1.2.6 1.2.7 2 2.1	How data can be shared (de-identification status, disclosure review) How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.) How data can be used (data use limitations) Other (specify) Data Linkage Authorizations and Applicable Regulations/Policies	Information not available/found Information not available/found Information not available/found	Information not available/found Information not available/found Information not available/found	
1.2.4 1.2.5 1.2.6 1.2.7 2	How data can be shared (de-identification status, disclosure review) How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.) How data can be used (data use limitations) Other (specify) Data Linkage Authorizations and Applicable	Information not available/found Information not available/found Information not available/found	Information not available/found Information not available/found Information not available/found	

	Source
	[1] NDACAN Toom Mosting
	[1] NDACAN Team Meeting
	[2]
	https://www.ndacan.acf.hhs.gov/datasets/dataset-
	<pre>details.cfm?ID=255 (Accessed: 4/19/23)</pre>
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Γ	the governance) [1] NDACAN Team Meeting
	[1] NDACAN Team Meeting
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AFCARS		1	
		-	Source
	N/A	N/A	
	-		
Other (specify)		Does not authorize/specify	[1] NDACAN Team Meeting Su
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Tribal regulations/policies		N/A	[1] NDACAN Team Meeting Su
	beyond ethnoracial identity of Native American. [1]		
			[2] NDACAN Email Communic
	,		
	the iv-E agency involvement.) [2]		
State regulations/policies	Information not available/found	Information not available/found	
Federal regulations/policies	Information not available/found	Information not available/found	
International regulations/policies	N/A	N/A	
Contractual obligations			
Repository policies			
			he governance)
	Information not available/found	Information not available/found	
	-		
	Information not available/found	Information not available/found	
	Information not available/found	Information not available/found	
data use agreement, data access			
		1	
committee/group approval, IRB LOD, etc.)			
committee/group approval, IRB LOD, etc.) How data can be used (data use	Information not available/found	Information not available/found	
	Federal regulations/policiesInternational regulations/policiesContractual obligationsRepository policies	Raw Language IRB/equivalent Privacy Board N/A Idetermination N/A Local/state/federal laws N/A Institutional Certification N/A Other (specify) Does not authorize/specify - NDACAN currently only approves data linkages that are at the aggregate-level (as per NDACAN Director). If NDACAN were to receive a request to link external data with AFCARS the Individual-level, the Children's Bureau would linkly also need to provide input / decision on whether that linkage is an appropriate use of the data, in addition to NDACAN Director. At this stage, requests to link AFCARS data at the individual-level with external data have not been received. NDACAN does not store linkable IDs (or any other PII/PHI) per their ATO. The states collect the child welfare data and produce abstracts for NDACAN, states hold the PII/PHI and must encrypt the original participant IDs prior to sending the data to NDACAN. NDACAN receives basic demographic information from the states (DOB, Race, Ethnicity, Sev) – NDACAN does not receive: SSN, Telephone #, Address, or geographical information below the county-level [1] Applicable Regulations/policies Information not available/found Tribal regulations/policies Information not available/found Tribal regulations/policies Information not available/found Social Security Act (Section 479) authorizes data collection. Renewals and extensions of AFCARS case-level information on all children in foster care and children who have been adopted or placed in a guardianship with title IV-E agencip involvement." [2]	Raw Language Interpretation IRB/equivalent Privacy Board N/A N/A Local/ystac/federal laws N/A N/A Local/ystac/federal laws N/A N/A Institutional Certification N/A N/A Data originator agreements/policies N/A N/A Other (specify) Does not authorize/specify - NDACAN currently only approves data N/A Other (specify) Does not authorize/specify - NDACAN currently only approves data Does not authorize/specify NDACAN were to receive a request to link external data with AFCARS the individual-level, the Children's Sureau would likely ato nee to provide input / decision on whether that linkage is an appropriate use of the data, in addition to NDACAN Director. A this stage, requests to link AFCARS data at the individual-level, the Children's Sureau would likely ato nee to provide collect the child weftare data and produce abstracts for NDACAN; states held the PI/PHII part their ADO. The states collect the child weftare data and produce abstracts for NDACAN; states held the PI/PHII and music encrypt the original participant IDb protr to sending the data to NDACAN. NDACAN the Cerebres back demographic Information not available/found Tribal regulations/policies Information not available/found Information not available/found N/A Tribal regulations/policies Information not available/found Information not

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ze/specify	[1] NDACAN Team Meeting Summary
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	[2] NDACAN Email Communication
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2.2.7	Other (specify)	Raw Language	Interpretation	Source
	Other (specify)		Information not available/found	
3	Data Sharing			
3.1	Authorizations and Applicable			
	Regulations/Policies		1	
3.1.1	Authorizations		1. Contractual agreement between NDACAN and Children's Bureau	
3.1.1.1	Assent	N/A	N/A	
3.1.1.2	Consent	N/A	N/A	
3.1.1.3	IRB/equivalent Privacy Board	N/A - No IRB approval is necessary for the states to collect information, or	N/A	[1] NDACAN Team Meeting
5.1.1.5	determination	to forward the data to the Children's Bureau. [1]		
3.1.1.4	Local/state/federal laws	Information not available/found	Information not available/found	
3.1.1.5	Institutional Certification	N/A		N/A
3.1.1.6	Data originator agreement	N/A	N/A	N/A
3.1.1.7	Repository agreements/policies	N/A - NDACAN Contributor Agreement is only required for the deposition of external data to NDACAN, and does not apply to the AFCARS data. [1]	N/A	[1] NDACAN Team Meeting
3.1.1.8	Other	The initial AFCARS program was authorized in the 1990s, NDACAN had established a memorandum of understanding (MoU) between NDACAN (archive) and the data depositor (Children's Bureau) while NDACAN was under a cooperative agreement. NDACAN is currently authorized by contract with the Children's Bureau to receive AFCARS data, so the MoU is no longer applicable. [1]	Contractual agreement between NDACAN and Children's Bureau authorizes data sharing	[1] NDACAN Team Meeting
3.1.2	Applicable Regulations/Policies			
3.1.2.1	Local regulations/policies	Information not available/found	Information not available/found	
3.1.2.2	Tribal regulations/policies	N/A - There is no information about tribes or tribal data within AFCARS, beyond ethnoracial identity of Native American. [1]	N/A	[1] NDACAN Team Meeting
3.1.2.3	State regulations/policies	Information not available/found	Information not available/found	
3.1.2.4	Federal regulations/policies	Information not available/found	Information not available/found	
3.1.2.5	International regulations/policies	N/A	N/A	
3.1.2.6	Contractual obligations	Information not available/found	Information not available/found	
3.1.2.7	Repository policies	Information not available/found	Information not available/found	
3.2	Governance for data linkage, sharing, acce	ess, and use based on data sharing authorization or applicable regulat	ions/policies (i.e., the origin of th	e governance)
3.2.1	Whether the data can be linked	Does not authorize/specify - linkage (with external data) is not specified in any authorization. [1]	Does not authorize/specify	[1] NDACAN Team Meeting
3.2.2	With what other data can it be linked or	Does not authorize/specify - linkage (with external data) is not specified in	Does not authorize/specify	[1] NDACAN Team Meeting
	can it not be linked (scope of linkage)	any authorization. [1]		
3.2.3	Whether data can be shared	The initial AFCARS program was authorized in the 1990s, NDACAN had established a memorandum of understanding (MoU) between NDACAN (archive) and the data depositor (Children's Bureau) while NDACAN was under a cooperative agreement. NDACAN is currently authorized by contract with the Children's Bureau to receive AFCARS data, so the MoU is no longer applicable. [1]	Contractual agreement between NDACAN and Children's Bureau specifies that AFCARS data can be shared through NDACAN.	[1] NDACAN Team Meeting

Dataset 4 - A	Arcaks			
		Raw Language	-	
3.2.4	How data can be shared (de-identification status, disclosure review)	AFCARS comes to NDACAN with no PII whatsoever, with none of the other pieces of data listed above – except maybe dates. Dates are submitted with AFCARS (such as birth date or date of removal) but these are either masked or permuted so that original dates are not included in the distributed files. In short, nothing on the list above (except the counties) is included in the data users' receive [1] NDACAN does not store linkable IDs (or any other PII/PHI) per their ATO; linkage would not be possible using AFCARS data stored in NDACAN. [1] Before distributing the AFCARS data, NDACAN makes certain manipulations to the foster care data to protect the privacy of the children in foster care. - The county FIPS code for the children from counties with fewer than 1,000 records in the annual database are recoded to indicate not provided for reasons of confidentiality. - The child's day of birth (DOB) is recoded to the 15th of the month. NOTE: All derived age variables are based on the actual DOB, so may not agree with an age computed from the recoded DOB. - All other dates in the file are adjusted to the recoded date of birth so that the span of time between any two dates is preserved. As a result, all dates in the file are recoded, but all time spans are accurate. [2] Confidentiality Protections in the NDACAN Administrative Datasets. [3]	other dates accordingly)	[1] ND [2] https:/ er_gui (Access [3] Con NDAC/
3.2.5	How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.)	Information not available/found	Information not available/found	
3.2.6	How data can be used (data use limitations)	Does not authorize/specify	Does not authorize/specify	
3.2.7	Other (specify)	Information not available/found	Information not available/found	
4	Data Access			
4.1	Authorizations and Applicable Regulations/Policies			
4.1.1	Authorizations		 Contractual agreement between Children's Bureau and NDACAN NDACAN Terms of Use Agreement 	
4.1.1.1	Assent	N/A	N/A	
4.1.1.2	Consent	N/A	N/A	
4.1.1.3	IRB/equivalent Privacy Board determination	N/A - No (IRB approval is not required to access AFCARS data), but researchers who work at a college or university are required to report their research to their own IRB. [1]	N/A	[1] ND
4.1.1.4	Local/state/federal laws	Information not available/found	Information not available/found	
4.1.1.5	Institutional Certification	N/A	N/A	
4.1.1.6	Data originator agreement	N/A	N/A	

Source

NDACAN Team Meeting

<u>ps://www.ndacan.acf.hhs.gov/datasets/pdfs_us</u> guides/afcars-userguide-2000-present.pdf cessed: 4/19/23)

Confidentiality Protections document from ACAN Team

NDACAN Team Meeting

ataset 4 -	AFCARS			
		Raw Language	Interpretation	9
4.1.1.7	Repository agreements/policies	NDACAN is authorized by the Children's Bureau to provide access to AFCARS to individual researchers who provide their contact information and submit a Terms of Use Agreement. [1] The Children's Bureau authorizes NDACAN to share the data with researchers (under contractual agreement). The Terms of Use Agreement specifies how the data can be used by researchers - the origin of this authorization / terms of use agreement may need to be traced back to when NDACAN was established. [1]	 Contractual agreement between Children's Bureau and NDACAN NDACAN Terms of Use Agreement 	[1] NDACAN Team Mee
4.1.1.8	Other (specify)	NDACAN is authorized by the Children's Bureau to provide access to AFCARS to individual researchers who provide their contact information and submit a Terms of Use Agreement. [1] The Children's Bureau authorizes NDACAN to share the data with researchers (under contractual agreement). The Terms of Use Agreement specifies how the data can be used by researchers - the origin of this authorization / terms of use agreement may need to be traced back to when NDACAN was established. [1]	Two repository agreements authorize data access: 1. Contractual agreement between Children's Bureau and NDACAN 2. NDACAN Terms of Use Agreement	[1] NDACAN Team Mee
4.1.2	Applicable Regulations/Policies			
4.1.2.1	Local regulations/policies	Information not available/found	Information not available/found	
4.1.2.2	Tribal regulations/policies	N/A - There is no information about tribes or tribal data within AFCARS, beyond ethnoracial identity of Native American. [1]	N/A	[1] NDACAN Team Mee
4.1.2.3	State regulations/policies	Information not available/found	Information not available/found	
4.1.2.4	Federal regulations/policies	Information not available/found	Information not available/found	
4.1.2.5	International regulations/policies	N/A	N/A	
4.1.2.6	Contractual obligations	Information not available/found	Information not available/found	

Source
Source [1] NDACAN Team Meeting
[1] NDACAN Team Meeting
[1] NDACAN Team Meeting

Dataset 4 - A	AFCARS			
		Raw Language	Interpretation	
4.1.2.7	Repository policies	NDACAN provides individuals with authorization to use the AFCARS datasets (as formatted and provided by NDACAN) if they submit a Terms of Use Agreement. NDACAN reviews and approves this document, which contains a description of their research purpose and their affirmation to limit their use of the data to research and not re-sale, attempts to identify individuals, or other activities defined as misuse in the Agreement and by U.S. laws. Please refer to the Terms of Use Agreement PDF on this web page: <u>https://www.ndacan.acf.hhs.gov/datasets/request-dataset.cfm</u> [1] The Children's Bureau authorizes NDACAN to share the data with researchers (under contractual agreement). The Terms of Use Agreement specifies how the data can be used by researchers - the origin of this authorization / terms of use agreement may need to be traced back to when NDACAN was established. [1]	NDACAN policy	[1] ND
4.2	Governance for data linkage, sharing, acce	ess, and use based on data access authorization or applicable regulation	ons/policies (i.e., the origin of th	e gove
4.2.1	Whether the data can be linked	Does not authorize/specify - linkage (with external data) is not specified in any authorization. [1]		[1] NC
4.2.2	With what other data can it be linked or can it not be linked (scope of linkage)	Does not authorize/specify - linkage (with external data) is not specified in any authorization. [1]	Does not authorize/specify	[1] ND

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Dataset 4 - A	AFCARS			
		Raw Language	Interpretation	
4.2.3	Whether data can be shared	The initial AFCARS program was authorized in the 1990s, NDACAN had established a memorandum of understanding (MoU) between NDACAN (archive) and the data depositor (Children's Bureau) while NDACAN was under a cooperative agreement. NDACAN is currently authorized by contract with the Children's Bureau to receive AFCARS data, so the MoU is no longer applicable. [1]	Contractual agreement between NDACAN and Children's Bureau specifies that AFCARS data can be shared through NDACAN	[1] ND
4.2.4	How data can be shared (de-identification status, disclosure review)	AFCARS comes to NDACAN with no PII whatsoever, with none of the other pieces of data listed above – except maybe dates. Dates are submitted with AFCARS (such as birth date or date of removal) but these are either masked or permuted so that original dates are not included in the distributed files. In short, nothing on the list above (except the counties) is included in the data users' receive. [1] NDACAN does not store linkable IDs (or any other PII/PHI) per their ATO; linkage would not be possible using AFCARS data stored in NDACAN. [1] Before distributing the AFCARS data, NDACAN makes certain manipulations to the foster care data to protect the privacy of the children in foster care. - The county FIPS code for the children from counties with fewer than 1,000 records in the annual database are recoded to indicate not provided for reasons of confidentiality. - The child's day of birth (DOB) is recoded to the 15th of the month. NOTE: All derived age variables are based on the actual DOB, so may not agree with an age computed from the recoded DOB. - All other dates in the file are adjusted to the recoded date of birth so that the span of time between any two dates is preserved. As a result, all dates in the file are recoded, but all time spans are accurate. [2] Confidentiality Protections in the NDACAN Administrative Datasets. [3]	Contractual agreement between NDACAN and Children's Bureau specifies that AFCARS data shared through NDACAN: 1. Data must be de-identified of all 18 HIPAA identifiers 2. Data must undergo disclosure review of data prior to sharing (removing county FIPS code with >1,000 records, recode DoB to the 15th and adjust all other dates accordingly)	(Acces [3] Cor NDACA

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os://www.ndacan.acf.hhs.gov/datasets/pdfs_us guides/afcars-userguide-2000-present.pdf_ cessed: 4/19/23)

Confidentiality Protections document from ACAN Team

Dataset 4 -	AFCARS			
		Raw Language	Interpretation	-
4.2.5	How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.)	NDACAN may request additional information or deny a request for a dataset if the research purpose written on their Terms of Use Agreement is unclear, indicates a situation where additional researchers on a team need to submit their own Terms of Use Agreements, or indicates an inappropriate use of the data. Such instances are forwarded to the NDACAN Director for review. [1] NDACAN staff review all requests for AFCARS data; occasionally, the Children's Bureau CORs will review special requests, but they are typically not involved. [1] No technical controls, except for a 10-day download window. Individuals who request datasets from NDACAN supply a research purpose which is checked by the NDACAN Archiving Assistant to prevent non-approved		[1] NC
4.2.6	How data can be used (data use limitations)	usage. [1] The User agrees to use the Research Data only for purposes that support the User's task defined in Section I.1 above. The User also agrees to ensure the integrity, security, and confidentiality of the Research Data by complying with the terms of this Agreement and applicable law, including the Privacy Act of 1974 (5 U.S.C. 552a). [1]	NDACAN Terms of Use Agreement specifies that the data can be used by researchers in accordance with their approved research described in Section I.1 of the Terms of Use Agreement	<u>https:</u> orms/
4.2.7	Other (specify)	Information not available/found	Information not available/found	+
5	Data Use		· · · ·	1
5.1	Authorizations and Applicable			
•	Regulations/Policies			
5.1.1	Authorizations			
5.1.1.1	Assent	N/A	N/A	
5.1.1.2	Consent	N/A	N/A	-
5.1.1.3	IRB/equivalent Privacy Board determination	Information not available/found - the authorizations for data use may need to be traced back to when NDACAN was established. [1]	N/A	[1] ND
5.1.1.4	Local/state/federal laws	Information not available/found	Information not available/found	+
5.1.1.5	Institutional Certification	Information not available/found	N/A	1
5.1.1.6	Data originator agreement	Information not available/found	N/A	+

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://www.ndacan.acf.hhs.gov/datasets/order_f
/termsofuseagreement.pdf (Accessed:
/23)
DACAN Team Meeting

		Raw Language	Interpretation	
5.1.1.7	Repository agreements/policies	The Children's Bureau authorizes NDACAN to share the data with researchers (under contractual agreement). The Terms of Use Agreement specifies how the data can be used by researchers - the origin of this authorization / terms of use agreement may need to be traced back to when NDACAN was established. [1]	NDACAN Terms of Use Agreement authorizes data use	[1] N
5.1.1.8	Other (specify)	Information not available/found	Information not available/found	+
5.1.2	Applicable Regulations/Policies			-
5.1.2.1	Local regulations/policies	Information not available/found	Information not available/found	
5.1.2.2	Tribal regulations/policies	N/A - There is no information about tribes or tribal data within AFCARS, beyond ethnoracial identity of Native American. [1]	N/A	[1] N
5.1.2.3	State regulations/policies	Information not available/found	Information not available/found	-
5.1.2.4	Federal regulations/policies	Information not available/found	Information not available/found	
5.1.2.5	International regulations/policies	N/A	N/A	
5.1.2.6	Contractual obligations Repository policies	Information not available/foundNDACAN provides individuals with authorization to use the AFCARSdatasets (as formatted and provided by NDACAN) if they submit a Terms ofUse Agreement. NDACAN reviews and approves this document, whichcontains a description of their research purpose and their affirmation tolimit their use of the data to research and not re-sale, attempts to identifyindividuals, or other activities defined as misuse in the Agreement and byU.S. laws. Please refer to the Terms of Use Agreement PDF on this webpage: https://www.ndacan.acf.hhs.gov/datasets/request-dataset.cfm [1]The Children's Bureau authorizes NDACAN to share the data withresearchers (under contractual agreement). The Terms of Use Agreementspecifies how the data can be used by researchers - the origin of thisauthorization / terms of use agreement may need to be traced back towhen NDACAN was established. [1]	Information not available/found NDACAN policy f	[1] NI

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ataset 4 - A	FCARS			
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5.2.1	Whether the data can be linked	Does not authorize/specify - linkage (with external data) is not specified in any authorization. [1]	Does not authorize/specify	[1] NDACAN Team Meetir
5.2.2	With what other data can it be linked or can it not be linked (scope of linkage)	Does not authorize/specify - linkage (with external data) is not specified in any authorization. [1]	Does not authorize/specify	[1] NDACAN Team Meetin
5.2.3	Whether data can be shared	Information not available/found	Information not available/found	
5.2.4	How data can be shared (de-identification status, disclosure review)		Information not available/found	
5.2.5	How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.)	Information not available/found	Information not available/found	
5.2.6	How data can be used (data use limitations)	The User agrees to use the Research Data only for purposes that support the User's task defined in Section I.1 above. The User also agrees to ensure the integrity, security, and confidentiality of the Research Data by complying with the terms of this Agreement and applicable law, including the Privacy Act of 1974 (5 U.S.C. 552a). [1]	NDACAN Terms of Use Agreement specifies that the data can be used by researchers in accordance with their approved research described in Section I.1 of the Terms of Use Agreement	https://www.ndacan.acf. orms/termsofuseagreeme
5.2.7	Other (specify)	Information not available/found	Information not available/found	
6	PII Elements			

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e/found	
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greement	[1]
n be used ance with described s of Use	https://www.ndacan.acf.hhs.gov/datasets/order_f orms/termsofuseagreement.pdf (Accessed: 4/19/23)
e/found	

Dataset 4 - A	FCARS			
		Raw Language	Interpretation	
6.1	PII elements collected	NDACAN receives basic demographic information from the states (DOB, Race, Ethnicity, Sex) – NDACAN does not receive original participant IDs, SSN, Telephone #, Address, or geographical information (below the county- level), which are PII held by the states. [1] The AFCARS datasets made available to researchers by the Children's Bureau, via NDACAN, contain no PII. [2]	Participant ID, SSN, telephone number, address, and geographical location are collected by states but not held as part of the AFCARS data	
6.2	PII elements holder (i.e., party that holds the PII)	Individual states collect child welfare data and produce abstracts for NDACAN; the states hold the PII/PHI and must encrypt the original participant IDs prior to sending the data to NDACAN. [1]	Data originator (individual states)	[1] ND
6.3	Use of common data model, if any, for data collection	N/A - Not that staff is aware of. [1]	N/A	[1] NC
7	Prior Data Linkages		,	'
7.1	Dataset linked with other datasets			1

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AFCARS Email Communication

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		d NYTD (both housed in NDACAN) and Family First Prevention Services t data (not housed at NDACAN) – which are all systems under the uildren's Bureau and share a common "AFCARS" ID to allow for linkage. if those count as outside sources then yes. Otherwise AFCARS can't be ked at an individual level with any other data. [1] *FPSA removed from t of previously linked datasets by NDACAN staff in email communication uth in foster care, including sex, race, ethnicity, date of birth, and foster re status. It also collects information about the outcomes of those youth o have aged out of foster care. States began collecting data in 2010, and e first data set was submitted voluntarily by the 50 states, the strict of Columbia, and the Commonwealth of Puerto Rico. The NCANDS porting year is based on the FFY calendar which spans October 1 to ptember 30. States submit case-level data, called a Child File, by nstructing an electronic file of child-specific records for each report of eged child abuse and neglect that received a CPS response in the form of investigation or alternative response. Case-level data include formation about the characteristics of the reports of abuse and neglect, e children involved, the types of maltreatment, the CPS findings, the risk ctors of the child and the caregivers, the services provided, and the repetrators. [1] • meet the law's mandate, ACF published a proposed rule in the Federal gister on July 14, 2006, and a final rule on February 26, 2008. The guilation establishes the National Youth in Transition Database (NYTD) di requires that States engage in two data collection activities. First, ates are to collect information on each youth who receives independent ing services paid for or provided by the State agency that administers the lafee Program. Second, States are to collect demographic and outcome formation on certain youth in foster care whom the State will follow over ne to collect additional outcome information. This information will allow F to track which independent living services St	Interpretation	
7.1.1	Name of other linked dataset	As commented, AFCARS can only be linked by individual IDs with NCANDS and NYTD (both housed in NDACAN) and Family First Prevention Services Act data (not housed at NDACAN) – which are all systems under the Children's Bureau and share a common "AFCARS" ID to allow for linkage. So if those count as outside sources then yes. Otherwise AFCARS can't be linked at an individual level with any other data. [1] *FPSA removed from list of previously linked datasets by NDACAN staff in email communication The National Youth in Transition Database (NYTD) collects information on youth in foster care, including sex, race, ethnicity, date of birth, and foster care status. It also collects information about the outcomes of those youth who have aged out of foster care. States began collecting data in 2010, and the first data set was submitted in May 2011. [2]	 National Child Abuse and Neglect Data System (NCANDS) National Youth in Transition Database (NYTD) 	[1] NI [2] <u>htt</u> <u>techn</u> 4/19/
7.1.2	Other dataset type (clinical, EHR, survey, claims, SDOH, etc.)	Every year, NCANDS data are submitted voluntarily by the 50 states, the District of Columbia, and the Commonwealth of Puerto Rico. The NCANDS reporting year is based on the FFY calendar which spans October 1 to September 30. States submit case-level data, called a Child File, by constructing an electronic file of child-specific records for each report of alleged child abuse and neglect that received a CPS response in the form of an investigation or alternative response. Case-level data include information about the characteristics of the reports of abuse and neglect, the children involved, the types of maltreatment, the CPS findings, the risk factors of the child and the caregivers, the services provided, and the perpetrators. [1] To meet the law's mandate, ACF published a proposed rule in the Federal	f	[1] <u>htt</u> ncand [2] <u>htt</u> nytd (<i>i</i> [3] <u>htt</u> service first/d Service %20Da
		Register on July 14, 2006, and a final rule on February 26, 2008. The regulation establishes the National Youth in Transition Database (NYTD) and requires that States engage in two data collection activities. First, States are to collect information on each youth who receives independent living services paid for or provided by the State agency that administers the Chafee Program. Second, States are to collect demographic and outcome information on certain youth in foster care whom the State will follow over time to collect additional outcome information. This information will allow ACF to track which independent living services States provide and assess the collective outcomes of youth. [2]		
		As jurisdictions consider how to provide Title IV-E prevention services to children and families who are served in the community and are otherwise unknown to the Title IV-E agency (also known as a Community Pathway),		

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https://www.acf.hhs.gov/cb/research-datanology/reporting-systems/nytd (Accessed: 9/23)

https://www.acf.hhs.gov/cb/fact-sheet/aboutnds (Accessed: 4/25/23)

https://www.acf.hhs.gov/cb/fact-sheet/aboutl (Accessed: 4/25/23)

https://campaigns.pcgus.com/humanices/family-

/documents/Family%20First%20Prevention%20 vices%20Act_Community%20Pathways%20and Data%20Reporting.pdf (Accessed: 4/25/23)

Dataset 4 - A	AFCARS			
		Raw Language	Interpretation	Source
		they must develop processes to collect and report data that is required by the federal Administration for Children and Families (ACF). The Family First Prevention Services Act (FFPSA) data elements to be reported to ACF are defined in Revised Technical Bulletin #1, and one of these elements is a unique child identifier (current or future AFCARS record number). [3] *FPSA removed from list of previously linked datasets by NDACAN staff in email communication		
7.1.3	Other dataset source(s)	As commented, AFCARS can only be linked by individual IDs with NCANDS and NYTD (both housed in NDACAN) and Family First Prevention Services Act (FFPSA) data (not housed at NDACAN) – which are all systems under the Children's Bureau and share a common "AFCARS" ID to allow for linkage. So if those count as outside sources then yes. Otherwise AFCARS can't be linked at an individual level with any other data. [1] *FPSA removed from list of previously linked datasets by NDACAN staff in email communication	Sources of data for AFCARS linkage: NCANDS and NYTD which are housed in NDACAN	
7.1.4	Linking methodology (PPRL or non-PPRL); linkage technology	Information not available/found	Information not available/found	
7.1.5	PII elements used for the linkage	Information not available/found	Information not available/found	
7.1.6	Entity resolver (data originator or data linker or third party)	Information not available/found	Information not available/found	
7.1.7	Party performing the linkages	Information not available/found	Information not available/found	
7.1.8	Linkage quality assessment	Information not available/found	Information not available/found	
7.1.9	Linked data sharing method (linkage maps or pre-linked dataset)	Information not available/found	Information not available/found	

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	Governance			Dataset 1 - NCCR	2				Dataset 2 - CDC					Dataset 3 - T-MSI	S	
		Data Collection	Data Linkage	Data Sharing	Data Access	Data Use	Data Collection	Data Linkage	Data Sharing	Data Access	Data Use	Data Collection	Data Linkage	Data Sharing		Data Use
1	Authorization/s															
	Assent					N/A	N/A					N/A	N/A	N/A		N/A
1.2	Consent	Consent authorizes data collection for some data providers who originally obtained the data under a research consent		Consent authorizes data sharing for some data providers		N/A	N/A					N/A	N/A	N/A	N/A	N/A
1.3	IRB/equivalent Privacy Board determination	IRB approval authorizes data collection for certain states (e.g., New Jersey)	N/A	IRB approval authorizes data sharing for some data providers		IRB approval from the state registry authorizes data use (as needed/if applicable)	≥ N/A				RIDURA specifies that for data access, a user must obtain IRB LOD from researcher's institution (as needed / applicable)	N/A	CMS Privacy Board approval of a RIF application specifying linkage authorizes data linkage			
1.4	Local/state/federal law	State regulations/policies authorizes data collection by central cancer registries as part of public health surveillance	N/A	Sections 405, 410, 412 and 413 of the Public Health Service Act (42 U.S.C. §§ 284, 285, 285a-1 and 285a- 2 authorize data sharing	-		State laws/regulations authorizes data collection					Three Federal laws authorize data collection: 1. Section 4753 of the Balanced Budget Act of 1997 2. Section 6504 of the Patient Protection and Affordable Care Act 3. Medicaid and CHIF Managed Care Final Rule			CMS Privacy Board authorizes data access	
1.5	Institutional Certification	Institutional Certification authorizes data collection for some state or regional cancer registries	N/A				N/A					N/A	N/A			

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Governance			Dataset 1 - NCCF	,	[Legend: Blank cell	i în Table 1 = înfoi		Die/found; N/A = inf	ormation confirmed to	o not exist]			Dataset 3 - T-MSI	c	
	Data Collection	Data Linkage	Data Sharing	Data Access	Data Use	Data Collection	Data Linkage	Data Sharing		Data Use	Data Collection	Data Linkage	Data Sharing	Data Access	Data Use
6 Data originator agreement	N/A	authorize data linkage (as needed /	data sharing			N/A					N/A	N/A			
1.7 Repository agreements/policies	N/A				NCCR Data Use Agreement authorizes data use	N/A			Registration Information and Data Use Restrictions Agreement (RIDURA) authorizes data access	Data Use Restrictions	N/A	between CMS and the Participating Agency	Exchange Agreement (IEA)	Data Use Agreement authorizes data access	Data Use Agreer (DUA) authorize data use
1.8 Other (specify)			Two contracts authorize data sharing: 1. Contract between SEER registries and NCI 2. Subcontract between NPCR registries and NAACCR and grant between NPCR registries and NAACCR			N/A									
Applicable Regulat 2.1 Local regulations/policies	N/A	N/A													T-MSIS policy

International reglations/policies NA NA </th <th></th> <th></th> <th></th> <th></th> <th></th> <th></th> <th>NANCE</th> <th>ATASET GOVE</th> <th>SE CASE 2 - D</th> <th>TABLE 1: U</th> <th></th> <th></th> <th></th> <th></th> <th></th> <th></th> <th></th>							NANCE	ATASET GOVE	SE CASE 2 - D	TABLE 1: U							
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2.1 Read Not		S	Dataset 3 - T-MSI				OVID	Dataset 2 - CDC C				CR	Dataset 1 - NCC			Governance	
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2.3 Sum of space (space (spac											N/A	N/A	N/A	N/A	N/A		2.2
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Instructional regulations/policies Infernational regulations for registries operated b/ a part under N/A															regulations/policies the participating NCCR registries: Arkansas, California, Connecticut, Florida, Georgia, Hawaii, Idaho, Illinois, Iowa, Kentucky, Louisiana, Massachusetts, Michigan, New Jersey, New Mexico, New York, Ohio, Pennsylvania, Seattle (Puget Sound), Tennessee, Texas,	regulations/policies	
Image: selection specified Image: selection specified <th< td=""><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></th<>																	
I regulations/policies I contractual I contratual I contractual I cont	1. Privacy Act Rule 2. HIPAA Privacy Rule	2. HIPAA Privacy Rule	2. HIPAA Privacy											N/A	N/A		2.4
ObligationsObligations for registries operated (an egded / if applicable) 2. Obligations for NACCRServices Agreement (an egded / if applicable) 2. Obligations for appraticipating through a participating through 								N/A	N/A	N/A		N/A	N/A	N/A	N/A		2.5
Image: series of the series														Services Agreement (as needed / if applicable) 2. Business Associate Agreement (BAA) (as needed / if	obligations for registries operated by the state health department to the NCI 2. Obligations for registries participating through a grant under	Obligations	2.6
		Center (ResDAC)		Center (ResDAC)		surveillance restricted access data policy	Information and Data Use Restrictions Agreement (RIDURA)	surveillance restricted access			NCCR policy	NCCR policy		N/A	N/A	Repository Policies	2.7
Joint Linking/Sharing/Access/Use Governance Based on Authorizations and Applicable Regulations/PoliciesMathematical ControlMathematical ControlMath																	

									DATASET GOVI							
	Governance			Dataset 1 - NCC	R	[Legend: Blank o	cell in Table 1 = infor	mation not availa	able/found; N/A = in Dataset 2 - CDC		d to not exist]			Dataset 3 - T-MSI	s	
		Data Collection	Data Linkage	Data Sharing		Data Use	Data Collection	Data Linkage	Data Sharing	Data Access	Data Use	Data Collection		Data Sharing	Data Access	Data Use
3.1	Whether the data can be linked	Certain state laws/regulations specify that the data can be linked (e.g., Lousiana)	Data originator agreements specify	Data originator agreements specify that the data can be linked	DUA specifies that users are not authorized to link data across SEER databases							Does not authorize/specify	 1. CMS Privacy Board authorizes data linkage for researchers for research purposes via an approved RIF Application that specifies the scope of linkage 2. CMS Privacy Board, Chief Data Officer approval of a letter of justification for linkage, and Information Exchange Agreement (IEA) authorizes data linkage for federal entities performing linkage with non- standard TAFs containing PII 		CMS Privacy Board	Does not authorize/specify
3.2	With what other data can it be linked or can it not be linked (scope of linkage)	Certain state laws/regulations specify the scope of linkage (e.g., Idaho)		Data originator agreements specify that the data can be linked according to the protocol for linkage approved by the data provider	DUA specifies that users are not authorized to link data across SEER databases							Does not authorize/specify	 CMS policy and Data Use Agreement specify that data can only be linked to external data in accordance with the RIF Application approved by the CMS Privacy Board which specifies the scope of linkage Information Exchange Agreement (IEA) between CMS and Participating Agency specifies the scope of linkage for federal entities performing linkage with non-standard TAFs containing PII 		CMS policy and Data Use Agreement specify that data can only be linked to external data in accordance with the RIF Application approved by the CMS Privacy Board which specifies the scope of linkage	authorize/specify

ATASET GOVERNANCE	
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					[Legend: Blank			DATASET GOVEF ble/found; N/A = info		ed to not exist]					
Governance			Dataset 1 - NCCR					Dataset 2 - CDC C	OVID				Dataset 3 - T-MSI	5	
	Data Collection	Data Linkage	Data Sharing	Data Access	Data Use	Data Collection	Data Linkage	Data Sharing	Data Access	Data Use	Data Collection	Data Linkage	Data Sharing	Data Access	Data Use
.3 Whether data can be shared	Data Collection Does not authorize/specify		 Consent and IRB approval specify that data can be shared (when applicable if consent and IRB were used by data provider) Sections 405, 410, 412 and 413 of the Public Health Service Act (42 U.S.C. §§ 284, 285, 285a-1 and 285a- 2) specify that NCI can share data 		Data Use	Data Collection	Data Linkage	Data Sharing	Data Access	Data Use	HIPAA Privacy Rule that CMS is subject	CMS policy, Data Use Agreement, and Information Exchange Agreement (IEA) authorize data sharing of linked data by federal	CMS policy, Data Use Agreement, and Information Exchange	Does not authorize/specify	Does not authorize/speci
			3. Contracts between SEER registries and NCI, subcontracts between NPCR registries and NAACCR and grants between NPCR registries and NAACCR specify that data can be shared												
	Does not authorize/specify	identifiers (except	NCI, and Subcontract between NPCR registries and					RIDURA specifies that COVID-19 data shared from various jurisdictions: 1. Must be de- identified of all direct identifiers prior to sharing 2. Must undergo disclosure review to suppress data fields with low frequency (<5) prior to sharing			to under the Privacy Act specifies that T- MSIS data be de- identified of all 18 HIPAA identifiers prior to sharing.	specifies that federal entities performing data linkage using non-standard TAFs containing PII must take the data into their SORN under the Privacy Act 2. CMS policy specifies that federal entities performing data linkage must agree to treat secondarily shared data as if the entity is a HIPAA Covered Entity and follow a process similar to CMS for releasing data including entering into a DUA	that de-identified data can be shared 2. CMS policy specifies that federal entities performing data linkage using non-standard TAFs containing PII must take the data into their SORN under the Privacy Act 3. CMS policy specifies that federal entities performing	must undergo the WRDC Review Process which is disclosure review by CCW VRDC staff of analysis outputs prior to removing output data from the VRDC	authorize/specif

					[Legend: <u>Blank ce</u> l			DATASET GOVE able/found; N/A = inf	RNANCE	o not exist]					
Governance			Dataset 1 - N	CCR				Dataset 2 - CDC	COVID				Dataset 3 - T-N	ISIS	
	Data Collection	Data Linkage	Data Sharing	Data Access	Data Use	Data Collection	Data Linkage	Data Sharing	Data Access	Data Use	Data Collection	Data Linkage	Data Sharing	Data Access	Data Use
3.5 How data can be	Does not			NCCR specifies that	NCCR specifies that				CDC COVID-19 case	RIDURA specifies	Does not	Does not		CMS specifies that	Does not
accessed (access	authorize/specify			for data access, a	for data access, a				surveillance restricted	d that for data access,	authorize/specify	authorize/specify		for data access, a	authorize/specify
type, data use				user:	user:				access data policy	a user:				user:	
agreement, data				1. Must submit a Data	1. Must submit a Data				specifies that users	1. Must sign and				1. Must submit RIF	
access				Analysis Plan	Analysis Plan				review the following	complete the				Data Use Agreement	t,
committee/group				2. Must execute the	2. Must execute the				documents to	RIDURA				Attachment A: RIF	
approval, IRB				NCCR DUA	NCCR DUA				determine interest in	2. Obtain IRB LOD				Application, RIF	
LOD, etc.)				3. Must obtain review	3. Must obtain review	,			accessing the COVID-	from researcher's				Application Key	
				and approval by the	and approval by the				19 Case Surveillance	institution (as				Personnel	
				NCI Office of Data	NCI Office of Data				Restricted Access	needed / applicable				Supplement, RIF	
				Sharing and the	Sharing and the				Detailed Data file:	3. Must access the				Specifications	
				Surveillance Research	Surveillance Research				1. CDC COVID-19	data through GitHuk				Worksheet, and Data	a
				Program's Data	Program's Data				Case Surveillance	private repository				Management Plan	
				Release group on the	Release group on the				Restricted Access					Self-Attestation	
				proposed research	proposed research				Detailed Data:					Questionnaire (DMP	
				4. Must obtain IRB	4. Must obtain IRB				Summary, Guidance,					SAQ)	
				LOD from the	LOD from the				Limitations					2. Must obtain	
				researcher's	researcher's				Information, and					review and approval	I
				institution, or from	institution, or from				Restricted Access					from ResDAC team	
				NCI central IRB	NCI central IRB				Data Use Agreement					on the proposed	
				(BRANY) if the	(BRANY) if the				Information					research	
				researchers	researchers				2. Data Dictionary for					3. Must obtain	
				institution does not	institution does not				the COVID-19 Case					review and approval	1
				have an IRB (as	have an IRB (as				Surveillance					from CMS' Data	
				needed /applicable)	needed / applicable)				Restricted Access					Privacy Safeguard	
				5. Must obtain IRB	5. Must obtain IRB				Detailed Data					Program (DPSP) on	
				approval from the	approval from the				3. After reviewing the					the Data	
				state registry	state registry				above information,					Management Plan	
					6. Must submit using				the user must					Self-Attestation	
				an institutional	an insititutional				complete the					Questionnaire (DMP	
				account (known as	account (known as				RIDURA, which					SAQ)	
					eRA Commons) and				specifies that for data					4. Must obtain IRB	
				obtain verification of	obtain verification of				access the user:					LOD from the	
				Signing Official by the	Signing Official by the				(a). Obtain IRB LOD					requesting institution	n
				NCI Office of Data	NCI Office of Data				from researcher's					5. Must obtain	
				Sharing and the	Sharing and the				institution (as					review and approval	1
					Surveillance Research				needed /applicable)					from CMS Privacy	
				Program's Data	Program's Data				(b). Must access the					Board on the	
				Release group	Release group				data through GitHub					proposed research	
				7. Must access and	7. Must access and				private repository					6. Must access data	
				use the data within	use the data within				,					through the VRDC or	r
				SEER*Stat (client	SEER*Stat (client									through encrypted	
				server software) or	server software) or									shipped disks	
				NCCR Data Platform	NCCR Data Platform										

						[Legend: Blank cel			ATASET GOVER le/found; N/A = infc	RNANCE	o not exist]					
	Governance	Dataset 1 - NCCR				Dataset 2 - CDC COVID				Dataset 3 - T-MSIS						
		Data Collection	Data Linkage	Data Sharing	Data Access	Data Use	Data Collection	Data Linkage	Data Sharing	Data Access	Data Use	Data Collection	Data Linkage	Data Sharing	Data Access	Data Use
3.6	How data can be	Does not			NCCR Data Use	NCCR Data Use				RIDURA specifies that	RIDURA specifies	Does not	CMS Privacy Board		Does not	1. T-MSIS policy
	used (including data	authorize/specify			Agreement specifies	Agreement specifies				the COVID-19 Case	that the COVID-19	authorize/specify	specifies that TAFs		authorize/specify	specifies that there
	use limitations)				that Authorized User	that Authorized User				Surveillance	Case Surveillance		can be used for			must be a research
					will use or disclose the	will use or disclose				Restricted Data	Restricted Data		resesarch purposes			use to justify the
					Data only for the	the Data only for the				Access can be used	Access can be used					initial disclosure and
					purposes for	purposes for				for broad research	for broad research					findings from the
					approved research	approved research				(must be of public	(must be of public					research must be
										health significance)	health significance)					publicly available.
																2. Data Use
																Agreement (DUA)
																specifies that data
																will be used solely
																for the study
																described in detail in
																the RIF Request
																Application
3.7	Other (specify)	Does not										Does not	Does not		Does not	Does not
		authorize/specify										authorize/specify	authorize/specify		authorize/specify	authorize/specify

NCCR (Dataset 1) and CDC COVID (Dataset 2) linkage	Can the datasets be linked? Yes, NCCR and CDC COVID can be linked provided:	What limitations do the linked datasets inherit?	What controls do the linked dataset r
and CDC COVID	Yes, NCCR and CDC COVID can be linked provided:		
		Researchers/users:	For sharing NCCR data, SEER staff must:
(Dataset 2) linkage	A. SEER staff:	1a. Must only link NCCR data based on applicable state	1a. Share NCCR data fully de-identified of all
(Dutuset 2) millage	1. Share NCCR data fully de-identified of all direct	laws which specify the scope of linkage (e.g., Idaho) and	identifiers (including exact ages and dates and
	identifiers (including exact ages and dates and	in accordance with protocol for linkage approved by the	geographic information, except quintiles) [N
	geographic information, except quintiles) [Control	data providers (i.e., state registry) [NCCR]	- · · · · · · · · · · · · · · · · · · ·
	1a]	1b. Must use or disclose NCCR data only for the purposes	-
	B. CDC COVID staff:	for approved research [NCCR]	2a. De-identify data of all direct identifiers [(COVID]
	2.De-identify data of all direct identifiers [Control 2a]	2a. Must use CDC COVID data for broad research (must	2b. Perform disclosure review to suppress da
	3.Perform disclosure review to suppress data fields	be of public health significance) [CDC COVID]	with low frequency (<5) prior to sharing CDC
	with low frequency (<5) prior to sharing CDC COVID		data [CDC COVID]
	data [Control 2b]		
			For accessing NCCR data, researchers/users
	C. The researcher/user:		1b. Submit Data Analysis Plan [NCCR]
	1. Obtains authorizations for data linkage and		1c. Execute the NCCR DUA [NCCR]
	sharing for CDC COVID [Authorization gap 1] -		1d. Obtain review by and approval from the
	Assumption		Office of Data Sharing and the Surveillance F
	2. Links NCCR data only based on applicable state		Program's Data Release group on the propos
	laws which specify the scope of linkage (e.g., Idaho)		research [NCCR]
	and in accordance with protocol for linkage		1e. Obtain IRB LOD from the researcher's ins
	approved by the data provider/s (i.e., state registry)		or from NCI central IRB (BRANY) if the resear
	[Limitation 1a]		institution does not have an IRB (as
	3. Uses or disclose linked NCCR and CDC COVID data		needed/applicable) [NCCR]
	only for the purposes for approved research which must be of public health significance [Limitations 1b,		1f. Obtain IRB approval from the state regist 1g. Use an institutional account (known as e
	2a]		Commons) and obtain verification of Signing
	4. Submits NCCR Data Analysis Plan, NCCR DUA, and		by the NCI Office of Data Sharing and the Su
	CDC COVID Restricted Access Data Use Agreement		Research Program's Data Release group [NC
	(RIDURA) [Control 1b, 1c, 2b]		1h. Access the data from SEER*Stat (client se
	5. Obtains approval from NCI Office of Data Sharing		software) [NCCR]
	and the Surveillance Research Program's Data		
	Release group on the proposed linkage [Control 1d]		For accessing CDC COVID data, researchers
	6. Obtains IRB LOD from the researcher's institution		must:
	for NCCR and CDC COVID data (or NCI BRANY as		2b. Execute the Restricted Access Data Use
	needed for NCCR) and IRB approval from the NCCR		Agreement (RIDURA) [CDC COVID]
	state registry [Control 1e, 1f, 2c]		2c. Obtain IRB LOD from researcher's institu
	7. Uses an institutional account (known as eRA		needed/applicable) [CDC COVID]
	Commons) and obtains verification of Signing		2e. Access data from CDC GitHub private rep
	Official by the NCI Office of Data Sharing and the		[CDC COVID]
	Surveillance Research Program's Data Release group		
	[Control 1g]		
	8. Works with CDC COVID staff to upload data		
	obtained from CDC GitHub private repository into		
	SEER*Stat (client server software), where NCCR data		
	can be accessed [Controls 1h, 2e] - Assumption for		
	NCCR and CDC COVID		

require?	What authorization gaps exist?
	2a. For CDC COVID-19, information on
all direct	authorizations for linkage and sharing is not
and	available/found.
NCCR]	
[CDC	
LCDC	
data fields	
DC COVID	
ers must:	
e NCl Research	
osed	
osca	
nstitution,	
archers	
stry [NCCR]	
eRA	
ng Official	
Surveillance	
server	
Server	
rs/users	
2	
tution (as	
epository	

		Can the datasets be linked?	What limitations do the linked datasets inherit?	What controls do the linked dataset re
2	NCCR (Dataset 1)	Yes, NCCR and T-MSIS can be linked provided:	Researchers/users:	For sharing NCCR data, SEER staff must:
	and T-MSIS (Dataset	A. SEER staff:	1a. Must only link NCCR data based on applicable state	1a. Share NCCR data fully de-identified of all
	linkage	1. Share NCCR data fully de-identified of all direct	laws which specify the scope of linkage (e.g., Idaho) and	identifiers (including exact ages and dates and
		identifiers (including exact ages and dates and	in accordance with protocol for linkage approved by the	geographic information, except quintiles) [N
		geographic information, except quintiles) [Control	data providers (i.e., state registry) [NCCR]	
		1a]	1b. Must use or disclose NCCR data only for the purposes	For sharing T-MSIS data:
			for approved research [NCCR]	A. Federal entities who create linked T-MS
		B. Federal entities who create linked T-MSIS data		and share the linked data must:
		and share the linked data:	Federal entities who create linked T-MSIS data:	3a. De-identify T-MSIS data of all 18 HIPAA id
		2. De-identify T-MSIS data of all 18 HIPAA identifiers	3a. Must only link T-MSIS data in accordance with the RIF	as per HIPAA [T-MSIS]
		as per HIPAA [Control 3a]	Application approved by the CMS Privacy Board which	3b. Take the data into their SORN under the
		3. Take the data into their SORN under the Privacy	specifies the scope of linkage and in accordance with the	Act when performing data linkage using non
		Act when performing data linkage using non-	Information Exchange Agreement (IEA) between CMS	TAFs containing PII [T-MSIS]
		standard TAFs containing PII [Control 3b]	and Participating Agency which specifies the scope of	3c. Treat secondarily shared data as if they a
		4. Treat secondarily shared data as if they are a	linkage for federal entities performing linkage with non-	HIPAA Covered Entity and follow a process s
		HIPAA Covered Entity and follow a process similar to	standard TAFs containing PII [T-MSIS]	CMS for releasing data including entering int
		CMS for releasing data including entering into a DUA		with the researcher [T-MSIS]
		with the researcher [Control 3c]	Researchers/users:	B. CCW VRDC staff must:
		5. Links NCCR data only based on applicable state	3b. Must use T-MSIS data for research use that justifies	3d. Perform disclosure review of analysis out
		laws for participating NCCR registries, in accordance	the initial disclosure and solely for the study described in	prior to sharing output data from the VRDC
		with protocol for linkage approved by the NCCR data	detail in the RIF Request Application, and must ensure	
		provider/s, the RIF Application approved by ResDAC	findings are publicly available [T-MSIS]	For accessing NCCR data, researchers/users
		team and CMS Privacy Board, and the Information		1b. Submit Data Analysis Plan [NCCR]
		Exchange Agreement (IEA) between CMS and		1c. Execute the NCCR DUA [NCCR]
		Participating Agency (for federal entities performing		1d. Obtain review by and approval from the
		linkage with non-standard TAFs containing PII)-all off		Office of Data Sharing and the Surveillance F

require?	What	authorization gaps exist?
all direct and [NCCR]	None	
ISIS data		
identifiers		
ne Privacy on-standard		
y are a s similar to into a DUA		
outputs C [T-MSIS]		
ers must:		
ne NCI e Research		

Can the datasets be linked?	What limitations do the linked datasets inherit?	What controls do the linked dataset require?	What authorization gaps exist?
which specify the scope of linkage [Limitations 1a,		Program's Data Release group on the proposed	
3a]		research [NCCR]	
C. CCW VRDC staff:		1e. Obtain IRB LOD from the researcher's institution,	
6. Perform disclosure review of analysis outputs		or from NCI central IRB (BRANY) if the researchers	
prior to sharing output data from the VRDC [Control		institution does not have an IRB (as needed /	
3d]		applicable) [NCCR]	
		1f. Obtain IRB approval from the state registry [NCCR]	
D. The researcher/user:		1g. Use an institutional account (known as eRA	
1. Uses or discloses linked NCCR and T-MSIS data		Commons) and obtain verification of Signing Official	
only for the purposes for approved research for		by the NCI Office of Data Sharing and the Surveillance	
NCCR and research use that justifies the initial		Research Program's Data Release group [NCCR]	
disclosure and solely for the study described in the		1h. Access the data from SEER*Stat (client server	
T-MSIS RIF Request Application, and ensures findings		software) [NCCR]	
are publicly available [Limitations 1b, 3b]			
2. Submits NCCR Data Analysis Plan, NCCR DUA, T-		For accessing T-MSIS data, researchers/users must:	
MSIS RIF Data Use Agreement, Attachment A: RIF		3e. Submit RIF Data Use Agreement, Attachment A:	
Application, RIF Application Key Personnel		RIF Application, RIF Application Key Personnel	
Supplement, RIF Specifications Worksheet, and Data		Supplement, RIF Specifications Worksheet, and Data	
Management Plan Self-Attestation Questionnaire		Management Plan Self-Attestation Questionnaire	
(DMP SAQ) [Controls 1b, 1c, 3e]		(DMP SAQ) [T-MSIS]	
3. Obtains approval from NCI Office of Data Sharing		3f. Obtain review and approval from ResDAC team on	
and the Surveillance Research Program's Data		the proposed research [T-MSIS]	
Release group, ResDAC team, and CMS Privacy Board		3g. Obtain review and approval from CMS' Data	
on the proposed linkage [Control 1d, 3f, 3g]		Privacy Safeguard Program (DPSP) on the Data	
4. Obtains IRB LOD from the researcher's institution		Management Plan Self-Attestation Questionnaire	
for NCCR and T-MSIS (or NCI BRANY as needed for		(DMP SAQ) [T-MSIS]	
NCCR) and IRB approval from the NCCR state registry		3h. Obtain IRB LOD from the requesting institution [T-	
[Controls 1e, 1f, 3h] 5. Uses an institutional account (known as eRA		MSIS]	
Commons) and obtains verification of Signing Official		3i. Access data from the VRDC or through encrypted shipped disks [T-MSIS]	
by the NCI Office of Data Sharing and the		אוויף בע מואא נו-ויוטטן	
Surveillance Research Program's Data Release group			
for NCCR [Control 1g]			
6. Works with T-MSIS and NCCR to establish federal			
agency authorization for T-MSIS linkage with NCCR			
and for use within SEER*Stat [Controls 1h, 3i] -			
Assumption for NCCR and T-MSIS			

		Can the datasets be linked?	What limitations do the linked datasets inherit?	What controls do the linked dataset re
3	CDC COVID (Dataset	Yes, CDC COVID and T-MSIS can be linked provided:	Researchers/users:	For sharing CDC COVID data, staff must:
	2) and T-MSIS	A. CDC COVID staff:	2a. Must use CDC COVID data for broad research (must	2a. De-identify data of all direct identifiers [C
	(Dataset 3) linkage	1.De-identify data of all direct identifiers [Control 2a]	be of public health significance) [CDC COVID]	COVID]
		2.Perform disclosure review to suppress data fields		2b. Perform disclosure review to suppress da
		with low frequency (<5) prior to sharing CDC COVID	Federal entities who create linked T-MSIS data:	with low frequency (<5) prior to sharing CDC
		data [Control 2b]	3a. Must only link T-MSIS data in accordance with the RIF	data [CDC COVID]
			Application approved by the CMS Privacy Board which	
		B. Federal entities who create linked T-MSIS data	specifies the scope of linkage and in accordance with the	For sharing T-MSIS data:
		and share the linked data:	Information Exchange Agreement (IEA) between CMS	A. Federal entities who create linked T-MSI
		3. De-identify T-MSIS data of all 18 HIPAA identifiers	and Participating Agency which specifies the scope of	and share the linked data must:
		as per HIPAA [Control 3a]	linkage for federal entities performing linkage with non-	3a. De-identify T-MSIS data of all 18 HIPAA id
		4. Take the data into their SORN under the Privacy	standard TAFs containing PII [T-MSIS]	as per HIPAA [T-MSIS]
		Act when performing data linkage using non-		3b. Take the data into their SORN under the
		standard TAFs containing PII [Control 3b]	Researchers/users:	Act when performing data linkage using non
		5. Treat secondarily shared data as if they are a	3b. Must use T-MSIS data for research use that justifies	TAFs containing PII [T-MSIS]
		HIPAA Covered Entity and follow a process similar to	the initial disclosure and solely for the study described in	3c. Treat secondarily shared data as if they a
		CMS for releasing data including entering into a DUA	detail in the RIF Request Application, and must ensure	HIPAA Covered Entity and follow a process s
		with the researcher [Control 3c]	findings are publicly available [T-MSIS]	CMS for releasing data including entering int
		6. Link T-MSIS data only in accordance with the RIF		with the researcher [T-MSIS]
		Application approved by the CMS Privacy Board		B. CCW VRDC staff must:
		which specifies the scope of linkage and in		3d. Perform disclosure review of analysis out
		accordance with the Information Exchange		prior to sharing output data from the VRDC
		Agreement (IEA) between CMS and Participating		
		Agency which specifies the scope of linkage for		For accessing CDC COVID data, researchers,
		federal entities performing linkage with non-		must:
		standard TAFs containing PII [Limitation 3a]		2b. Execute the Restricted Access Data Use
		C. CCW VRDC staff:		Agreement (RIDURA) [CDC COVID]

require?	What authorization gaps exist?
[CDC	2a. For CDC COVID-19, information on authorizations for linkage and sharing is not available/found.
data fields DC COVID	
ISIS data	
identifiers	
ne Privacy on-standard	
are a similar to into a DUA	
outputs C [T-MSIS]	
rs/users	
2	

Can the datasets be linked?	What limitations do the linked datasets inherit?	What controls do the linked dataset re
7. Perform disclosure review of analysis outputs		2c. Obtain IRB LOD from researcher's institut
prior to sharing output data from the VRDC [Control		needed/applicable) [CDC COVID]
3d]		2e. Access data from CDC GitHub private rep
		[CDC COVID]
D. The researcher/user:		
1. Obtains authorizations for data linkage and		For accessing T-MSIS data, researchers/use
sharing for CDC COVID [Authorization gap 1] -		3e. Submit RIF Data Use Agreement, Attachr
Assumption		RIF Application, RIF Application Key Personn
2. Uses the linked CDC COVID data and T-MSIS data		Supplement, RIF Specifications Worksheet, a
for broad research use (must be of public health		Management Plan Self-Attestation Question
significance) that justifies the initial disclosure and		(DMP SAQ) [T-MSIS]
solely for the study described in the T-MSIS RIF		3f. Obtain review and approval from ResDAC
Request Application, and ensures findings are		the proposed research [T-MSIS]
publicly available [Limitations 2a, 3b]		3g. Obtain review and approval from CMS' D
3. Submits CDC COVID Restricted Access Data Use		Privacy Safeguard Program (DPSP) on the Da
Agreement (RIDURA), T-MSIS RIF Data Use		Management Plan Self-Attestation Question
Agreement, Attachment A: RIF Application, RIF		(DMP SAQ) [T-MSIS]
Application Key Personnel Supplement, RIF		3h. Obtain IRB LOD from the requesting inst
Specifications Worksheet, and Data Management		MSIS]
Plan Self-Attestation Questionnaire (DMP SAQ)		3i. Access data from the VRDC or through en
[Controls 2b, 3e]		shipped disks [T-MSIS]
4. Obtains approval from ResDAC team on the		
proposed linkage [Control 3f]		
5. Obtains approval from CMS' Data Privacy		
Safeguard Program (DPSP) on the Data Management		
Plan Self-Attestation Questionnaire (DMP SAQ)		
[Control 3g]		
6. Obtains IRB LOD from the researcher's		
institutions [Controls 2c, 3h]		
7. Works with T-MSIS and CDC COVID to establish		
federal agency authorization for T-MSIS linkage with		
CDC COVID and either (1) upload data obtained		
from CDC GitHub private repository into VRDC,		
where T-MSIS data can be accessed - or - (2) obtain		
T-MSIS data in encrypted shipped disks and upload		
to CDC GitHub private repository [Controls 2e, 3i] -		
Assumption for CDC COVID and T-MSIS		

require?	What authorization gaps exist?
ution (as	
epository	
sers must:	
hment A:	
nnel	
, and Data	
onnaire	
AC team on	
' Data	
Data	
onnaire	
stitution [T-	
encrypted	

	Can the datasets be linked?	What limitations do the linked datasets inherit?	What controls do the linked dataset re
All datasets	Yes, NCCR, CDC COVID, and T-MSIS can be linked	Researchers/users:	For sharing NCCR data, SEER staff must:
	provided:	1a. Must only link NCCR data based on applicable state	1a. Share NCCR data fully de-identified of all
		laws which specify the scope of linkage (e.g., Idaho) and	identifiers (including exact ages and dates ar
	A. SEER/CDC COVID/CCW VRDS staff:	in accordance with protocol for linkage approved by the	geographic information, except quintiles) [N
	1. Share NCCR, CDC COVID, and T-MSIS data fully de-	data providers (i.e., state registry) [NCCR]	
	identified of all direct identifiers [Controls 1a, 2a, 3a]	1b. Must use or disclose NCCR data only for the purposes	For sharing CDC COVID data, staff must:
	2. Perform disclosure review	for approved research [NCCR]	2a. De-identify data of all direct identifiers [C
	-for CDC COVID data, to suppress data fields with low		COVID]
	frequency (<5) prior to sharing	2a. Must use CDC COVID data for broad research (must	2b. Perform disclosure review to suppress da
	-for T-MSIS data, to review analysis outputs prior to	be of public health significance) [CDC COVID]	with low frequency (<5) prior to sharing CDC
	sharing output data from the VRDC		data [CDC COVID]
	[Controls 2b, 3d]	3b. Must use T-MSIS data for research use that justifies	
		the initial disclosure and solely for the study described in	For sharing T-MSIS data:
	B. Federal entities who create linked T-MSIS data	detail in the RIF Request Application, and must ensure	A. Federal entities who create linked T-MSI
	and share the linked data:	findings are publicly available [T-MSIS]	and share the linked data must:
	3. Take the data into their SORN under the Privacy		3a. De-identify T-MSIS data of all 18 HIPAA ic
	Act when performing data linkage using non-	Federal entities who create linked T-MSIS data:	as per HIPAA [T-MSIS]
	standard TAFs containing PII [Control 3b]	3a. Must only link T-MSIS data in accordance with the RIF	3b. Take the data into their SORN under the
	4. Treat secondarily shared data as if they are a	Application approved by the CMS Privacy Board which	Act when performing data linkage using non-
	HIPAA Covered Entity and follow a process similar to	specifies the scope of linkage and in accordance with the	TAFs containing PII [T-MSIS]
	CMS for releasing data including entering into a DUA	Information Exchange Agreement (IEA) between CMS	3c. Treat secondarily shared data as if they a
	with the researcher [Control 3c]	and Participating Agency which specifies the scope of	HIPAA Covered Entity and follow a process si
	5. Link NCCR data only based on applicable state	linkage for federal entities performing linkage with non-	CMS for releasing data including entering int
	laws for participating NCCR registries, in accordance	standard TAFs containing PII [T-MSIS]	with the researcher [T-MSIS]
	with protocol for linkage approved by the NCCR data		B. CCW VRDC staff must:
	providers, and the RIF Application approved by		3d. Perform disclosure review of analysis out
	ResDAC team and CMS Privacy Board and in		prior to sharing output data from the VRDC [
	accordance with the Information Exchange		

require?	What authorization gaps exist?
	2a. For CDC COVID-19, information on
all direct and	authorizations for linkage and sharing is not available/found.
[NCCR]	
[CDC	
lebe	
data fields	
DC COVID	
ISIS data	
identifiers	
Duitana	
ne Privacy on-standard	
are a	
s similar to into a DUA	
outputs C [T-MSIS]	

Can the datasets be linked?	What limitations do the linked datasets inherit?	What controls do the linked dataset re
Agreement (IEA) between CMS and Participating		For accessing NCCR data, researchers/users
Agency - all of which specify the scope of linkage		1b. Submit Data Analysis Plan [NCCR]
[Limitations 1a, 3a]		1c. Execute the NCCR DUA [NCCR]
		1d. Obtain review by and approval from the
C. The researcher/user:		Office of Data Sharing and the Surveillance R
1. Obtains authorizations for data linkage and		Program's Data Release group on the propos
sharing for CDC COVID [Authorization gap 1] -		research [NCCR]
Assumption		1e. Obtain IRB LOD from the researcher's ins
2. Uses the linked NCCR, CDC COVID and T-MSIS		or from NCI central IRB (BRANY) if the resear
data for broad research use (must be of public		institution does not have an IRB (as
health significance) that justifies the initial disclosure		needed/applicable) [NCCR]
and solely for the study described in the T-MSIS RIF		1f. Obtain IRB approval from the state regist
Request Application, and ensures findings are		1g. Use an institutional account (known as e
publicly available [Limitations 1b, 2a, 3b]		Commons) and obtain verification of Signing
3. Submits NCCR Data Analysis Plan, NCCR DUA, and		by the NCI Office of Data Sharing and the Su
CDC COVID Restricted Access Data Use Agreement		Research Program's Data Release group [NC
(RIDURA), T-MSIS RIF Data Use Agreement,		1h. Access the data from SEER*Stat (client se
Attachment A: RIF Application, RIF Application Key		software) [NCCR]
Personnel Supplement, RIF Specifications		software) [INCOM]
Worksheet, and Data Management Plan Self-		For accessing CDC COVID data, researchers,
_		
Attestation Questionnaire (DMP SAQ) [Controls 1b,		must:
1c, 2b, 3e]		2b. Execute the Restricted Access Data Use
4. Obtains approval from NCI Office of Data Sharing		Agreement (RIDURA) [CDC COVID]
and the Surveillance Research Program's Data		2c. Obtain IRB LOD from researcher's institu
Release group and ResDAC team on the proposed		needed/applicable) [CDC COVID]
linkage [Controls 1d, 3f]		2e. Access data from CDC GitHub private rep
5. Obtains IRB LOD from the researcher's institution		[CDC COVID]
for NCCR, CDC COVID and T-MSIS data (or NCI BRANY		
as needed for NCCR) and IRB approval from the		For accessing T-MSIS data, researchers/use
NCCR state registry [Controls 1e, 1f, 2c, 3h]		3e. Submit RIF Data Use Agreement, Attachr
6. Uses an institutional account (known as eRA		RIF Application, RIF Application Key Personn
Commons) and obtains verification of Signing Official		Supplement, RIF Specifications Worksheet, a
by the NCI Office of Data Sharing and the		Management Plan Self-Attestation Question
Surveillance Research Program's Data Release group		(DMP SAQ) [T-MSIS]
for NCCR [Control 1g]		3f. Obtain review and approval from ResDAC
7. Works with T-MSIS, NCCR, and CDC COVID staff to		the proposed research [T-MSIS]
establish federal agency authorization for T-MSIS		3g. Obtain review and approval from CMS' D
linkage with NCCR and CDC COVID and to upload		Privacy Safeguard Program (DPSP) on the Da
CDC COVID data obtained from CDC GitHub private		Management Plan Self-Attestation Question
repository and T-MSIS data obtained via encrypted		(DMP SAQ) [T-MSIS]
shipped disks to SEER*Stat (client server software),		3h. Obtain IRB LOD from the requesting inst
where NCCR data can be accessed [Controls 1h, 2e,		MSIS]
3i] - Assumption for NCCR, CDC COVID and T-MSIS		3i. Access data from the VRDC or through en
		shipped disks [T-MSIS]

require?	What authorization gaps exist?
ers must:	
e NCI	
Research	
osed	
nstitution,	
archers	
ctry [NCCP]	
stry [NCCR] eRA	
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Surveillance	
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encrypted	

	OVERNANCE INFORMATION		
Use Case 2: W Dataset 5 - N		ediatric cancer survivors? Or what is the impact of COVID-19 infection on future pediatric can	cer outco
Dalasel 5 - I	Dataset Source	National Childhead Canaar Desistry (NCCD)	1
		National Childhood Cancer Registry (NCCR)	
	Dataset Source Agency	NIH/NCI	
	Dataset Type (Clinical, EHR, Survey, SDOH, etc		
	Information Sources	Website, interview with NCCR staff member	
Dataset 5 - N			1
		Raw Language	
1	Data Collection		
1.1	Authorizations and Applicable		
	Regulations/Policies		
1.1.1	Authorizations		1. Conten
			2. IRB app
			3. State La
			4. Institut
1.1.1.1	Accont	Patients are not asked to provide consent for information to be reported to the central cancer registry.	Informati
1.1.1.1	Assent		informatio
		[1]	
		We work with some data providers that obtained data originally under a research consent (PPCR, COG). In those cases, local IRBs have been part of reviewing if the consent covers broad data sharing or	
		not and the process to reconsent individuals. This may also involve obtaining additional organizational	
		approvals. We may also work with BRANY as the central IRB for NCI to determine if the NCCR is a data	
		repository that is exempt from human subjects research as it is all secondary research. We are also	
		requiring investigators to obtain IRB approval in the first year of use to monitor how IRBs view the	
		NCCR. [2]	
1.1.1.2	Consent	Patients are not asked to provide consent for information to be reported to the central cancer registry.	Consent a
1.1.1.2	consent	[1]	originally
		We work with some data providers that obtained data originally under a research consent (PPCR,	onginany
		COG). In those cases, local IRBs have been part of reviewing if the consent covers broad data sharing or	-
		not and the process to reconsent individuals. This may also involve obtaining additional organizational	
		approvals. We may also work with BRANY as the central IRB for NCI to determine if the NCCR is a data	
		repository that is exempt from human subjects research as it is all secondary research. We are also	
		requiring investigators to obtain IRB approval in the first year of use to monitor how IRBs view the	
		NCCR. [2]	
1.1.1.3	IRB/equivalent Privacy Board determination	New Jersey has a Data Repository IRB approved protocol the Rutgers uses to oversee the activities of	IRB appro
1.1.1.3		the registry in data collection and its eventual use for research. The New Jersey repository IRB covers	Jersey)
		all data collection including SEER	JEISEY
		sponsored data linkages include the GHI linkage, SEER-Medicare, SEER-Medicaid, and will also cover	
		linkages with CVS and Walgreens. The data repository also covers non-traditional data sources for	
		incidence, treatment and follow-up such	
		as Meaningful Use, claims, NDI, etc. [1]	
		מי אוכמווווקומו ספר, כומוווופ, אסו, כנכ. [1]	

comes?	
Interpretation	Source
ent (if applicable) pproval for some states (e.g., New Jersey) e Laws/Regulations (if applicable) eutional Certification (if applicable)	
ation not available/found	[1] NCCR Meeting[2] NCCR Email Communication
t authorizes data collection for some data providers who ly obtained the data under a research consent	[1] NCCR Meeting[2] NCCR Email Communication
roval authorizes data collection for certain states (e.g., New	[1] NCCR Meeting

et 5 - NCCR Data		· · · · ·	-
	Raw Language	Interpretation	Source
L.1.4 Local/state/federal laws	Central cancer registries collect information about cancer diagnosis and treatment according to state	State regulations/policies authorizes data collection by central cancer	[1] NCCR Meeting
	laws. As a reportable illness, healthcare providers disclose information about cancer patients to the	registries as part of public health surveillance	[2] NCCR Email Communication
	central cancer registry and sharing this information is exempt from HIPAA		
	https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/disclosures-public-health-		
	activities/index.html . Therefore, patients are not asked to provide consent for information to be		
	reported to the central cancer registry. In some cases, the state health department directly manages		
	the activities of the central cancer registries but in other cases this is contracted to another entity,		
	usually a university (as is the case in Florida, Georgia, Kentucky, etc.). Additionally, some state laws and	t l	
	regulations about reporting information about cancer patients ranges from outdated to regularly		
	updated by state legislatures or health departments. Some registries are bound by law to be incident-		
	only and do not have authority to hold longitudinal, post-cancer information (Michigan). It is		
	important to read state law and regulations for each state when there are questions about what kind		
	of data are reported by providers to the central cancer registry (see attached examples). Subsequently,		
	SEER registries have a contractual relationship with the NCI to license de-identified data to the NCI.		
	With NPCR registries, the direct relationship is with NAACCR and Information Management Services,		
	Inc. (IMS) (serves as the honest broker) to hold data. Additionally, IMS executes Interconnection		
	Services Agreements with each registry in a few cases Business Associate Agreements to act as an		
	honest broker and IT vendor for each registry's isolated environment in the IMS private data center.		
	For some projects, central cancer registries do seek IRB approval but thus far this does not apply to		
	NCCR data submissions. [1]		
	All cancer registries are authorized by the state regulations health care providers are responsible for		
	reporting cancer diagnosis to the central cancer registry (in some cases, the registry is the state health		
	department, or subcontractor to the state health department e.g., for California, UCSF operates		
	regional registries for the state health department)'. Regulations vary by state (NCCR staff sent list of		
	sample state legislature that are tracked) – for example, Michigan registries are not permitted to hold		
	longitudinal data, on incidence data. State legislature typically defines 1) what is required to be		
	reported, 2) who is required to report, 3) where the reporting is done, and 4) in what format (typically		
	states will say whatever is in the NAACCR format should be reported – but not very detailed, which is		
	why NCCR obtains other data like pharmacy data). The state laws are not backed up by any federal		
	laws. Providers are exempted from having to tell or ask patients about the disclosure of PII to the		
	central cancer registry. [1]		
	State regulations/policies authorize original data collection by central cancer registries as part of public		
	health surveillance. Data are then de-identified and licensed to the NCI under contract. Most data flow		
	through this process, even if the data provider is centrally coordinated by NCI (such as Walgreens, Rite		
	Aid, and CVS providing pharmacy claims). Some data are obtained through PPRL and cannot be		
	provided to registries, but only held by the NCI.		
	The NCI is part of the National Institutes of Health (NIH) and the NIH is an entity of the Public Health		
	Service (Sections 202 and 401 of the Public Health Service Act, 42 U.S.C. §§ 203, 281). Pursuant to		
	Section 402 of the Public Health Service Act (42 U.S.C. § 282), the Director of the NIH has the authority		
	to conduct certain functions in furtherance of the public health purposes of Section 301 of the Public		
	Health Service Act. The NCI is authorized to conduct the cancer research, control and information		
	dissemination activities described herein pursuant to Sections 405, 410, 412 and 413 of the Public		
	Health Service Act (42 U.S.C. §§ 284, 285, 285a-1 and 285a-2). [2]		
		Institutional Costification authorization data anti-	
I.1.5 Institutional Certification	State or regional central cancer registries may obtain institutional certification to collect and retain	Institutional Certification authorizes data collection for some state or	[1] NCCR Email Communication
	data about cancer patients. [1]	regional cancer registries	
L.1.6 Data originator agreement	N/A	N/A	
I.1.7 Repository agreements/policie	s N/A	N/A	
1.1.8 Other (specify)	Information not available/found	Information not available/found	
	es N/A	N/A	

Dataset 5 - NG	CCR Data			
		Raw Language	Interpretation	Source
1.1.2.3	State regulations/policies	Data from Cancer in North America (CiNA) (North American Association of Central Cancer Registries (NAACCR) 1995-2018 and the NCI's Surveillance, Epidemiology and End Results (SEER) Registries), submitted December 2020). Registries include: California, Connecticut, Florida, Georgia, Hawaii, Idaho, Illinois, Iowa, Kentucky, Louisiana, Massachusetts, New Jersey, New Mexico, New York, Ohio, Pennsylvania, Seattle (Puget Sound), Tennessee, Texas, Utah, Wisconsin. These 23 NCCR registries represent 66% of all U.S. children, adolescents, and young adults ages 0-39 based on 2018 U.S. Populations.	State regulations/policies the participating NCCR registries: Arkansas, California, Connecticut, Florida, Georgia, Hawaii, Idaho, Illinois, Iowa, Kentucky, Louisiana, Massachusetts, Michigan, New Jersey, New Mexico, New York, Ohio, Pennsylvania, Seattle (Puget Sound), Tennessee, Texas, Utah, and Wisconsin	 [1] <u>https://datacatalog.ccdi.cancer.gov/dataset/NCCR-NCCRExplorer</u> (Accessed: 4/28/23) [2] NCCR Email Communication
1.1.2.4	Federal regulations/policies	N/A - the state laws are not backed up by any federal laws. [1]	N/A	[1] NCCR Meeting
1.1.2.5	International regulations/policies	N/A	N/A	
1.1.2.6	Contractual obligations	All cancer registries are authorized by the state regulations health care providers are responsible for reporting cancer diagnosis to the central cancer registry (in some cases, the registry is the state health department, or subcontractor to the state health department e.g., for California, UCSF operates regional registries for the state health department)'. [1]	 Contractual obligations for registries operated by the state health department to the NCI Obligations for registries participating through a grant under NAACCR 	[1] NCCR Meeting [2] NCCR Email Communication
		Contractual obligations for registries operated by the state health department to the NCI. Some registries participate through a grant under NAACCR. [2]		
1.1.2.7	Repository policies	N/A	N/A	
1.2	Governance for data linkage, sharing, acc	ess, and use based on data collection authorization or applicable regulations/policies (i.e., the	e origin of the governance)	
1.2.1	Whether the data can be linked	External Linkages. Louisiana Tumor Registry (LTR) data may be linked with external databases in order to improve the accuracy and completeness of follow-up data or for research. Health care provider shall mean every licensed health care facility and licensed health care provider, as defined in R.S. 40:1231.1(A), in the state of Louisiana. [1]	Certain state laws/regulations specify that the data can be linked (e.g.,	[1] SEER Legal Authority for DetailedPharmacy Treatment Data Collection from NCCR Staff[2] NCCR Email Communication
		State public health surveillance laws vary in restrictions on use of linked data but generally matching patients from different data sources to the cancer registry data, adding to traditional registry data, and then de-identifying data for submission to the NCI is permitted. [2]	ł	
1.2.2	With what other data can it be linked or can it not be linked (scope of linkage)	Idaho Code Title 57, Chapter 17, 57-1703 (6) defines the scope of data collection: "Population-based" refers to all cancers and reportable benign tumors diagnosed and/or treated within the state of Idaho by hospitals or other facilities providing screening, diagnostic or therapeutic services to patients with respect to cancer, and from physicians, surgeons, and all other health care providers diagnosing or providing treatment for cancer patients.' Linkages to gather treatment and other information are specifically allowed in 57-1805(5): 'Nothing in this chapter shall prevent the department or authorized contractor from identifying and reporting cases using data linkages with death records, statewide cancer registries, and other potential sources.' [1]	Certain state laws/regulations specify the scope of linkage (e.g., Idaho)	 [1] SEER Legal Authority for Detailed Pharmacy Treatment Data Collection from NCCR Staff [2] NCCR Email Communication
		patients from different data sources to the cancer registry data, adding to traditional registry data, and then de-identifying data for submission to the NCI is permitted. [2]		
1.2.3	Whether data can be shared	Does not authorize/specify	Does not authorize/specify	[1] SEER Legal Authority for Detailed Pharmacy Treatment Data Collection from NCCR Staff
1.2.4	How data can be shared (de-identification status, disclosure review)	Does not authorize/specify	Does not authorize/specify	[1] SEER Legal Authority for Detailed Pharmacy Treatment Data Collection from NCCR Staff
1.2.5	How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.)	Does not authorize/specify	Does not authorize/specify	[1] SEER Legal Authority for Detailed Pharmacy Treatment Data Collection from NCCR Staff
1.2.6	How data can be used (data use limitations) Does not authorize/specify	Does not authorize/specify	[1] SEER Legal Authority for Detailed Pharmacy Treatment Data Collection from NCCR Staff
1.2.7	Other (specify)	Does not authorize/specify	Does not authorize/specify	[1] SEER Legal Authority for Detailed Pharmacy Treatment Data Collection from NCCR Staff
2	Data Linkage			
	Authorizations and Applicable			
2.1	Regulations/Policies			
	Regulations/Policies Authorizations			
		Information not available/found Information not available/found	Information not available/found Information not available/found	

	NCCR Data	Development	
2.1.1.3	IRB/equivalent Privacy Board determination	Raw Language	N/A
2.1.1.5			IN/A
2.1.1.4	Local/state/federal laws	N/A	N/A
2.1.1.5	Institutional Certification	N/A	N/A
2.1.1.6		The linked data will come to NCI/NCCR de-identified when NCCR is ready to receive data, NCCR will post the requirements for linkage SEER data (https://seer.cancer.gov/tools/submission.html), so NAACCR (subcontractor) will submit under Call for Data. [1] For each linkage, registries review and approve a protocol specific to that linkage. Approvals are granted by senior personnel at the registry and are often reviewed by legal advisors within the state health departments who manage the registry or the registry sub-contractor. In some cases, data providers and registries sign additional Data Sharing (or Use) Agreements. This usually happens between the registry and IMS. In some cases, a MOU or MOA is signed between a data provider and the NCI. [1] Below is a table of the VPR-only registries that are participating in linkage with the NCCR. These nine registries have a Data Sharing Agreement with IMS allowing IMS to link the data and agreeing for data on prior/subsequent cancers to be incorporated into the NCCR. The table shows whether the registry would like the full record incorporated or just a list of basic data items (which now included stage and treatment). It also identifies whether the registry would like IMS to extract the data for incorporation into the NCCR. [1] Data Sharing (or Use) Agreement or a hosting agreement (ISA) or BAA executed between IMS and the data provider (as needed / if applicable) authorizes data storage, linkage, management, and destruction of original data [2]	Three agr 1. Protoco linkage 2. Data Sl executed 3. MOU o data linka
2.1.1.7	Repository agreements/policies	Information not available/found	Informati
2.1.1.8	Other (specify)	Information not available/found	Informati
2.1.2	Applicable Regulations/Policies		
2.1.2.1	Local regulations/policies	N/A	N/A
2.1.2.2	Tribal regulations/policies	N/A - No tribal data. [1]	N/A
2.1.2.3	State regulations/policies	N/A	N/A
2.1.2.4	Federal regulations/policies	N/A	N/A
2.1.2.5	International regulations/policies	N/A	N/A
2.1.2.6	Contractual obligations	So far, NCCR has not released any linked data (still setting up the mechanisms to do that). The way it usually works depending on if its NPCR registry (under NAACCR subcontract) or SEER registry (direct contract with NCI), they sign an Interconnection Services Agreement, and in some cases also a BAA with IMS if required by the registry. The purpose of these agreements are for IMS to act as the honest broker to hold the PII and perform the linkage using Match Pro there is an addendum to some of these contracts specifically for NCCR, since it was novel that the PII be held in one file across all registries because care is received/given across state lines across the participant's lifetime. [1]	1. Interco 2. Busine
	Repository policies	N/A	N/A

Interpretation	Source
agreements authorize data linkage (as needed / if applicable):	[1] NCCR Meeting
ocol for linkage approved by the data provider authorizes data	[2] NCCR Email Communication
Sharing (or Use) Agreement or a hosting agreement (ISA) or BAA	
ed between IMS and the data provider authorize data linkage	
J or MOA executed between NCI and the data provider authorizes	
nkage	
ation not available/found	
ation not available/found	
	[1] NCCR Meeting
connection Convince Assessment (or needed (if earlieship)	
rconnection Services Agreement (as needed / if applicable) ness Associate Agreement (BAA) (as needed / if applicable)	[1] NCCR Meeting
the governance)	

aset 5 - NG		Raw Language	
2.2.1	Whether the data can be linked	The linked data will come to NCI/NCCR de-identified when NCCR is ready to receive data, NCCR will post the requirements for linkage SEER data (<u>https://seer.cancer.gov/tools/submission.html</u>), so NAACCR (subcontractor) will submit under Call for Data. [1] For each linkage, registries review and approve a protocol specific to that linkage. Approvals are granted by senior personnel at the registry and are often reviewed by legal advisors within the state health departments who manage the registry or the registry sub-contractor. In some cases, data providers and registries sign additional Data Sharing (or Use) Agreements. This usually happens between the registry and IMS. In some cases, a MOU or MOA is signed between a data provider and the NCI. [1]	Data origi
		Below is a table of the VPR-only registries that are participating in linkage with the NCCR. These nine registries have a Data Sharing Agreement with IMS allowing IMS to link the data and agreeing for data on prior/subsequent cancers to be incorporated into the NCCR. The table shows whether the registry would like the full record incorporated or just a list of basic data items (which now included stage and treatment). It also identifies whether the registry would like IMS to extract the data for incorporation into the NCCR. [1]	
		State public health surveillance laws vary in restrictions on use of linked data but generally matching patients from different data sources to the cancer registry data, adding to traditional registry data, and then de-identifying data for submission to the NCI is permitted. [2]	
2.2.2	With what other data can it be linked or can it not be linked (scope of linkage)	The linked data will come to NCI/NCCR de-identified when NCCR is ready to receive data, NCCR will post the requirements for linkage SEER data (<u>https://seer.cancer.gov/tools/submission.html</u>), so NAACCR (subcontractor) will submit under Call for Data. [1] For each linkage, registries review and approve a protocol specific to that linkage. Approvals are granted by senior personnel at the registry and are often reviewed by legal advisors within the state health departments who manage the registry or the registry sub-contractor. In some cases, data providers and registries sign additional Data Sharing (or Use) Agreements. This usually happens between the registry and IMS. In some cases, a MOU or MOA is signed between a data provider and the NCI. [1] Below is a table of the VPR-only registries that are participating in linkage with the NCCR. These nine registries have a Data Sharing Agreement with IMS allowing IMS to link the data and agreeing for data on prior/subsequent cancers to be incorporated into the NCCR. The table shows whether the registry would like the full record incorporated or just a list of basic data items (which now included stage and treatment). It also identifies whether the registry would like IMS to extract the data for incorporation into the NCCR. [1] State public health surveillance laws vary in restrictions on use of linked data but generally matching patients from different data sources to the cancer registry data, adding to traditional registry data, and then de-identifying data for submission to the NCI is permitted. [2]	Data origi according
2.2.3 2.2.4	Whether data can be shared How data can be shared (de-identification status, disclosure review)	Information not available/found Generally, we have many policies to follow per original agreements with data providers. We do not share any geographic identifiers, although we do provide geographically-calculated fields in the form of quintiles (e.g., Yost Index at the time of cancer diagnosies calculated at the census tract level using original address provided to the registries but stripped of census tract and address by the time it is received by NCI for release). We also only provide calculated time between dates (i.e., no dates or month/year) or age in years or categorical groupings. We also have a data access committee that will review all requests for individual-level data and will require IRB review of those data requests by investigators prior to release. [1]	Information Data origi (except qu
2.2.5	How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.)	Information not available/found	Informati

Interpretation	Source
iginator agreements specify that the data can be linked	[1] NCCR Meeting
	[2] NCCR Email Communication
iginator agreements specify that the data can be linked	[1] NCCR Meeting
ng to the protocol for linkage approved by the data provider	[2] NCCR Email Communication
ation not available/found	
iginator agreements specify that no geographic identifiers	[1] NCCR Email Communication
quintiles), exact dates, or exact ages will be shared	
ation not available/found	
ation not available/found	

		Raw Language	
2.2.7	Other (specify)	Information not available/found	Informat
3	Data Sharing		
3.1	Authorizations and Applicable Regulations/Policies		
3.1.1	Authorizations		
3.1.1.1	Assent	Information not available/found	Informat
3.1.1.2	Consent	Patients are not asked to provide consent for information to be reported to the central cancer registry. [1] We work with some data providers that obtained data originally under a research consent (PPCR, COG). In those cases, local IRBs have been part of reviewing if the consent covers broad data sharing or not and the process to reconsent individiuals. This may also involve obtaining additional organizational	r
		approvals. We may also work with BRANY as the central IRB for NCI to determine if the NCCR is a data repository that is exempt from human subjects research as it is all secondary research. We are also requiring investigators to obtain IRB approval in the first year of use to monitor how IRBs view the NCCR. [2]	
3.1.1.3	IRB/equivalent Privacy Board determination	For some projects, central cancer registries do seek IRB approval, but thus far this does not apply to NCCR data submissions. [1]	IRB appro
		IRB approval authorizes data collection for certain states (e.g., Wisconsin) [2]	
		We work with some data providers that obtained data originally under a research consent (PPCR, COG). In those cases, local IRBs have been part of reviewing if the consent covers broad data sharing or	
		not and the process to reconsent individuals. This may also involve obtaining additional organizational approvals. We may also work with BRANY as the central IRB for NCI to determine if the NCCR is a data repository that is exempt from human subjects research as it is all secondary research. We are also requiring investigators to obtain IRB approval in the first year of use to monitor how IRBs view the NCCR. [2]	
3.1.1.4	Local/state/federal laws	The NCI is part of the National Institutes of Health (NIH) and the NIH is an entity of the Public Health Service (Sections 202 and 401 of the Public Health Service Act, 42 U.S.C. §§ 203, 281). Pursuant to Section 402 of the Public Health Service Act (42 U.S.C. § 282), the Director of the NIH has the authority to conduct certain functions in furtherance of the public health purposes of Section 301 of the Public Health Service Act. The NCI is authorized to conduct the cancer research, control and information dissemination activities described herein pursuant to Sections 405, 410, 412 and 413 of the Public Health Service Act (42 U.S.C. §§ 284, 285, 285a-1 and 285a-2). [1]	Sections U.S.C. §§
3.1.1.5	Institutional Certification	Information not available/found	Informat
3.1.1.6	Data originator agreement	NPCR-NCCR registries have a DAA (Data Assurances Agreement) with NCI to allow NCI to release data. SEER-NCCR registries agree to NCI's release of data under contract. Both types of registries agree to data release when they approve protocols for data linkages against their own registry data. [1]	Protocol sharing
		The details of how NCI will release data are generally described in original protocols approved by registries and data providers. SEER-NCCR registries must also complete NIH DMSP as part of their contracts with NCI. Other agreements with data providers may generally describe data sharing and data destruction policies. [1]	
3.1.1.7	Repository agreements/policies	Information not available/found	Informat

Interpretation	Source
ation not available/found	
ation not available/found	[1] NCCR Meeting
t authorizes data sharing for some data providers	[1] NCCR Meeting
	[2] NCCR Email Communication
	[1] NCCR Meeting
	[2] NCCR Email Communication
s 405, 410, 412 and 413 of the Public Health Service Act (42	[1] NCCR Email Communication
§ 284, 285, 285a-1 and 285a-2 authorize data sharing	
ation not available/found	
ol for linkage approved by the data provider authorizes data	[1] NCCR Email Communication
ation not available/found	

)ataset 5 - I	NCCR Data		
		Raw Language	
3.1.1.8	Other	SEER registries have a contractual relationship with the NCI to license de-identified data to the NCI. With NPCR registries, the direct relationship is with NAACCR and IMS to hold data. [1]	Two cont 1. Contra 2. Subcor
		Not all SEER registries participate in NCCR – SEER registries have a contractual relationship with NCI and license the data to the NCI to be used in data releases in the de-identified form:	NPCR reg
		-IMS is the honest broker and they hold the PII on behalf of the registries that own the data -For the NPCR registries that participate, they have a subcontract through NAACCR to submit the data to IMS to be de-identified and submitted to NCCR so, NPCR has a direct relationship with NAACCR, not NCI. [1]	
		Currently, the 5 NPCR registries that participate do so through a sub award from NAACCR's NCCR contract with NCI. Beginning in 2023, additional registries covering Oregon, Arkansas, Colorado, Missouri, etc. will join via the NAACCR sub award or, if they are already a SEER research support registry, through a task order with the NCI. The main implication is that when NCI has a direct relationship with the registries there is better access to defining submission standards and using the technology infrastructure that makes data submission, cleaning, linkages, etc. easier. [1]	
		Contractual obligations for registries operated by the state health department to the NCI. Some registries participate through a grant under NAACCR. [2]	
		NPCR-NCCR registries have a DAA (Data Assurances Agreement) with NCI to allow NCI to release data. SEER-NCCR registries agree to NCI's release of data under contract. Both types of registries agree to data release when they approve protocols for data linkages against their own registry data. [2]	
3.1.2	Applicable Regulations/Policies		
3.1.2.1	Local regulations/policies	Information not available/found	Informat
3.1.2.2	Tribal regulations/policies	N/A - No tribal data. [1]	N/A
3.1.2.3	State regulations/policies	Information not available/found	Informati
3.1.2.4	Federal regulations/policies	Information not available/found	Informati
3.1.2.5	International regulations/policies	N/A	N/A
3.1.2.6	Contractual obligations	Information not available/found	Informati
3.1.2.7	Repository policies	Information not available/found	Informat
3.2		ess, and use based on data sharing authorization or applicable regulations/policies (i.e., the c	
3.2.1	Whether the data can be linked	NPCR-NCCR registries have a DAA (Data Assurances Agreement) with NCI to allow NCI to release data. SEER-NCCR registries agree to NCI's release of data under contract. Both types of registries agree to data release when they approve protocols for data linkages against their own registry data. [1]	Data orig
3.2.2	With what other data can it be linked or can it not be linked (scope of linkage)	NPCR-NCCR registries have a DAA (Data Assurances Agreement) with NCI to allow NCI to release data. SEER-NCCR registries agree to NCI's release of data under contract. Both types of registries agree to data release when they approve protocols for data linkages against their own registry data. [1]	Data orig according

Interpretation	Source
ntracts authorize data sharing:	[1] NCCR Meeting
ract between SEER registries and NCI	[2] NCCR Email Communication
ontract between NPCR registries and NAACCR and grant between	
egistries and NAACCR	
ation not available/found	
	[1] NCCR Meeting
ation not available/found	
ation not available/found	
ation not available /found	[1] NCCP Empil Communication
ation not available/found ation not available/found	[1] NCCR Email Communication
the governance)	
iginator agreements specify that the data can be linked	[1] NCCR Email Communication
igniator agreements speeny that the data can be inked	
iginator agreements specify that the data can be linked	[1] NCCR Email Communication
ng to the protocol for linkage approved by the data provider	

		Raw Language	
3.2.3		COG). In those cases, local IRBs have been part of reviewing if the consent covers broad data sharing or not and the process to reconsent individiuals. This may also involve obtaining additional organizational approvals. We may also work with BRANY as the central IRB for NCI to determine if the NCCR is a data repository that is exempt from human subjects research as it is all secondary research. We are also requiring investigators to obtain IRB approval in the first year of use to monitor how IRBs view the	
		NPCR-NCCR registries have a DAA (Data Assurances Agreement) with NCI to allow NCI to release data. SEER-NCCR registries agree to NCI's release of data under contract. Both types of registries agree to data release when they approve protocols for data linkages against their own registry data. [2]	
3.2.4	status, disclosure review)	and license the data to the NCI to be used in data releases in the de-identified form: -IMS is the honest broker and they hold the PII on behalf of the registries that own the data -For the NPCR registries that participate, they have a subcontract through NAACCR to submit the data	1. Contrac NPCR regi for sharing geographi 2. Data or (except qu
3.2.5		Contract between SEER registries and NCI, and Subcontract between NCI and NAACCR who then awards grants to NPCR, specifies that data must be de-identified for sharing through NCCR (including removal of PII, dates, and geographic information). Protocols and other agreements with original data providers cover NCI's data release practices. [2]	Informatio
5.2.5			
5.2.5	data use agreement, data access committee/group approval, IRB LOD, etc.)		

Interpretation	Source
Interpretation ent and IRB approval specify that data can be shared (when ole if consent and IRB were used by data provider) ons 405, 410, 412 and 413 of the Public Health Service Act (42 § 284, 285, 285a-1 and 285a-2) specify that NCI can share data acts between SEER registries and NCI, subcontracts between gistries and NAACCR and grants between NPCR registries and 8 specify that data can be shared 8 specify that data can be shared	Source [1] NCCR Email Communication [2] NCCR Email Communication
ract between SEER registries and NCI, and Subcontract between egistries and NAACCR, specifies that data must be de-identified ing through NCCR (including removal of PII, dates, and ohic information) originator agreements specify that no geographic identifiers quintiles), exact dates, or exact ages will be shared	 [1] NCCR Meeting [2] NCCR Email Communication
tion not available/found	
tion not available/found	

		Raw Language	
3.2.7	Other (specify)	Information not available/found	Informati
4	Data Access		
4.1	Authorizations and Applicable		
	Regulations/Policies		
4.1.1	Authorizations		
4.1.1.1	Assent	Information not available/found	Informati
4.1.1.2	Consent	Information not available/found	Informati
4.1.1.3	IRB/equivalent Privacy Board determination	Information not available/found	Informati
4.1.1.4	Local/state/federal laws	Information not available/found	Informati
4.1.1.5	Institutional Certification	Information not available/found	Informati
4.1.1.6	Data originator agreement	Information not available/found	Informati
4.1.1.7	Repository agreements/policies	There will be a DUA for NCCR data approved by the registries and NCI as part of the SEER data access request process. NCI is in the process of planning the tiered access process for researchers and others to use NCCR data that will be similar to the existing SEER processes (see 1/17/2023 ppt attached and https://seer.cancer.gov/data/access.html). [1] This National Childhood Cancer Registry (NCCR) Research Data Use Agreement (DUA) (the "Agreement") outlines the terms and conditions for access to data in the National Cancer Institute (NCI) NCCR Research, Research Plus, Specialized, and Customized Databases (collectively, the "Databases"). [2] NCCR Data Use Agreement authorizes data access to researchers. NCCR data access committee will review all requests for individual-level data. NCI is evaluating the possibilities of having the NCCR Data Platform deemed exempt from human subjects research. All data requestors will be required to have IRB approval in the first year of the NCCR Data Platform. [3]	NCCR Dat
4.1.1.8		Information not available/found	Informati
4.1.2	Applicable Regulations/Policies		
4.1.2.1	Local regulations/policies	Information not available/found	Informati
4.1.2.2	Tribal regulations/policies	N/A - No tribal data. [1]	N/A
4.1.2.3	State regulations/policies	Information not available/found	Informati
4.1.2.4	Federal regulations/policies	Information not available/found	Informati
4.1.2.5	International regulations/policies	N/A	N/A
4426	Contractual abligations		1
4.1.2.6		Information not available/found	Informati
4.1.2.7	Repository policies	There will be a DUA for NCCR data approved by the registries and NCI as part of the SEER data access request process. NCI is in the process of planning the tiered access process for researchers and others to use NCCR data that will be similar to the existing SEER processes (see 1/17/2023 ppt attached and <u>https://seer.cancer.gov/data/access.html</u>). [1] This National Childhood Cancer Registry (NCCR) Research Data Use Agreement (DUA) (the "Agreement") outlines the terms and conditions for access to data in the National Cancer Institute (NCI) NCCR Research, Research Plus, Specialized, and Customized Databases (collectively, the "Databases"). [2]	NCCR pol
4.2	Governance for data linkage, sharing, acce	'ss, and use based on data access authorization or applicable regulations/policies (i.e., the or	igin of the
4.2.1	Whether the data can be linked		DUA spec
			database
		NCCR DUA does not allow Data Linkage across SEER Databases [1]	
4.2.2	With what other data can it be linked or		DUA spec
	can it not be linked (scope of linkage)	NCCR DUA does not allow Data Linkage across SEER Databases	database
4.2.3	Whether data can be shared	Information not available/found	Informati
4.2.4	How data can be shared (de-identification status, disclosure review)	Information not available/found	Informati

Interpretation	Source
tion not available/found	
tion not available/found	[1] NCCR Meeting
tion not available/found	[1] NCCR Meeting
tion not available/found	
tion not available/found	
tion not available/found	
tion not available/found	
ata Use Agreement authorizes data access	[1] NCCR Meeting
	[2] <u>https://seer.cancer.gov/data-</u>
	software/documentation/seerstat/nov2022/nccr-dua- nov2022.html (Accessed: 4/28/23)
	[3] NCCR Email Communication
tion not available/found	
tion not available/found	
	[1] NCCR Meeting
tion not available/found	
tion not available/found	
tion not available/found	
olicy	[1] NCCR Meeting
	[2] https://seer.cancer.gov/data-
	software/documentation/seerstat/nov2022/nccr-dua-
	<u>nov2022.html</u> (Accessed: 4/28/23)
he governance)	1
ecifies that users are not authorized to link data across SEER	[1] https://seer.cancer.gov/data-
es	software/documentation/seerstat/nov2022/nccr-dua-
	nov2022.html (Accessed: 4/28/23)
ecifies that users are not authorized to link data across SEER	[1] https://seer.cancer.gov/data-
ses	software/documentation/seerstat/nov2022/nccr-dua-
	nov2022.html (Accessed: 4/28/23)+A1
tion not available/found	
tion not available/found	

ataset 5 - No		Raw Language	
4.2.5	How data can be accessed (access type,	There will be a DUA for NCCR data approved by the registries and NCI as part of the SEER data access	NCCR spe
1.2.3	data use agreement, data access		1. Must
	committee/group approval, IRB LOD, etc.)		2. Must e
			3. Must
			and the
		or geographically-associated derived variables like the Yost index) will be required to submit a data	propose
		analysis plan and possibly IRB-approval. NCI has a central IRB (BRANY) for this purpose if investigators	4. Must
		do not use their own IRB. [1]	central I
			(as need
		If researcher puts in a request that requires IRB approval, they can go through the central IRB for	5. Must
		NCCR. Each project has its own DUA (if necessary) and NCCR tracks limitations or restrictions moving	6. Must
		forward for researchers looking to obtain data, there will be a NCCR DUA (which will be similar to the	and obta
		SEER DUA). [1]	Sharing
			7. Must
		Currently, the process is planned as researchers submit an institutional account (known by eRA	software
		Commons) and have a Signing Official verified by NCI's Office of Data Sharing and the Surveillance	
		Research Program for access to SEER*Stat or the NCCR Data Platform. If they require individual-level	
		data through the Data Platform there will be an additional process to provide a data analysis plan and	
		more information to approve release of a custom dataset. For additional information about what data	
		will be in the Data Platform in the first year, see the sample codebook. [1]	
		An NCCR dataset will be available in SEER*Stat that cannot be downloaded but researchers can	
		compute various statistics in that software. Data providers (claims, PPCR, etc.) and registries sign	
		various data sharing agreements and approve protocols to share data SEER Stat will construct a	
		standard registry dataset for all the registry data coming in, which will be updated annually and	
		available via SEER*Stat to approved researchers (but download of the data won't be permitted –	
		SEER*Stat is not an enclave, but a client server software. [1]	
		Central IRB Review (slide 6):	
		Likely no IRB review required from users of Tier 1-3 for SEER Data Products	
		-Awaiting review and decision of the BRANY cIRB -Will have similar review for NCCR Data Products to determine need for IRB review	
		IRB might be required by the user's home institution	
		-NCI SRP retained the services of Biomedical Research Alliance of New York (BRANY)	
		-Offers the services of a central IRB. [2]	
		Must access and use the data within SEER*Stat (client server software) or NCCR Data Platform. [3]	
4.2.6	How data can be used (data use limitations)	There will be a DUA for NCCR data approved by the registries and NCI as part of the SEER data access	NCCR Da
			disclose 1
		National Childhood Cancer Registry (NCCR) Research Data Use Agreement:	
		Use and Disclosure Restricted: Use and Disclosure Restricted: Authorized User will use or disclose the	
		Data only for the purposes for which they were supplied. Requests for data with increased risk to re-	
		identify individuals will require additional application materials and Authorized User will only use data	
		for the purposes approved by the NCI. [2]	
4.2.7	Other (specify)	Information not available/found	Informati
	Data Use		1
	Authorizations and Applicable		
5.1			1
	Regulations/Policies		
.1.1	Authorizations	N/A Consent does not apply [1]	NI / A
1.1 5.1.1.1	Authorizations Assent	N/A - Consent does not apply [1] N/A - Consent does not apply [1]	N/A N/A
1.1 5.1.1.1 5.1.1.2	Authorizations Assent Consent	N/A - Consent does not apply [1]	N/A
1.1 5.1.1.1 5.1.1.2	Authorizations Assent	N/A - Consent does not apply [1] Some state registries have stated that researchers seeking to use their data at the individual level	N/A IRB appro
1.1 5.1.1.1 5.1.1.2	Authorizations Assent Consent	N/A - Consent does not apply [1] Some state registries have stated that researchers seeking to use their data at the individual level would need to go through the state registry's IRB and it is not enough that NCI has a process for	N/A IRB appr
.1.1 5.1.1.1 5.1.1.2 5.1.1.3	Authorizations Assent Consent	N/A - Consent does not apply [1] Some state registries have stated that researchers seeking to use their data at the individual level	N/A IRB appro applicabl
5.1 5.1.1 5.1.1.1 5.1.1.2 5.1.1.3 5.1.1.4 5.1.1.5	Authorizations Assent Consent IRB/equivalent Privacy Board determination	N/A - Consent does not apply [1] Some state registries have stated that researchers seeking to use their data at the individual level would need to go through the state registry's IRB and it is not enough that NCI has a process for reviewing requests (NCCR is working through this). [1]	

Interpretation	Source
pecifies that for data access, a user:	[1] NCCR Meeting
t submit a Data Analysis Plan	-
	[2] Updated Data Release Process PPT from NCCR
t execute the NCCR DUA	[3] NCCR Email Communication
t obtain review and approval by the NCI Office of Data Sharing	
e Surveillance Research Program's Data Release group on the	
ed research	
t obtain IRB LOD from the researcher's institution, or from NCI	
IRB (BRANY) if the researchers institution does not have an IRB	
ded / applicable)	
t obtain IRB approval from the state registry	
t submit using an insititutional account (known as eRA Commons)	
tain verification of Signing Official by the NCI Office of Data	
g and the Surveillance Research Program's Data Release group	
t access and use the data within SEER*Stat (client server	
re) or NCCR Data Platform	
Data Use Agreement specifies that Authorized User will use or	[1] NCCR Meeting
e the Data only for the purposes for approved research	[2] <u>https://seer.cancer.gov/data-</u>
	software/documentation/seerstat/nov2022/nccr-dua-
	nov2022.html (Accessed: 4/28/23)
	(
ation not available/found	
	[1] NCCR Meeting
	[1] NCCR Meeting
proval from the state registry authorizes data use (as needed/if	[1] NCCR Meeting
ble)	[2] Updated Data Release Process PPT from NCCR
ation not available/found	
ation not available/found	
ation not available/found	

ataset 5 - N		Raw Language	
5.1.1.7	Repository agreements/policies	There will be a DUA for NCCR data approved by the registries and NCI as part of the SEER data access request process. NCI is in the process of planning the tiered access process for researchers and others to use NCCR data that will be similar to the existing SEER processes (see 1/17/2023 ppt attached and <u>https://seer.cancer.gov/data/access.html</u>). [1] When requesting access to the SEER Research Plus Data, you must agree to the NCCR Research Data Use Agreement as well. The NCCR data will be made available through SEER*Stat along with the SEER Research Plus Data. [2]	NCCR Data
5.1.1.8	Other (specify)	Information not available/found	Informatio
5.1.2	Applicable Regulations/Policies		
5.1.2.1	Local regulations/policies	Information not available/found	Informatio
5.1.2.2	Tribal regulations/policies State regulations/policies	N/A - No tribal data. [1] Information not available/found	N/A Informatio
5.1.2.4	Federal regulations/policies	Information not available/found	Informatio
5.1.2.5	International regulations/policies	Information not available/found	Informatio
5.1.2.6	Contractual obligations	Information not available/found	Informatio
5.1.2.7	Repository policies	There will be a DUA for NCCR data approved by the registries and NCI as part of the SEER data access request process. NCI is in the process of planning the tiered access process for researchers and others to use NCCR data that will be similar to the existing SEER processes (see 1/17/2023 ppt attached and <u>https://seer.cancer.gov/data/access.html</u>). [1] When requesting access to the SEER Research Plus Data, you must agree to the NCCR Research Data Use Agreement as well. The NCCR data will be made available through SEER*Stat along with the SEER Research Plus Data. [2]	NCCR poli
5.2 5.2.1	Governance for data linkage, sharing, acce Whether the data can be linked	ess, and use based on data access authorization or applicable regulations/policies (i.e., the or Information not available/found	i gin of the Informatic
5.2.2	With what other data can it be linked or can it not be linked (scope of linkage)	Information not available/found	Informatio
5.2.3	Whether data can be shared	Information not available/found	Informatio
5.2.4	How data can be shared (de-identification status, disclosure review)	Information not available/found	Informatio
5.2.5	How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.)	There will be a DUA for NCCR data approved by the registries and NCI as part of the SEER data access request process. NCI is in the process of planning the tiered access process for researchers and others to use NCCR data that will be similar to the existing SEER processes (see 1/17/2023 ppt attached and https://seer.cancer.gov/data/access.html). Researchers seeking individual-level information and combinations of datasets and fields that increase the risk of re-identifiability (census-tract information or geographically-associated derived variables like the Yost index) will be required to submit a data analysis plan and possibly IRB-approval. NCI has a central IRB (BRANY) for this purpose if investigators do not use their own IRB. [1] If researcher puts in a request that requires IRB approval, they can go through the central IRB for NCCR. Each project has its own DUA (if necessary) and NCCR tracks limitations or restrictions moving forward for researchers looking to obtain data, there will be a NCCR DUA (which will be similar to the SEER DUA). [1]	NCCR spec 1. Must su 2. Must of and the Su proposed 4. Must of central IRE (as needed 5. Must of 6. Must su and obtain Sharing an 7. Must ac
		Currently, the process is planned as researchers submit an institutional account (known by eRA Commons) and have a Signing Official verified by NCI's Office of Data Sharing and the Surveillance Research Program for access to SEER*Stat or the NCCR Data Platform. If they require individual-level data through the Data Platform there will be an additional process to provide a data analysis plan and more information to approve release of a custom dataset. For additional information about what data will be in the Data Platform in the first year, see the sample codebook. [1] An NCCR dataset will be available in SEER*Stat that cannot be downloaded but researchers can compute various statistics in that software. Data providers (claims, PPCR, etc.) and registries sign various data sharing agreements and approve protocols to share data SEER Stat will construct a standard registry dataset for all the registry data coming in, which will be updated annually and available via SEER*Stat to approved researchers (but download of the data won't be permitted – SEER*Stat is not an enclave, but a client server software. [1]	software)

Interpretation	Source
ata Use Agreement authorizes data use	[1] NCCR Meeting
J	[2] https://seer.cancer.gov/data-
	software/documentation/seerstat/nov2022/nccr-dua-
	<u>nov2022.html</u> (Accessed: 4/28/23)
tion not available/found	
tion not available/found	
	[1] NCCR Meeting
tion not available/found	
tion not available/found	
tion not available/found	
tion not available/found	
blicy	[1] NCCR Meeting
	[2] <u>https://seer.cancer.gov/data-</u>
	software/documentation/seerstat/nov2022/nccr-dua-
	<u>nov2022.html</u> (Accessed: 4/28/23)
he governance)	
tion not available/found	
tion not available/found	
tion not available/found	
tion not available/found	
pecifies that for data access, a user:	[1] NCCR Meeting
submit a Data Analysis Plan	[2] Updated Data Release Process PPT from NCCR
execute the NCCR DUA	
	[3] NCCR Email Communication
obtain review and approval by the NCI Office of Data Sharing	
Surveillance Research Program's Data Release group on the	
d research	
obtain IRB LOD from the researcher's institution, or from NCI	
IRB (BRANY) if the researchers institution does not have an IRB	
ded / applicable)	
obtain IRB approval from the state registry	
submit using an insititutional account (known as eRA Commons)	
-	
ain verification of Signing Official by the NCI Office of Data	
and the Surveillance Research Program's Data Release group	
access and use the data within SEER*Stat (client server	
e) or NCCR Data Platform	
-,	

Dataset 5 - N	ICCR Data			
		Raw Language	Interpretation	Source
		Central IRB Review (slide 6): Likely no IRB review required from users of Tier 1-3 for SEER Data Products -Awaiting review and decision of the BRANY cIRB -Will have similar review for NCCR Data Products to determine need for IRB review IRB might be required by the user's home institution -NCI SRP retained the services of Biomedical Research Alliance of New York (BRANY) -Offers the services of a central IRB. [2] Must access and use the data within SEER*Stat (client server software) or NCCR Data Platform. [3]		
5.2.6	How data can be used (data use limitations	 National Childhood Cancer Registry (NCCR) Research Data Use Agreement: Use and Disclosure Restricted: Use and Disclosure Restricted: Authorized User will use or disclose the Data only for the purposes for which they were supplied. Requests for data with increased risk to re-identify individuals will require additional application materials and Authorized User will only use data for the purposes approved by the NCI. [1] 	NCCR Data Use Agreement specifies that Authorized User will use or disclose the Data only for the purposes for approved research	[1] <u>https://seer.cancer.gov/data-</u> software/documentation/seerstat/nov2022/nccr-dua- <u>nov2022.html</u> (Accessed: 4/28/23)
5.2.7	Other (specify)	Information not available/found	Information not available/found	
6	PII Elements			
6.1	PII elements collected PII elements collected PII elements holder (i.e., party that holds the PII) Use of common data model, if any, for data collection	In general, linkages are performed using patient name, address, SSN, phone number, cancer diagnosis, date of diagnosis. PII is also not captured in the NCCR. PII is captured by registries as part of normal state-mandated public health surveillance. PII is stripped from submissions by the registries to the NCI for the NCCR. Other data providers (e.g., claims, PPCR, etc.) also provide PII to perform patient matching and IMS performs matching in isolated parts of the data center owned by registries. IMS does maintain a PII-based file for systematic approaches to national-level patient-matching for linkages where patients are likely to move around and need to be de-deuplicated across state lines. [1] Please also confirm our understanding that the PII resides with the individual registries (for both SEER and NCPR registries), and that the honest broker (IMS) performs the linkage with ISA, DUA or DSA, and BAAs in place. Correct. Registry data conforms to the NAACCR layout. IMS transforms data to match common SEER data elements, like the SEER recode of cancer diagnoses. When a data provider holds data with a standard then we work them to use that standard, for example, radiotherapy in the ASTRO minimal dataset. Some cancer centers (https://cancercontrol.cancer.gov/research-emphasis/supplement/childhood-cancer-registry plus MSK and Children's Hospital of Atlanta) have provided data in OMOP and we have an ongoing data harmonization effort to map all cancer center data received to OMOP for release in the data platform. When OMOP does not have concepts from historical data in clinical and genomic information systems we will use caDSR, PCDC data dictionaries, etc. ExtractEHR does not align to a common data model at this time. NCCR will consider using OMOP for SEER submissions. [1]	of diagnosis are collected but not held in NCCR Data originator (NPCR registries, SEER registries, and other providers) OMOP is used by some cancer centers provding data	[1] NCCR Meeting [1] NCCR Meeting [1] NCCR Meeting [1] NCCR Meeting
7	Prior Data Linkages			
7.1	Dataset linked with other datasets			
7.1.1	Name of other linked dataset	N/A	N/A	
7.1.2	Other dataset type (clinical, EHR, survey, claims, SDOH, etc.)	NCCR (and IMS) uses PII to perform data linkage using Match Pro (originally developed for NCCR; which will be soon used for P3RL in the next few years). In addition, the NCCR data platform did use HealthVerity's P3RL mechanism to link some registry data to Medicaid claims (this data will also be available through the NCCR data platform), but because the way HealthVerity obtains the data, the data cannot go back into the registry's isolated enclaves/data centers in an identified format, rather, it the data can only be used de-identified (due to the Medicaid data – so that data will be de-identified in the NCCR data platform). [1]	Registry, Claims, EHR, SDOH	[1] NCCR Meeting [2] NCCR Email Communication
		Registry, Claims, EHR, SDOH [2]		

aset s - N	CCR Data		• • • • • • • •	
		Raw Language	Interpretation	Source
7.1.3	Other dataset source(s)		Participating NCCR registries that are authorized to link data, COG, PPCR	[1] NCCR Meeting
		registries have a Data Sharing Agreement with IMS allowing IMS to link the data and agreeing for data		
		on prior/subsequent cancers to be incorporated into the NCCR. The table shows whether the registry	using PPRL	[2] NCCR Email Communication
		would like the full record incorporated or just a list of basic data items (which now included stage and		
		treatment). It also identifies whether the registry would like IMS to extract the data for incorporation		
		into the NCCR. [1]		
		COG, PPCR, Pharmacy providers, Medical insurance providers, Data aggregators using PPRL [2]		
7.1.4	Linking methodology (PPRL or non-PPRL);	NCCR (and IMS) uses PII to perform data linkage using Match Pro (originally developed for NCCR; which	MatchPro or PPRL (when required)	[1] NCCR Meeting
	linkage technology	will be soon used for P3RL in the next few years). In addition, the NCCR data platform did use		[2] NCCR Email Communication
		HealthVerity's P3RL mechanism to link some registry data to Medicaid claims (this data will also be		
		available through the NCCR data platform), but because the way HealthVerity obtains the data, the		
		data cannot go back into the registry's isolated enclaves/data centers in an identified format, rather, it		
		the data can only be used de-identified (due to the Medicaid data – so that data will be de-identified in		
		the NCCR data platform). [1]		
		Match*Pro is used for data linkage. PPRL methods when required. Match*Pro will have PPRL		
		technology for matches in the future. [2]		
7.1.5	PII elements used for the linkage	In general, linkages are performed using patient name, address, SSN, phone number, cancer diagnosis,	Patient name, address, SSN, phone number, cancer diagnosis, and date	[1] NCCR Meeting
		date of diagnosis.	of diagnosis are used for linkage when data are held in the registry	[2] NCCR Email Communication
			enclaves	
		PII is also not captured in the NCCR. PII is captured by registries as part of normal state-mandated		
		public health surveillance.		
		Dill is stringed from submissions by the registrics to the NCI for the NCCD. Other data regulators (a.g.		
		PII is stripped from submissions by the registries to the NCI for the NCCR. Other data providers (e.g.,		
		claims, PPCR, etc.) also provide PII to perform patient matching and IMS performs matching in isolated		
		parts of the data center owned by registries.		
		IMS does maintain a PII-based file for systematic approaches to national-level patient-matching for		
		linkages where patients are likely to move around and need to be de-deuplicated across state lines. [1]		
		Patient name, address, SSN, phone number, cancer diagnosis, and date of diagnosis are used for		
		linkage when data are held in the registry enclaves. [2]		
7.1.6	Entity resolver (data originator or data	Information Management Services, Inc (IMS) uses PII to perform data linkage using Match Pro. [1]	IMS (Honest Broker) or HealthVerity	[1] NCCR Meeting
7.1.0		intormation management services, inc (invis) uses fit to perform data inikage using match Pro. [1]		
	linker or third party)			[2] NCCR Email Communication
		We have also worked with HealthVerity. [2]		
7.1.7	Party performing the linkages		IMS (Honest Broker)	[1] NCCR Meeting
		With NPCR registries, the direct relationship is with NAACCR and Information Management Services,		
		Inc (IMS) (serves as the honest broker) to hold data. [1]		
7.1.8	Linkage quality assessment	We have routine practices to evaluate patient matching. Sometimes manual review is done by IMS or	Manual review or other linkage quality assessment methods	[2] NCCR Email Communication
		registries.		
7.1.9	Linked data sharing method (linkage maps	Information not available/found	Information not available/found	
	or pre-linked dataset)			

	COVID-19 Case Surveillance Restricted Ac		
	Dataset Source	CDC COVID Data Tracker	
	Dataset Source Agency	CDC	
	Dataset Type (Clinical, EHR, Survey, SDOH, etc.) Information Sources	Clinical/Case surveillance data	
		Website; CDC staff	
ataset 6 -	· COVID-19	Powlonguogo	Interpretation
1	Data Collection	Raw Language	interpretation
1.1	Authorizations and Applicable		
1.1	Regulations/Policies		
1.1.1	Authorizations		
1.1.1.1	Assent	N/A - COVID-19 case surveillance data are collected by	N/A
		jurisdictions and are shared voluntarily with CDC. [1]	
1.1.1.2	Consent	N/A - COVID-19 case surveillance data are collected by	N/A
		jurisdictions and are shared voluntarily with CDC. [1]	
1.1.1.3	IRB/equivalent Privacy Board determination	N/A - COVID-19 case surveillance data are collected by	N/A
		jurisdictions and are shared voluntarily with CDC. [1]	
1.1.1.4	Local/state/federal laws	COVID-19 is a mandatory reportable condition in all U.S. state	State laws/regulations authorizes data collectio
		health departments, several territorial health departments, and two local health departments (New York City and District	
		of Columbia). These state, territorial, and local health	
		departments determine what information laboratories and	
		health care providers in their areas are asked to collect. The	
		state, territorial and local health departments confirm cases of	
		COVID-19 based on national standardized criteria and may	
		gather additional information on the cases reported. The data	
		elements can be found on the Human Infection with 2019	
		Novel Coronavirus Case Report Form (CRF). [1]	
1.1.1.5	Institutional Certification	N/A - COVID-19 case surveillance data are collected by	N/A
		jurisdictions and are shared voluntarily with CDC. [1]	
1.1.1.6	Data originator agreement	N/A - COVID-19 case surveillance data are collected by	N/A
		jurisdictions and are shared voluntarily with CDC. [1]	
1.1.1.7	Repository agreements/policies	N/A - COVID-19 case surveillance data are collected by	N/A
		jurisdictions and are shared voluntarily with CDC. [1]	
1.1.1.8	Other (specify)	N/A - COVID-19 case surveillance data are collected by	N/A
		jurisdictions and are shared voluntarily with CDC. [1]	
1.1.2	Applicable Regulations/Policies		
1.1.2.1	Local regulations/policies	Information not available/found	Information not available/found
1.1.2.2	Tribal regulations/policies	Information not available/found	Information not available/found
1.1.2.3	State regulations/policies	Information not available/found	Information not available/found
1.1.2.4 1.1.2.5	Federal regulations/policies International regulations/policies	Information not available/found N/A - COVID-19 is a nationally notifiable disease. [1]	Information not available/found N/A
1.1.2.J			
1.1.2.6	Contractual obligations	Information not available/found	Information not available/found

nes?	
	Source
	[1] https://data.cdc.gov/Case-Surveillance/COVID-19-
	Case-Surveillance-Restricted-Access-Detai/mbd7-r32t_
	(Accessed: 4/26/23)
	[1] https://data.cdc.gov/Case-Surveillance/COVID-19-
	Case-Surveillance-Restricted-Access-Detai/mbd7-r32t
	(Accessed: 4/26/23) [1] https://data.cdc.gov/Case-Surveillance/COVID-19-
	Case-Surveillance-Restricted-Access-Detai/mbd7-r32t
	(Accessed: 4/26/23)
ection	[1] https://data.cdc.gov/api/views/mbd7-
	r32t/files/9aad836e-5aa5-4047-aa5c-
	15996becc87c?download=true&filename=summary_gui
	dance_and_limitations_information_and_restricted_acc
	ess_data_use_agreement_information_updated.pdf
	(Accessed: 4/26/23)
	[1] https://data.cdc.gov/Case-Surveillance/COVID-19-
	Case-Surveillance-Restricted-Access-Detai/mbd7-r32t
	(Accessed: 4/26/23)
	[1] https://data.cdc.gov/Case-Surveillance/COVID-19-
	Case-Surveillance-Restricted-Access-Detai/mbd7-r32t
	(Accessed: 4/26/23)
	[1] https://data.cdc.gov/Case-Surveillance/COVID-19-
	Case-Surveillance-Restricted-Access-Detai/mbd7-r32t
	(Accessed: 4/26/23)
	[1] <u>https://data.cdc.gov/Case-Surveillance/COVID-19-</u> Case-Surveillance-Restricted-Access-Detai/mbd7-r32t
	(Accessed: 4/26/23)
	[1] https://www.cdc.gov/coronavirus/2019-
	ncov/php/reporting-pui.html (Accessed: 4/28/23)

Dataset 6 -	COVID-19		
		Raw Language	Interpretation
1.1.2.7	Repository policies	Information not available/found	Information not available/found
1.2		se based on data collection authorization or applicat	
1.2.1	Whether the data can be linked	Information not available/found	Information not available/found
1.2.2	With what other data can it be linked or can it not be linked (scope of linkage)	-	Information not available/found
1.2.3	Whether data can be shared	Information not available/found	Information not available/found
1.2.4	How data can be shared (de-identification status, disclosure review)	Information not available/found	Information not available/found
1.2.5	How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.)	Information not available/found	Information not available/found
1.2.6	How data can be used (data use limitations)	Information not available/found	Information not available/found
1.2.7	Other (specify)	Information not available/found	Information not available/found
2	Data Linkage		
2.1	Authorizations and Applicable		
	Regulations/Policies		
2.1.1	Authorizations		
2.1.1.1	Assent	Information not available/found	Information not available/found
2.1.1.2	Consent	Information not available/found	Information not available/found
2.1.1.3	IRB/equivalent Privacy Board determination	Information not available/found	Information not available/found
2.1.1.4	Local/state/federal laws	Information not available/found	Information not available/found
2.1.1.5	Institutional Certification	Information not available/found	Information not available/found
2.1.1.6	Data originator agreement	Information not available/found	Information not available/found
2.1.1.7	Repository agreements/policies	Information not available/found	Information not available/found
2.1.1.8	Other (specify)	Information not available/found	Information not available/found
2.1.2	Applicable Regulations/Policies		
2.1.2.1	Local regulations/policies	Information not available/found	Information not available/found
2.1.2.2	Tribal regulations/policies	Information not available/found	Information not available/found
2.1.2.3	State regulations/policies	Information not available/found	Information not available/found
2.1.2.4	Federal regulations/policies	Information not available/found	Information not available/found
2.1.2.5	International regulations/policies	N/A - COVID-19 is a nationally notifiable disease. [1]	N/A
2.1.2.6	Contractual obligations	Information not available/found	Information not available/found
2.1.2.7	Repository policies	Information not available/found	Information not available/found
2.2	Governance for data linkage, sharing, access, and u	se based on data linkage authorization or applicable	regulations/policies (i.e., the origin of the gover
2.2.1	Whether the data can be linked	Information not available/found	Information not available/found
2.2.2	With what other data can it be linked or can it not be linked (scope of linkage)	Information not available/found	Information not available/found
2.2.3	Whether data can be shared	Information not available/found	Information not available/found
2.2.4	How data can be shared (de-identification status, disclosure review)	Information not available/found	Information not available/found
2.2.5	How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.)	Information not available/found	Information not available/found
2.2.6	How data can be used (data use limitations)	Information not available/found	Information not available/found
2.2.7	Other (specify)	Information not available/found	Information not available/found
3	Data Sharing		
3.1	Authorizations and Applicable		
•	Regulations/Policies		
3.1.1	Authorizations		
3.1.1.1	Assent	Information not available/found	Information not available/found
	Consent	Information not available/found	Information not available/found
3.1.1.2			

	Course .
	Source
overna	nce)
	[1] https://www.cdc.cov/coropovirus/2010
	[1] <u>https://www.cdc.gov/coronavirus/2019-</u> <u>ncov/php/reporting-pui.html</u> (Accessed: 4/28/23)
ernance	2)

Dataset 6 -	COVID-19			
		Raw Language	Interpretation	Source
3.1.1.4	Local/state/federal laws	Information not available/found	Information not available/found	
3.1.1.5	Institutional Certification	Information not available/found	Information not available/found	
3.1.1.6	Data originator agreement	Information not available/found	Information not available/found	
3.1.1.7	Repository agreements/policies	Information not available/found	Information not available/found	
3.1.1.8	Other	Information not available/found	Information not available/found	
3.1.2	Applicable Regulations/Policies			
3.1.2.1	Local regulations/policies	Information not available/found	Information not available/found	
3.1.2.2	Tribal regulations/policies	Information not available/found	Information not available/found	
3.1.2.3	State regulations/policies	Information not available/found	Information not available/found	
3.1.2.4	Federal regulations/policies	Information not available/found	Information not available/found	
3.1.2.5	International regulations/policies	N/A - COVID-19 is a nationally notifiable disease. [1]	N/A	[1] <u>https://www.cdc.gov/coronavirus/2019-</u> ncov/php/reporting-pui.html (Accessed: 4/28/23)
3.1.2.6	Contractual obligations	Information not available/found	Information not available/found	
3.1.2.7	Repository policies	This case surveillance publicly available dataset has 33	CDC COVID-19 case surveillance restricted access	<pre>[1] https://data.cdc.gov/api/views/mbd7-</pre>
		elements for all COVID-19 cases shared with CDC and includes	data policy	r32t/files/9aad836e-5aa5-4047-aa5c-
		demographics, geography (county and state of residence), any		15996becc87c?download=true&filename=summary gui
		exposure history, disease severity indicators and outcomes,		dance and limitations information and restricted acc
		and presence of any underlying medical conditions and risk		ess_data_use_agreement_information_updated.pdf
		behaviors. [1]		
3.2	Governance for data linkage, sharing, access, and u	se based on data sharing authorization or applicable regu	ations/policies (i.e., the origin of the governanc	e)
3.2.1	Whether the data can be linked	Information not available/found	Information not available/found	
3.2.2	With what other data can it be linked or can it not be linked (scope of linkage)	Information not available/found	Information not available/found	
3.2.3	Whether data can be shared	Information not available/found	Information not available/found	
3.2.4	How data can be shared (de-identification status,	This case surveillance publicly available dataset has 33	RIDURA specifies that COVID-19 data shared from	[1] <u>https://data.cdc.gov/Case-Surveillance/COVID-19-</u>
	disclosure review)	elements for all COVID-19 cases shared with CDC and includes	various jurisdictions:	Case-Surveillance-Restricted-Access-Detai/mbd7-r32t
		demographics, geography (county and state of residence), any	1. Must be de-identified of all direct identifiers prior	
		exposure history, disease severity indicators and outcomes,	to sharing	[2]
		and presence of any underlying medical conditions and risk	2. Must undergo disclosure review to suppress data	https://data.cdc.gov/api/views/mbd7-
		behaviors. [1]	fields with low frequency (<5) prior to sharing	r32t/files/9aad836e-5aa5-4047-aa5c-
				15996becc87c?download=true&filename=summary_gui
		To prevent the release of data that could be used to identify		dance and limitations information and restricted acc
		persons, data cells are suppressed for low frequency (< 5)		ess data use agreement information updated.pdf
		records. Records are never removed from the dataset, but		
		individual field values are suppressed for geographic areas with		
		low reporting counts (in the restricted access dataset) or rare		
		combinations of demographic characteristics (sex, age group,		
		race, ethnicity) (in both the restricted access and public use		
		datasets). Suppressed values are re-coded to the NA answer		
		option. [1]		
		No direct identifiers or characteristics that might lead to		
		identification have been included in the data provided. [2]		
3.2.5	How data can be accessed (access type, data use	Information not available/found	Information not available/found	
	agreement, data access committee/group approval,			
226	IRB LOD, etc.)			
3.2.6	How data can be used (data use limitations)	Information not available/found	Information not available/found	
3.2.7	Other (specify)	Information not available/found	Information not available/found	
4	Data Access			
4.1	Authorizations and Applicable			
	Regulations/Policies			

	COVID-19		
		Raw Language	Interpretation
4.1.1	Authorizations	Information act and include formal	
4.1.1.1	Assent	Information not available/found	Information not available/found
4.1.1.2	Consent	Information not available/found	Information not available/found
4.1.1.3	IRB/equivalent Privacy Board determination	Information not available/found	Information not available/found
4.1.1.4	Local/state/federal laws Institutional Certification	Information not available/found Information not available/found	Information not available/found
4.1.1.5		Information not available/found	Information not available/found Information not available/found
	Data originator agreement		-
4.1.1.7		Please review the following documents to determine your interest in accessing the COVID-19 Case Surveillance Restricted Access Detailed Data file: 1) CDC COVID-19 Case Surveillance Restricted Access Detailed Data: Summary, Guidance, Limitations Information, and Restricted Access Data Use Agreement Information 2) Data Dictionary for the COVID-19 Case Surveillance Restricted Access Detailed Data The next step is to complete the Registration Information and Data Use Restrictions Agreement (RIDURA). Once complete, CDC will review your agreement. After access is granted, Ask SRRG (<u>eocevent394@cdc.gov</u>) will email you information about how to access the data through GitHub. If you have questions about obtaining access, email <u>eocevent394@cdc.gov</u> . [1]	Registration Information and Data Use Restriction Agreement (RIDURA) authorizes data access
4.1.1.8	Other (specify)	Information not available/found	Information not available/found
4.1.2	Applicable Regulations/Policies		
4.1.2.1	Local regulations/policies	Information not available/found	Information not available/found
4.1.2.2	Tribal regulations/policies	Information not available/found	Information not available/found
4.1.2.3	State regulations/policies	Information not available/found	Information not available/found
4.1.2.4	Federal regulations/policies	Information not available/found	Information not available/found
4.1.2.5	International regulations/policies	Information not available/found	Information not available/found
4.1.2.6	Contractual obligations	Information not available/found	Information not available/found
4.1.2.7		Please review the following documents to determine your interest in accessing the COVID-19 Case Surveillance Restricted Access Detailed Data file: 1) CDC COVID-19 Case Surveillance Restricted Access Detailed Data: Summary, Guidance, Limitations Information, and Restricted Access Data Use Agreement Information 2) Data Dictionary for the COVID-19 Case Surveillance Restricted Access Detailed Data The next step is to complete the Registration Information and Data Use Restrictions Agreement (RIDURA). Once complete, CDC will review your agreement. After access is granted, Ask SRRG (<u>eocevent394@cdc.gov</u>) will email you information about how to access the data through GitHub. If you have questions about obtaining access, email	Registration Information and Data Use Restrictio Agreement (RIDURA) authorizes data access
4.2	Governance for data linkage, sharing, access, and u	eocevent394@cdc.gov. [1] se based on data access authorization or applicable regula	tions/policies (i.e., the origin of the governa
4.2.1		Information not available/found	Information not available/found
4.2.2	With what other data can it be linked or can it not be linked (scope of linkage)	Information not available/found	Information not available/found
4.2.3	Whether data can be shared	Information not available/found	Information not available/found

	Source
trictions ss	 [1] <u>https://data.cdc.gov/Case-Surveillance/COVID-19-Case-Surveillance-Restricted-Access-Detai/mbd7-r32t</u> [2] <u>https://data.cdc.gov/api/views/mbd7-r32t/files/9aad836e-5aa5-4047-aa5c-</u>
	<u>15996becc87c?download=true&filename=summary_gui</u> <u>dance and limitations information and restricted acc</u> <u>ess data use agreement information updated.pdf</u>
trictions	[1] <u>https://data.cdc.gov/Case-Surveillance/COVID-19-</u>
SS	Case-Surveillance-Restricted-Access-Detai/mbd7-r32t [2]
	https://data.cdc.gov/api/views/mbd7-
	<u>r32t/files/9aad836e-5aa5-4047-aa5c-</u> 15996becc87c?download=true&filename=summary_gui
	dance and limitations information and restricted acc
	ess data use agreement information updated.pdf
vernance)

taset 6 -	COVID-19		
		Raw Language	Interpretation
4.2.4	How data can be shared (de-identification status, disclosure review)	Information not available/found	Information not available/found
4.2.5	How data can be accessed (access type, data use	Please review the following documents to determine your	CDC COVID-19 case surveillance restricted acce
	agreement, data access committee/group approval,	interest in accessing the COVID-19 Case Surveillance Restricted	data policy specifies that users review the follc
	IRB LOD, etc.)	Access Detailed Data file:	documents to determine interest in accessing
		1) CDC COVID-19 Case Surveillance Restricted Access Detailed	COVID-19 Case Surveillance Restricted Access
		Data: Summary, Guidance, Limitations Information, and	Detailed Data file:
		Restricted Access Data Use Agreement Information	1. CDC COVID-19 Case Surveillance Restricted A
		2) Data Dictionary for the COVID-19 Case Surveillance	Detailed Data: Summary, Guidance, Limitations
		Restricted Access Detailed Data	Information, and Restricted Access Data Use
		The next step is to complete the Registration Information and	Agreement Information
		Data Use Restrictions Agreement (RIDURA). Once complete,	2. Data Dictionary for the COVID-19 Case
		CDC will review your agreement. After access is granted, Ask	Surveillance Restricted Access Detailed Data
		SRRG (<u>eocevent394@cdc.gov</u>) will email you information	3. After reviewing the above information, the u
		about how to access the data through GitHub. If you have	must complete the RIDURA, which specifies th
		questions about obtaining access, email	data access the user:
		eocevent394@cdc.gov. [1]	(a). Obtain IRB LOD from researcher's institution
			needed /applicable)
		RIDURA:	(b). Must access the data through GitHub priva
		2. I am responsible for obtaining Institutional Review Board	repository
		review of projects when appropriate.	
		3. Access and use of the data and/or information does not	
		grant me permission to use any trade names trademarks,	
		services marks, product names, or logos of CDC or the	
		Department of Health and Human Services, except as may be	
		required for reasonable and customary use in describing the	
		CDC or the data and/or information. I will obtain express	
		written approval from CDC prior to any use of the	
		aforementioned. Though I agree to identify CDC as the source	
		of the data provided, I further agree to not imply or state in	

	Source
g the	[1] <u>https://data.cdc.gov/api/views/mbd7-r32t/files/9aad836e-5aa5-4047-aa5c-15996becc87c?download=true&filename=summary_guidance_and_limitations_information_and_restricted_access_data_use_agreement_information_updated.pdf</u> (Accessed: 4/28/23)
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ion (as	
vate	

	COVID-19	- ·		-
		Raw Language	Interpretation	Source
		any written form, that use of or any interpretation based on		
		the data are those of the original data sources or of CDC.		
		I understand that use of these data does not imply		
		endorsement by CDC. I will not attribute any analysis		
		conducted using these data to CDC.		
		5. I agree that while matching cases for public health purposes		
		is acceptable, I will not deliberately participate in or support		
		the combination of case surveillance data sets with other data		
		sets for the specific purpose of matching records to identify		
		individuals.		
		6. I understand that CDC has taken all reasonable steps for		
		privacy protections to ensure the identity of data subjects		
		cannot be disclosed. No direct identifiers or characteristics that		
		might lead to identification have been included in the data		
		provided. As such, I will not use the data to re-identify or		
		attempt to re-identify any individual included in the data and		
		will not use, publish or release the data in any personally		
		identifiable form. Should I inadvertently re-identify an		
		individual, I will notify CDC of such re-identification within		
		three (3) days of any such discovery. [2]		
		Your GitHub ID will be granted access to a private repository		
		containing data that we use to make it easier to share data		
		with you. If you do not have an ID, you can create one for free		
		at GitHub.com. After review, you will receive an email		
		invitation from a CDC staff member. [2]		
4.2.6	How data can be used (data use limitations)	Proposed use of the data:	RIDURA specifies that the COVID-19 Case	[1] https://data.cdc.gov/api/views/mbd7-
		-Title of Analysis		r32t/files/9aad836e-5aa5-4047-aa5c-
		-Brief description of proposed analysis	broad research (must be of public health	15996becc87c?download=true&filename=summary gu
		-Purpose of analysis / Public health significance	significance)	dance and limitations information and restricted ac
		-Describe the intended products from this analysis [1]	Significance	ess data use agreement information updated.pdf
427	Other (marify)	Information not available (found	Information not available /found	(Accessed: 4/26/23)
4.2.7	Other (specify)	Information not available/found	Information not available/found	
5	Data Use			
5.1	Authorizations and Applicable			
	Regulations/Policies			
5.1.1	Authorizations			
5.1.1.1	Assent	Information not available/found	Information not available/found	
5.1.1.2	Consent	Information not available/found	Information not available/found	
5.1.1.3	IRB/equivalent Privacy Board determination	Information not available/found	RIDURA specifies that for data access, a user must	[1] <u>https://data.cdc.gov/api/views/mbd7-</u>
	,		obtain IRB LOD from researcher's institution (as	r32t/files/9aad836e-5aa5-4047-aa5c-
			needed / applicable)	15996becc87c?download=true&filename=summary_gu
				dance and limitations information and restricted ac
				ess data use agreement information updated.pdf
				(Accessed: 4/26/23)
	Local /state /federal laws	Information not available found	Information not available (found	
5.1.1.4	Local/state/federal laws	Information not available/found	Information not available/found	
5.1.1.5	Institutional Certification	Information not available/found	Information not available/found	
5.1.1.6	Data originator agreement	Information not available/found	Information not available/found	

	COVID-19	Development		
		Raw Language	Interpretation	
5.1.1.7	Repository agreements/policies	Please review the following documents to determine your interest in accessing the COVID-19 Case Surveillance Restricted Access Detailed Data file: 1) CDC COVID-19 Case Surveillance Restricted Access Detailed Data: Summary, Guidance, Limitations Information, and Restricted Access Data Use Agreement Information 2) Data Dictionary for the COVID-19 Case Surveillance Restricted Access Detailed Data The next step is to complete the Registration Information and Data Use Restrictions Agreement (RIDURA). Once complete, CDC will review your agreement. After access is granted, Ask SRRG (<u>eocevent394@cdc.gov</u>) will email you information about how to access the data through GitHub. If you have questions about obtaining access, email <u>eocevent394@cdc.gov</u> . [1]	Registration Information and Data Use Restrictions Agreement (RIDURA) authorizes data use	[1] <u>https://</u> <u>Case-Surve</u> (Accessed:
5.1.1.8	Other (specify)	Information not available/found	Information not available/found	
	Applicable Regulations/Policies			
5.1.2.1	Local regulations/policies	Information not available/found	Information not available/found	
5.1.2.2	Tribal regulations/policies	Information not available/found	Information not available/found	
5.1.2.3	State regulations/policies	Information not available/found	Information not available/found	
5.1.2.4	Federal regulations/policies	Information not available/found	Information not available/found	
5.1.2.5	International regulations/policies	Information not available/found	Information not available/found	
5.1.2.6	Contractual obligations	Information not available/found	Information not available/found	
5.1.2.7	Repository policies	 Please review the following documents to determine your interest in accessing the COVID-19 Case Surveillance Restricted Access Detailed Data file: 1) CDC COVID-19 Case Surveillance Restricted Access Detailed Data: Summary, Guidance, Limitations Information, and Restricted Access Data Use Agreement Information 2) Data Dictionary for the COVID-19 Case Surveillance Restricted Access Detailed Data The next step is to complete the Registration Information and Data Use Restrictions Agreement (RIDURA). Once complete, CDC will review your agreement. After access is granted, Ask SRRG (eocevent394@cdc.gov) will email you information about how to access the data through GitHub. If you have questions about obtaining access, email eocevent394@cdc.gov. [1] 	CDC COVID-19 case surveillance restricted access data policy	[1] <u>https://</u> <u>Case-Surve</u> (Accessed:
		se based on data access authorization or applicable regula		e)
5.2.1	Whether the data can be linked	Information not available/found	Information not available/found	
5.2.2	With what other data can it be linked or can it not be linked (scope of linkage)		Information not available/found	
5.2.3	Whether data can be shared	Information not available/found	Information not available/found	ļ
5.2.4	How data can be shared (de-identification status, disclosure review)	Information not available/found	Information not available/found	

	Source
Restrictions	[1] https://data.cdc.gov/Case-Surveillance/COVID-19-
lse	Case-Surveillance-Restricted-Access-Detai/mbd7-r32t
	(Accessed: 4/28/23)
ted access	[1] <u>https://data.cdc.gov/Case-Surveillance/COVID-19-</u>
	Case-Surveillance-Restricted-Access-Detai/mbd7-r32t
	(Accessed: 4/28/23)
	· · · · · · · · · · · · · · · · · · ·
e governance)

Dataset 6 -	COVID-19			
		Raw Language	Interpretation	Source
5.2.5	How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.)	Raw Language2. I am responsible for obtaining Institutional Review Board review of projects when appropriate.3. Access and use of the data and/or information does not grant me permission to use any trade names trademarks, services marks, product names, or logos of CDC or the Department of Health and Human Services, except as may be required for reasonable and customary use in describing the CDC or the data and/or information. I will obtain express 	RIDURA specifies that for data access, a user: 1. Must sign and complete the RIDURA 2. Obtain IRB LOD from researcher's institution (as needed / applicable) 3. Must access the data through GitHub private repository	[1] https://data.cdc.gov/Case-Surveillance/COVID-19-Case- Surveillance-Restricted-Access-Detai/mbd7-r32t
5.2.6	How data can be used (data use limitations)	Proposed use of the data: -Title of Analysis -Brief description of proposed analysis -Purpose of analysis / Public health significance -Describe the intended products from this analysis [1]	RIDURA specifies that the COVID-19 Case Surveillance Restricted Data Access can be used for broad research (must be of public health significance)	[1] <u>https://data.cdc.gov/api/views/mbd7-</u> <u>r32t/files/9aad836e-5aa5-4047-aa5c-</u> <u>15996becc87c?download=true&filename=summary_gu</u> <u>dance and limitations information and restricted acc</u> <u>ess data use agreement information updated.pdf</u> (Accessed: 4/26/22)
5.2.7	Other (specify)	Information not available/found	Information not available/found	(Accessed: 4/26/23)
6	PII Elements			
6.1	PII elements collected	Human Infection with 2019 Novel Coronavirus Case Report Form (CRF) [1]	First name, last name, date of birth, sex, age (yr/mo/day), state and county of residence, race, ethnicity, and tribal name are collected from participants	 [1] <u>https://www.cdc.gov/coronavirus/2019-</u> <u>ncov/downloads/pui-form.pdf</u> [2] SSRG response email
6.2	PII elements holder (i.e., party that holds the PII)	Patient identifier information is not transmitted to the CDC, and reside within the state, territorial, and/or local health departments that report these cases to the CDC. [1]	State, territorial, and/or local health departments	[1] <u>https://www.cdc.gov/coronavirus/2019-</u> ncov/downloads/pui-form.pdf (Accessed: 4/26/23)
6.3	Use of common data model, if any, for data collection	Information not available/found	Information not available/found	
7	Prior Data Linkages			
7.1	Dataset linked with other datasets			
7.1.1	Name of other linked dataset	Information not available/found	Information not available/found	

Dataset 6 -	Dataset 6 - COVID-19					
		Raw Language	Interpretation	Source		
7.1.2	Other dataset type (clinical, EHR, survey, claims,	Information not available/found	Information not available/found			
	SDOH, etc.)					
7.1.3	Other dataset source(s)	Information not available/found	Information not available/found			
7.1.4	Linking methodology (PPRL or non-PPRL); linkage	Information not available/found	Information not available/found			
	technology					
7.1.5	PII elements used for the linkage	Information not available/found	Information not available/found			
7.1.6	Entity resolver (data originator or data linker or third	Information not available/found	Information not available/found			
	party)					
7.1.7	Party performing the linkages	Information not available/found	Information not available/found			
7.1.8	Linkage quality assessment	Information not available/found	Information not available/found			
7.1.9	Linked data sharing method (linkage maps or pre-	Information not available/found	Information not available/found			
	linked dataset)					

	- GOVERNANCE INFORMATION			
		ection on pediatric cancer survivors? Or what is the impact	of COVID-19 Infection on future pediatric canc	er outcomes?
Dataset 7 -	- T-MSIS Analytic Files (TAF)		1	1
	Dataset Source	Transformed Medicaid Statistical Information System (T-MSIS		
	Dataset Source Agency	CMS		
	Dataset Type (Clinical, EHR, Survey, SDOH, etc.)	Administrative/claims		
	Information Sources	Webiste, CMS staff meeting		
Dataset 7 ·	- T-MSIS Analytic Files (TAF)			
		Raw Language	Interpretation	Source
1	Data Collection			
1.1	Authorizations and Applicable Reg	gulations/Policies		
1.1.1	Authorizations		1. Section 4753 of the Balanced Budget Act of 1997	
			2. Section 6504 of the Patient Protection and	
			Affordable Care Act	
1.1.1.1	Assent	N/A	N/A	
1.1.1.2	Consent	N/A	N/A	
1.1.1.3	IRB/equivalent Privacy Board	N/A	N/A	
	determination			
1.1.1.4	Local/state/federal law	Section 4753 of the Balanced Budget Act of 1997, P.L. 105-33,	Three Federal laws authorize data collection:	[1] https://www.medicaid.gov/fe
1.1.1.4		amended section 1903(r) of the Act to include a statutory	1. Section 4753 of the Balanced Budget Act of 1997	guidance/downloads/SHO18008.
		requirement for states to submit claims data, enrollee	2. Section 6504 of the Patient Protection and	4/25/23)
		encounter data, and supporting information. Section 6504 of		[2] CMS Staff Meeting
		the Patient Protection and Affordable Care Act, P.L. 111-148,		[3]
		as amended by the Health Care and Education Reconciliation	3. Medicald and erm Managed care rina hale	https://www.federalregister.gov/
		Act, P.L. 111-152 (collectively, the Affordable Care Act)		3/2020-24758/medicaid-program
		strengthened this provision by requiring states to include		childrens-health-insurance-progr
		data elements the Secretary of Health and Human Services		(Accessed: 4/25/23)
		determines necessary for program integrity, program		(10003500. 4/25/25)
		oversight, and administration. The Medicaid managed care		
		regulation published in May 2016 further describes the		
		requirements for the submission of encounter data (see 42		
		CFR 438.242, 438.604 and 438.818). As part of encounter		
		data reporting, CMS expects states to report all actual		
		payment-related fields stipulated in the T-MSIS		
		documentation and referenced in the Medicaid managed		
		care regulations.		
		[1]		
4445				
1.1.1.5	Institutional Certification	N/A	N/A	
1.1.1.6	Data originator agreement	N/A N/A	N/A N/A	
1.1.1.7	Repository agreements/policies Other (specify)	Information not available/found	Information not available/found	
1.1.2	Applicable Regulations/Policies			
1.1.2.1	Local regulations/policies	Information not available/found	Information not available/found	<u> </u>
1.1.2.1	Tribal regulations/policies	Information not available/found	Information not available/found	
1.1.2.2	State regulations/policies	Information not available/found	Information not available/found	

outcomes?
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Source
] https://www.medicaid.gov/federal-policy-
idance/downloads/SHO18008.pdf (Accessed:
25/23)
] CMS Staff Meeting
]
tps://www.federalregister.gov/documents/2020/11/1
2020-24758/medicaid-program-medicaid-and-
ildrens-health-insurance-program-chip-managed-care
ccessed: 4/25/23)

	T-MSIS Analytic Files (TAF)			1
		Raw Language	Interpretation	
1.1.2.4	Federal regulations/policies	CMS is a covered entity under HIPAA and is subject to the	1. Privacy Act	[1] CMS Staff N
		Privacy Act when collecting, using, and disclosing data.	2. HIPAA Privacy Rule	
		(https://www.federalregister.gov/documents/2019/02/06/20		
		<u>19-01157/privacy-act-of-1974-system-of-records</u>)		
		[1]		
1.1.2.5	International regulations/policies	Information not available/found	Information not available/found	
1.1.2.6	Contractual obligations	Information not available/found	Information not available/found	
1.1.2.7	Repository policies	Information not available/found	Information not available/found	
1.2	Governance for data linkage, sharing	, access, and use based on data collection authorization	or applicable regulations/policies (i.e., the orig	in of the gove
1.2.1	Whether the data can be linked	Does not authorize/specify	Does not authorize/specify	
1.2.2	With what other data can it be linked or can it not be linked (scope of linkage)	Does not authorize/specify	Does not authorize/specify	
1.2.3	Whether data can be shared	CMS is a covered entity under HIPAA and is subject to the	HIPAA Privacy Rule that CMS is subject to under	[1] CMS Staff N
		Privacy Act when collecting, using, and disclosing data.	the Privacy Act specifies that de-identified data can	
		(https://www.federalregister.gov/documents/2019/02/06/20	be shared.	
		19-01157/privacy-act-of-1974-system-of-records)		
		[1]		
1.2.4	How data can be shared (de-	CMS is a covered entity under HIPAA and is subject to the	HIPAA Privacy Rule that CMS is subject to under	[1] CMS Staff N
	identification status, disclosure	Privacy Act when collecting, using, and disclosing data.	the Privacy Act specifies that T-MSIS data be de-	
	review)	(https://www.federalregister.gov/documents/2019/02/06/20	identified of all 18 HIPAA identifiers prior to	
		19-01157/privacy-act-of-1974-system-of-records)	sharing.	
		[1]		
1.2.5	How data can be accessed (access	Does not authorize/specify	Does not authorize/specify	
	type, data use agreement, data			
	access committee/group approval,			
	IRB LOD, etc.)			
1.2.6	How data can be used (data use limitations)	Does not authorize/specify	Does not authorize/specify	
1.2.7	Other (specify)	Does not authorize/specify	Does not authorize/specify	
2	Data Linkage			1
2.1	Authorizations and Applicable			
	Regulations/Policies			
2.1.1	Authorizations		1. CMS Privacy Board	
			2. Chief Data Officer	
			3. Information Exchange Agreement (IEA)	
2.1.1.1	Assent	N/A	N/A	
2.1.1.2	Consent	N/A	N/A	
2.1.1.3	IRB/equivalent Privacy Board	For standard T-MSIS Analytic Files (TAFs), the CMS Privacy	CMS Privacy Board approval of a RIF application	[1] CMS Staff N
	determination	Board authorizes linkage and use of the TAFs by researchers	specifying linkage authorizes data linkage	
		for research purposes. Linkage cannot occur if the Privacy		
		Board does not authorize the linkage as part of the RIF		
		application approval. [1]		

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vernance)	
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alasel / -	T-MSIS Analytic Files (TAF)			
		Raw Language	Interpretation	
2.1.1.4	Local/state/federal laws	Information not available/found	Information not available/found	
2.1.1.5	Institutional Certification	N/A	N/A	
2.1.1.6	Data originator agreement	N/A	N/A	
2.1.1.7	Repository agreements/policies	DATA USE AGREEMENT FOR USE OF CENTERS FOR MEDICARE	Information Exchange Agreement (IEA) between	[1]
		AND MEDICAID SERVICES (CMS) RESEARCH IDENTIFIABLE	CMS and the Participating Agency (on top of the	https://res
		FILES (RIFS):	Data Use Agreement) authorizes data linkage for	files/2022-
		Linking Data. Absent express written authorization from CMS,		%20RIF%20
		the Requesting Organization agrees not to link or attempt to	standard TAFs containing PII	4/25/23)
		link beneficiary level records included in the file(s) listed in		[2] <u>https://</u>
		Attachment $A - RIF$ Request Application to any other source		(Accessed:
		of information. A RIF Request Application to any other source		[3] https://
				Ids-and-put
		linkage of specific files that has been approved in accordance		-
		with section 3 constitutes express authorization from CMS to		[4] CMS Sta
		link files as described in the protocol. [1]		
		From the RIF Application:		
		"8. Please list any other data files or sources of information		
		that you are planning to use to support your research study.		
		(e.g., Provider of Services (POS) file, AMA Physician Master		
		file, etc.). If you will be linking or attempting to link to the		
		CMS files specified in section 5, please describe how you will		
		be linking the data.		
		Name of additional files		
		Purpose for using the data file in the analysis		
		If linking to CMS data, describe how linkage will occur		
		[2]		
		Data can be linked at beneficiary level to non-CMS data using		
		a beneficiary identifier?Yes [3]		
		"In addition to the research, Federal agencies are permitted		
		to create linked datasets (CMS data linked with another non-		
		CMS data source) and provide linked datasets to outside		
		researchers. CMS does not allow secondary use of CMS only -		
		(non-linked) files. If the data is linked, the federal agency		
		must take the data into their SORN and in addition to the		
		DUA authorizing the original research disclosure, there must		
		also be an IEA with CMS to specify the terms of the secondary		
		use. Because the other federal agency is not a HIPAA		
		Covered Entity, they must agree to treat the secondary		
		release as if they are a HIPAA Covered Entity and follow a		
		process similar to CMS for releasing the data for research		
		purposes, including entering into a DUA with the researcher."		
		[4]		
2.1.1.8	Other (specify)	Information not available/found	Information not available/found	
2.1.2	Applicable Regulations/Policies			
2.1.2.1	Local regulations/policies	Information not available/found	Information not available/found	
2.1.2.2	Tribal regulations/policies	Information not available/found	Information not available/found	
2.1.2.2				

Source

dac.org/sites/datadocumentation.resdac.org/ LO/Instructions%20-

Data%20Use%20Agreement.pdf (Accessed:

resdac.org/request-form/rif-application_ 4/25/23) resdac.org/articles/differences-between-rif--data-files (Accessed: 4/25/23)

f Meeting

2.1.2.5 International regulations/policies Information not available/found Information 2.1.2.6 Contractual obligations Information not available/found Information 2.1.2.7 Repository policies DATA USE AGREEMENT FOR USE OF CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) RESEARCH IDENTIFIABLE FILES (RIFS): CMS Reseating Data. Absent express written authorization from CMS, the Requesting Organization agrees not to link or attempt to link beneficiary level records included in the file(s) listed in Attachment A – RIF Request Application to any other source of information. A RIF Request Application to any other source of information. A RIF Request application to row CMS to link files as described in the protocol. [1] From the RIF Application: "8. Please list any other data files or sources of information that you are planning to use to support your research study. (e.g., Provider of Services (POS) file, AMA Physician Master file, etc.). If you will be linking or attempting to link to the CMS files specified in section 5, please describe how you will be linking the data. Name of additional files Purpose for using the data file in the analysis If linking to CMS data, describe how linkage will occur [2]		files/2022-10 %20RIF%20D 4/25/23) [2] <u>https://re</u> (Accessed: 4/ [3] <u>https://re</u> Ids-and-puf-c
2.1.2.5 International regulations/policies Information not available/found Information 2.1.2.6 Contractual obligations Information not available/found Information 2.1.2.7 Repository policies DATA USE AGREEMENT FOR USE OF CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) RESEARCH IDENTIFIABLE FILES (RIFS): CMS Reseat Linking Data. Absent express written authorization from CMS, the Requesting Organization agrees not to link or attempt to link beneficiary level records included in the file(s) listed in Attachment A – RIF Request Application to any other source of information. A RIF Request Application that includes the linkage of specific files that has been approved in accordance with section 3 constitutes express authorization from CMS to link files as described in the protocol. [1] From the RIF Application: "8. Please list any other data files or sources of information that you are planning to use to support your research study. (e.g., Provider of Services (POS) file, AMA Physician Master file, etc.). If you will be linking or attempting to link to the CMS files specified in section 5, please describe how you will be linking the data. Name of additional files Purpose for using the data file in the analysis If linking to CMS data, describe how linkage will occur [2]	on not available/found on not available/found arch Data Center (ResDAC) policy	https://resda files/2022-10 %20RIF%20D 4/25/23) [2] https://re (Accessed: 4/ [3] https://re Ids-and-puf-c
2.1.2.6 Contractual obligations Information not available/found Information 2.1.2.7 Repository policies DATA USE AGREEMENT FOR USE OF CENTERS FOR MEDICARE CMS Resea AND MEDICAID SERVICES (CMS) RESEARCH IDENTIFIABLE FILES (RIFS): Linking Data. Absent express written authorization from CMS, the Requesting Organization agrees not to link or attempt to link beneficiary level records included in the file(s) listed in Attachment A – RIF Request Application to any other source of information. A RIF Request Application that includes the linkage of specific files that has been approved in accordance with section 3 constitutes express authorization from CMS to link files as described in the protocol. [1] From the RIF Application: "8. Please list any other data files or sources of information that you are planning to use to support your research study. (e.g., Provider of Services (POS) file, AMA Physician Master file, etc.). If you will be linking or attempting to link to the CMS files specified in section 5, please describe how you will be linking the data. Name of additional files Purpose for using the data file in the analysis If linking to CMS data, describe how linkage will occur [2]	on not available/found arch Data Center (ResDAC) policy	https://resda files/2022-10 %20RIF%20D 4/25/23) [2] https://re (Accessed: 4/ [3] https://re Ids-and-puf-d
2.1.2.7 Repository policies DATA USE AGREEMENT FOR USE OF CENTERS FOR MEDICARE CMS Resea AND MEDICAID SERVICES (CMS) RESEARCH IDENTIFIABLE FILES (RIFS): Linking Data. Absent express written authorization from CMS, the Requesting Organization agrees not to link or attempt to link beneficiary level records included in the file(s) listed in Attachment A – RIF Request Application to any other source of information. A RIF Request Application that includes the linkage of specific files that has been approved in accordance with section 3 constitutes express authorization from CMS to link files as described in the protocol. [1] From the RIF Application: "8. Please list any other data files or sources of information that you are planning to use to support your research study. (e.g., Provider of Services (POS) file, AMA Physician Master file, etc.). If you will be linking or attempting to link to the CMS files specified in section 5, please describe how you will be linking the data. Name of additional files Purpose for using the data file in the analysis If linking to CMS data, describe how linkage will occur	arch Data Center (ResDAC) policy	https://resda files/2022-10 %20RIF%20D 4/25/23) [2] https://re (Accessed: 4/ [3] https://re Ids-and-puf-d
2.1.2.7 Repository policies DATA USE AGREEMENT FOR USE OF CENTERS FOR MEDICARE CMS Resea AND MEDICAID SERVICES (CMS) RESEARCH IDENTIFIABLE FILES (RIFS): Linking Data. Absent express written authorization from CMS, the Requesting Organization agrees not to link or attempt to link beneficiary level records included in the file(s) listed in Attachment A – RIF Request Application to any other source of information. A RIF Request Application that includes the linkage of specific files that has been approved in accordance with section 3 constitutes express authorization from CMS to link files as described in the protocol. [1] From the RIF Application: "8. Please list any other data files or sources of information that you are planning to use to support your research study. (e.g., Provider of Services (POS) file, AMA Physician Master file, etc.). If you will be linking or attempting to link to the CMS files specified in section 5, please describe how you will be linking the data. Name of additional files Purpose for using the data file in the analysis if linking to CMS data, describe how linkage will occur [2]	arch Data Center (ResDAC) policy	https://resda files/2022-10 %20RIF%20D 4/25/23) [2] https://re (Accessed: 4/ [3] https://re Ids-and-puf-d
FILES (RIFS): Linking Data. Absent express written authorization from CMS, the Requesting Organization agrees not to link or attempt to link beneficiary level records included in the file(s) listed in Attachment A – RIF Request Application to any other source of information. A RIF Request Application that includes the linkage of specific files that has been approved in accordance with section 3 constitutes express authorization from CMS to link files as described in the protocol. [1] From the RIF Application: "8. Please list any other data files or sources of information that you are planning to use to support your research study. (e.g., Provider of Services (POS) file, AMA Physician Master file, etc.). If you will be linking or attempting to link to the CMS files specified in section 5, please describe how you will be linking the data. Name of additional files Purpose for using the data file in the analysis If linking to CMS data, describe how linkage will occur [2]		files/2022-10 %20RIF%20D 4/25/23) [2] https://re (Accessed: 4/ [3] https://re Ids-and-puf-c
Linking Data. Absent express written authorization from CMS, the Requesting Organization agrees not to link or attempt to link beneficiary level records included in the file(s) listed in Attachment A – RIF Request Application to any other source of information. A RIF Request Application that includes the linkage of specific files that has been approved in accordance with section 3 constitutes express authorization from CMS to link files as described in the protocol. [1] From the RIF Application: "8. Please list any other data files or sources of information that you are planning to use to support your research study. (e.g., Provider of Services (POS) file, AMA Physician Master file, etc.). If you will be linking or attempting to link to the CMS files specified in section 5, please describe how you will be linking the data. Name of additional files Purpose for using the data file in the analysis If linking to CMS data, describe how linkage will occur [2]		[2] <u>https://re</u> (Accessed: 4/ [3] <u>https://re</u> Ids-and-puf-d
the Requesting Organization agrees not to link or attempt to link beneficiary level records included in the file(s) listed in Attachment A – RIF Request Application to any other source of information. A RIF Request Application that includes the linkage of specific files that has been approved in accordance with section 3 constitutes express authorization from CMS to link files as described in the protocol. [1] From the RIF Application: "8. Please list any other data files or sources of information that you are planning to use to support your research study. (e.g., Provider of Services (POS) file, AMA Physician Master file, etc.). If you will be linking or attempting to link to the CMS files specified in section 5, please describe how you will be linking the data. Name of additional files Purpose for using the data file in the analysis If linking to CMS data, describe how linkage will occur [2]		4/25/23) [2] <u>https://re</u> (Accessed: 4/ [3] <u>https://re</u> Ids-and-puf-c
 link beneficiary level records included in the file(s) listed in Attachment A – RIF Request Application to any other source of information. A RIF Request Application that includes the linkage of specific files that has been approved in accordance with section 3 constitutes express authorization from CMS to link files as described in the protocol. [1] From the RIF Application: "8. Please list any other data files or sources of information that you are planning to use to support your research study. (e.g., Provider of Services (POS) file, AMA Physician Master file, etc.). If you will be linking or attempting to link to the CMS files specified in section 5, please describe how you will be linking the data. Name of additional files Purpose for using the data file in the analysis If linking to CMS data, describe how linkage will occur [2] 		[2] <u>https://re</u> (Accessed: 4/ [3] <u>https://re</u> Ids-and-puf-d
Attachment A – RIF Request Application to any other source of information. A RIF Request Application that includes the linkage of specific files that has been approved in accordance with section 3 constitutes express authorization from CMS to link files as described in the protocol. [1] From the RIF Application: "8. Please list any other data files or sources of information that you are planning to use to support your research study. (e.g., Provider of Services (POS) file, AMA Physician Master file, etc.). If you will be linking or attempting to link to the CMS files specified in section 5, please describe how you will be linking the data. Name of additional files Purpose for using the data file in the analysis If linking to CMS data, describe how linkage will occur [2]	-	(Accessed: 4/ [3] https://re lds-and-puf-d
of information. A RIF Request Application that includes the linkage of specific files that has been approved in accordance with section 3 constitutes express authorization from CMS to link files as described in the protocol. [1] From the RIF Application: "8. Please list any other data files or sources of information that you are planning to use to support your research study. (e.g., Provider of Services (POS) file, AMA Physician Master file, etc.). If you will be linking or attempting to link to the CMS files specified in section 5, please describe how you will be linking the data. Name of additional files Purpose for using the data file in the analysis If linking to CMS data, describe how linkage will occur [2]		[3] <u>https://re</u> Ids-and-puf-d
 linkage of specific files that has been approved in accordance with section 3 constitutes express authorization from CMS to link files as described in the protocol. [1] From the RIF Application: "8. Please list any other data files or sources of information that you are planning to use to support your research study. (e.g., Provider of Services (POS) file, AMA Physician Master file, etc.). If you will be linking or attempting to link to the CMS files specified in section 5, please describe how you will be linking the data. Name of additional files Purpose for using the data file in the analysis If linking to CMS data, describe how linkage will occur [2] 		Ids-and-puf-d
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link files as described in the protocol. [1] From the RIF Application: "8. Please list any other data files or sources of information that you are planning to use to support your research study. (e.g., Provider of Services (POS) file, AMA Physician Master file, etc.). If you will be linking or attempting to link to the CMS files specified in section 5, please describe how you will be linking the data. Name of additional files Purpose for using the data file in the analysis If linking to CMS data, describe how linkage will occur [2]		[4] CMS Staff
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"8. Please list any other data files or sources of information that you are planning to use to support your research study. (e.g., Provider of Services (POS) file, AMA Physician Master file, etc.). If you will be linking or attempting to link to the CMS files specified in section 5, please describe how you will be linking the data. Name of additional files Purpose for using the data file in the analysis If linking to CMS data, describe how linkage will occur [2]		
that you are planning to use to support your research study. (e.g., Provider of Services (POS) file, AMA Physician Master file, etc.). If you will be linking or attempting to link to the CMS files specified in section 5, please describe how you will be linking the data. Name of additional files Purpose for using the data file in the analysis If linking to CMS data, describe how linkage will occur [2]		
(e.g., Provider of Services (POS) file, AMA Physician Master file, etc.). If you will be linking or attempting to link to the CMS files specified in section 5, please describe how you will be linking the data. Name of additional files Purpose for using the data file in the analysis If linking to CMS data, describe how linkage will occur [2]		
file, etc.). If you will be linking or attempting to link to the CMS files specified in section 5, please describe how you will be linking the data. Name of additional files Purpose for using the data file in the analysis If linking to CMS data, describe how linkage will occur [2]		
CMS files specified in section 5, please describe how you will be linking the data. Name of additional files Purpose for using the data file in the analysis If linking to CMS data, describe how linkage will occur [2]		
be linking the data. Name of additional files Purpose for using the data file in the analysis If linking to CMS data, describe how linkage will occur [2]		
Name of additional files Purpose for using the data file in the analysis If linking to CMS data, describe how linkage will occur [2]		
Purpose for using the data file in the analysis If linking to CMS data, describe how linkage will occur [2]		
If linking to CMS data, describe how linkage will occur [2]		
[2]		
Deterson he linked at her effective level to non-CMC data varies		
Data can be linked at beneficiary level to non-CMS data using a beneficiary identifier?Yes [3]		
"In addition to the research, Federal agencies are permitted		
to create linked datasets (CMS data linked with another non-		
CMS data source) and provide linked datasets to outside		
researchers. CMS does not allow secondary use of CMS only -		
(non-linked) files. If the data is linked, the federal agency		
must take the data into their SORN and in addition to the		
DUA authorizing the original research disclosure, there must		
also be an IEA with CMS to specify the terms of the secondary		
use. Because the other federal agency is not a HIPAA		
Covered Entity, they must agree to treat the secondary		
release as if they are a HIPAA Covered Entity and follow a		
process similar to CMS for releasing the data for research		
purposes, including entering into a DUA with the researcher." [4]		
2.2 Governance for data linkage, sharing, access, and use based on data linkage authorization or applicable	e regulations/nalisies (i.e., the evicin	of the gover

ac.org/sites/datadocumentation.resdac.org/ 0/Instructions%20-

Data%20Use%20Agreement.pdf (Accessed:

esdac.org/request-form/rif-application /25/23) esdac.org/articles/differences-between-rifdata-files (Accessed: 4/25/23) if Meeting

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		Raw Language	Interpretation		
2.1	Whether the data can be linked	DATA USE AGREEMENT FOR USE OF CENTERS FOR MEDICARE		[1]	
		AND MEDICAID SERVICES (CMS) RESEARCH IDENTIFIABLE	researchers for research purposes via an approved	https://resdac.c	
		FILES (RIFS):	RIF Application that specifies the scope of linkage	files/2022-10/In	
		Linking Data. Absent express written authorization from CMS,		%20RIF%20Data	
			of a letter of justification for linkage, and	4/25/23)	
		link beneficiary level records included in the file(s) listed in	Information Exchange Agreement (IEA) authorizes	[2] <u>https://resda</u>	
		Attachment A – RIF Request Application to any other source	data linkage for federal entities performing linkage	(Accessed: 4/25	
		of information. A RIF Request Application that includes the	with non-standard TAFs containing PII	[3] <u>https://resda</u>	
		linkage of specific files that has been approved in accordance with section 2 constitutes express authorization from CMS to		Ids-and-puf-dat	
		with section 3 constitutes express authorization from CMS to link files as described in the protocol. [1]		[4] CMS Staff M	
		link mes as described in the protocol. [1]			
		From the RIF Application:			
		"8. Please list any other data files or sources of information			
		that you are planning to use to support your research study.			
		(e.g., Provider of Services (POS) file, AMA Physician Master			
		file, etc.). If you will be linking or attempting to link to the			
		CMS files specified in section 5, please describe how you will			
		be linking the data.			
		Name of additional files			
		Purpose for using the data file in the analysis			
		If linking to CMS data, describe how linkage will occur			
		[2]			
		Data can be linked at beneficiary level to non-CMS data using			
		a beneficiary identifier?Yes [3]			
		For standard TAFs, the CMS Privacy Board authorizes linkage			
		and use of the TAFs by researchers for research purposes.			
		Linkage cannot occur if the Privacy Board does not authorize			
		the linkage as part of the RIF application approval.			
		[4]			
		For non-standard TAFs (i.e., with additional variables),			
		authorization includes CMS Privacy Board and the submission			
		of a letter to the Chief Data Officer. A federal agency			
		requesting access to non-standard research data must submit			
		a letter of justification to the CMS Chief Data Officer (CDO)			
		for approval. The CDO will consult with other CMS leadership			
		where appropriate before approving a non-standard data file			
		request (e.g., leadership from the Center for Medicaid & CHIP			
		Services on requests related to Medicaid data).			
		[4]			

c.org/sites/datadocumentation.resdac.org/ //Instructions%20ata%20Use%20Agreement.pdf (Accessed:

esdac.org/request-form/rif-application /25/23) esdac.org/articles/differences-between-rifdata-files (Accessed: 4/25/23)

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	T-MSIS Analytic Files (TAF)	Pour Language	Internetation	
222		Raw Language	Interpretation	[4]
2.2.2		DATA USE AGREEMENT FOR USE OF CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) RESEARCH IDENTIFIABLE FILES (RIFS): Linking Data. Absent express written authorization from CMS, the Requesting Organization agrees not to link or attempt to link beneficiary level records included in the file(s) listed in Attachment A – RIF Request Application to any other source of information. A RIF Request Application that includes the linkage of specific files that has been approved in accordance with section 3 constitutes express authorization from CMS to	1. CMS policy and Data Use Agreement specify that data can only be linked to external data in accordance with the RIF Application approved by	https://resdac.c files/2022-10/Ir
		 link files as described in the protocol. [1] From the RIF Application: "8. Please list any other data files or sources of information that you are planning to use to support your research study. (e.g., Provider of Services (POS) file, AMA Physician Master file, etc.). If you will be linking or attempting to link to the CMS files specified in section 5, please describe how you will be linking the data. Name of additional files Purpose for using the data file in the analysis If linking to CMS data, describe how linkage will occur [2] Data can be linked at beneficiary level to non-CMS data using a beneficiary identifier?Yes [3] For standard TAFs, the CMS Privacy Board authorizes linkage and use of the TAFs by researchers for research purposes. Linkage cannot occur if the Privacy Board does not authorize the linkage as part of the RIF application approval. 		
		Researchers can request linkages as part of research protocol. PII, such as SSN, are not released to researchers as part of the standard research files. o For linkages with external datasets (listed in the RIF application), the researchers must submit PII for linkages with the external datasets to CMS. o CMS facilitates the linkage (to BENE_ID) based on the PII provided. o CMS returns the crosswalk of BENE_ID to the requesting researcher. o The data that CMS releases does not contain SSN; CMS releases data with the identifier BENE_ID which is also used as the link key. [4]		

c.org/sites/datadocumentation.resdac.org/ //Instructions%20ata%20Use%20Agreement.pdf (Accessed:

sdac.org/request-form/rif-application (25/23) sdac.org/articles/differences-between-rif-

lata-files (Accessed: 4/25/23) Meeting

	T-MSIS Analytic Files (TAF)	Raw Language	Interpretation	So
		For non-standard TAFs (i.e., with additional variables), authorization includes CMS Privacy Board and the submission of a letter to the Chief Data Officer. A federal agency requesting access to non-standard research data must submit a letter of justification to the CMS Chief Data Officer (CDO) for approval. The CDO will consult with other CMS leadership where appropriate before approving a non-standard data file request (e.g., leadership from the Center for Medicaid & CHIP Services on requests related to Medicaid data). [4]		
2.2.3	Whether data can be shared	In addition to the research, Federal agencies are permitted to create linked datasets (CMS data linked with another non- CMS data source) and provide linked datasets to outside researchers. CMS does not allow secondary use of CMS only - (non-linked) files. If the data is linked, the federal agency must take the data into their SORN and in addition to the DUA authorizing the original research disclosure, there must also be an IEA with CMS to specify the terms of the secondary use. Because the other federal agency is not a HIPAA Covered Entity, they must agree to treat the secondary release as if they are a HIPAA Covered Entity and follow a process similar to CMS for releasing the data for research purposes, including entering into a DUA with the researcher. [1]	Exhange Agreement (IEA) authorize data sharing of linked data by federal entities but prohibit re- sharing of un-linked CMS data	[1] CMS Staff Meeting
2.2.4	How data can be shared (de- identification status, disclosure review)	In addition to the research, Federal agencies are permitted to create linked datasets (CMS data linked with another non-CMS data source) and provide linked datasets to outside researchers. CMS does not allow secondary use of CMS only - (non-linked) files. If the data is linked, the federal agency must take the data into their SORN and in addition to the DUA authorizing the original research disclosure, there must also be an IEA with CMS to specify the terms of the secondary use. Because the other federal agency is not a HIPAA Covered Entity, they must agree to treat the secondary release as if they are a HIPAA Covered Entity and follow a process similar to CMS for releasing the data for research purposes, including entering into a DUA with the researcher. [1]	 performing data linkage using non-standard TAFs containing PII must take the data into their SORN under the Privacy Act 2. CMS policy specifies that federal entities performing data linkage must agree to treat secondarily shared data as if the entity is a HIPAA 	[1] CMS Staff Meeting
2.2.5	How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.)	Does not authorize/specify	Does not authorize/specify	

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Dataset 7 -	T-MSIS Analytic Files (TAF)			
		Raw Language	Interpretation	
2.2.6	How data can be used (data use limitations)	For standard TAFs, the CMS Privacy Board authorizes linkage and use of the TAFs by researchers for research purposes. Linkage cannot occur if the Privacy Board does not authorize the linkage as part of the RIF application approval. [1]	CMS Privacy Board specifies that TAFs can be used for resesarch purposes	[1] CMS Staff M
2.2.7	Other (specify)	Does not authorize/specify	Does not authorize/specify	
3	Data Sharing			
3.1	Authorizations and Applicable			
	Regulations/Policies			
3.1.1	Authorizations		Information Exchange Agreement (IEA)	
3.1.1.1	Assent	N/A	N/A	
3.1.1.2	Consent	N/A	N/A	
3.1.1.3	IRB/equivalent Privacy Board determination	Information not available/found	Information not available/found	
3.1.1.4	Local/state/federal laws	Information not available/found	Information not available/found	
3.1.1.5	Institutional Certification	Information not available/found	Information not available/found	
3.1.1.6	Data originator agreement	Information not available/found	Information not available/found	
3.1.1.7	Repository agreements/policies	 INFORMATION EXCHANGE AGREEMENT BETWEEN THE CENTERS FOR MEDICARE & MEDICAID SERVICES AND Insert the Participating Agency FOR DISCLOSURE OF [Business Owner inserts brief description of exchanged data]: DESCRIPTION OF THE DATA THAT MAY BE DISCLOSED A. Data Covered by this Agreement [Business Owner list and describe the exchanges of data that correspond with the purposes and legal authority provided in the Purpose and Legal Authorities Sections.] 1 2 B. System(s) of Records CMS will provide CMS Data from the following SOR(s): [Business Owner list all the CMS Systems of Records, with notice information and routine use information, an example is provided] 1. [Example] Enrollment Data Base (EDB), System No. 09-70-0502; last modified at 73 FR 10249 (February 26, 2008), as amended at April 23, 2013 (78 FR 23938), February 18, 2016 (81 FR 8204) and February 14, 2018 (83 FR 6591). Data maintained in the EDB will be released pursuant to routine use number 2 and 10, as set forth in the SORN. [1] 	Information Exchange Agreement (IEA) between CMS and the Participating Agency (on top of the Data Use Agreement) authorizes data sharing of linked data by federal agencies performing linkage with non-standard TAFs	[1] IEA Templat
3.1.1.8	Other	Information not available/found	Information not available/found	
3.1.2	Applicable Regulations/Policies			
3.1.2.1	Local regulations/policies	Information not available/found	Information not available/found	
3.1.2.2	Tribal regulations/policies	Information not available/found	Information not available/found	
3.1.2.3	State regulations/policies	Information not available/found	Information not available/found	

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ataset 7 -	T-MSIS Analytic Files (TAF)			
		Raw Language	Interpretation	
3.1.2.4	Federal regulations/policies	CMS is a covered entity under HIPAA and is subject to the Privacy Act when collecting, using, and disclosing data. (<u>https://www.federalregister.gov/documents/2019/02/06/20</u> <u>19-01157/privacy-act-of-1974-system-of-records</u>) [1]	 Privacy Act HIPAA Privacy Rule 	[1] CMS Staff M
3.1.2.5	International regulations/policies	Information not available/found	Information not available/found	
3.1.2.6	Contractual obligations	Information not available/found	Information not available/found	
3.1.2.7	Repository policies	Information not available/found	Information not available/found	
3.2	Governance for data linkage, sharing	, access, and use based on data sharing authorization or	applicable regulations/policies (i.e., the origin	of the govern
3.2.1	Whether the data can be linked	Information not available/found	Information not available/found	
3.2.2	With what other data can it be linked or can it not be linked (scope of	Information not available/found	Information not available/found	
3.2.3	Whether data can be shared	In addition to the research, Federal agencies are permitted to create linked datasets (CMS data linked with another non- CMS data source) and provide linked datasets to outside researchers. CMS does not allow secondary use of CMS only - (non-linked) files. If the data is linked, the federal agency must take the data into their SORN and in addition to the DUA authorizing the original research disclosure, there must also be an IEA with CMS to specify the terms of the secondary use. Because the other federal agency is not a HIPAA Covered Entity, they must agree to treat the secondary release as if they are a HIPAA Covered Entity and follow a process similar to CMS for releasing the data for research purposes, including entering into a DUA with the researcher. [1]	Exhange Agreement (IEA) authorize data sharing of linked data by federal entities but prohibit re- sharing of un-linked CMS data	[1] CMS Staff N
3.2.4	How data can be shared (de- identification status, disclosure review)	In addition to the research, Federal agencies are permitted to create linked datasets (CMS data linked with another non- CMS data source) and provide linked datasets to outside researchers. CMS does not allow secondary use of CMS only - (non-linked) files. If the data is linked, the federal agency must take the data into their SORN and in addition to the DUA authorizing the original research disclosure, there must also be an IEA with CMS to specify the terms of the secondary use. Because the other federal agency is not a HIPAA Covered Entity, they must agree to treat the secondary release as if they are a HIPAA Covered Entity and follow a process similar to CMS for releasing the data for research purposes, including entering into a DUA with the researcher. [1]	shared 2. CMS policy specifies that federal entities performing data linkage using non-standard TAFs containing PII must take the data into their SORN under the Privacy Act 3. CMS policy specifies that federal entities	[1] CMS Staff M
3.2.5	How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.)	Information not available/found	Information not available/found	
3.2.6	How data can be used (data use limitations)	Information not available/found	Information not available/found	

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		Raw Language	Interpretation	
3.2.7	Other (specify)	Information not available/found	Information not available/found	
4	Data Access			1
4.1	Authorizations and Applicable			
	Regulations/Policies			
4.1.1	Authorizations		1. CMS Privacy Board	
			2. Data Use Agreement	
4.1.1.1	Assent	N/A	N/A	
4.1.1.2	Consent	N/A	N/A	
4.1.1.3	IRB/equivalent Privacy Board determination	Information not available/found	Information not available/found	
4.1.1.4	Local/state/federal laws	Data access is authorized through CMS Privacy Board	CMS Privacy Board authorizes data access	
		approval (the CMS Privacy Board consults with the data		
		owner, who reviews all data requests) and under the DUA.		
		[1]		
4.1.1.5	Institutional Certification	Information not available/found	Information not available/found	
4.1.1.6	Data originator agreement	Information not available/found	Information not available/found	
		The CMS Privacy Board consults with the data owner, who		
		reviews all data requests [1], so a data originator agreement		
		may exist.		
4.1.1.7	Repository agreements/policies	Data access is authorized through CMS Privacy Board	Data Use Agreement authorizes data access	[1] CMS Staff N
		approval (the CMS Privacy Board consults with the data		
		owner, who reviews all data requests) and under the DUA.		
		[1]		
4.1.1.8	Other (specify)	Information not available/found	Information not available/found	
4.1.2	Applicable Regulations/Policies			
4.1.2.1	Local regulations/policies	Information not available/found	Information not available/found	
4.1.2.2	Tribal regulations/policies	Information not available/found	Information not available/found	
4.1.2.3	State regulations/policies	Information not available/found	Information not available/found	

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		Raw Language	Interpretation	
4.1.2.4	Federal regulations/policies	CMS is a covered entity under HIPAA and is subject to the	1. Privacy Act	[1] CMS Staff N
		Privacy Act when collecting, using, and disclosing data.	2. HIPAA Privacy Rule	[2] <u>https://res</u>
		(https://www.federalregister.gov/documents/2019/02/06/20	3. Common Rule	waiver-approv
		19-01157/privacy-act-of-1974-system-of-records)		
		[1]		
		CMS must ensure that all research requests for protected		
		health information meet the requirements under the		
		Common Rule and the Health Insurance Portability and		
		Accountability Act (HIPAA) Privacy Rule. As a result,		
		researchers must submit the following as part of the research		
		request packet:		
		Common Rule		
		If subject to the Common Rule:		
		» Documentation of institutional review board (IRB)		
		approval of the research AND		
		» Informed consent of the research subjects or IRB		
		waiver of the requirement to obtain informed consent.		
		If exempt from the Common Rule:		
		» A signed and dated statement describing the basis for		
		exemption.		
		HIPAA Privacy Rule		
		Individual authorization of the use of the data for the		
		research OR		
		Documentation that an IRB or a Privacy Board has approved a		
		waiver of research subjects' authorization for use/disclosure		
		of information about them for research purposes.		
		The IRB study title must match the CMS data request study		
		title, otherwise, a brief explanation is required.		
		[2]		
4.1.2.5	International regulations/policies	Information not available/found	Information not available/found	
4.1.2.6	Contractual obligations	Information not available/found	Information not available/found	

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set / -	- T-MSIS Analytic Files (TAF)			1
		Raw Language	Interpretation	Source
.1.2.7	Repository policies	The Research Identifiable File (RIF) Data Use Agreement	CMS Research Data Center (ResDAC) policy	[1] <u>https://resdac.org/request-form/rif-data-use-</u>
		(DUA) is a legal agreement between CMS and a requesting		agreement (also see
		organization that documents the terms and conditions under		https://resdac.org/sites/datadocumentation.resdac.org/
		which the CMS data may be used, including CMS privacy and		files/2022-10/RIF%20Data%20Use%20Agreement.pdf)
		security requirements and data release policies. [1]		(Accessed: 4/25/23))
				[2] https://resdac.org/request-form/rif-application
		The Research Identifiable File (RIF) application collects		(Accessed: 4/25/23)
		information about the requesting organization and the		[3] <u>https://resdac.org/request-form/key-personnel-</u>
		research study, including detailed study aims, data required,		supplement (Accessed: 4/25/23)
		and dissemination of findings plan. The RIF application is used		[4] <u>https://resdac.org/request-form/rif-specifications-</u>
		by CMS to assess the feasibility of the research and		worksheet (Accessed: 4/25/23)
		compliance with CMS data use and release policies. [2]		[5] CMS Email Communication
				[6] IEA Template
		The Key Personnel Supplement collects information about		
		each request's key contacts including the requester,		
	collaborating organizations and additional contacts who should be included on notices about the project. [3]			
		The Specifications Worksheet is required for all RIF requests.		
		It collects detailed requester information, study/project data		
		extract details, shipping information, and method of		
		payment. It also includes a Part D event justification tab that		
		is required for all requests that include Part D data. The		
		Specifications Worksheet is used by the data distributor to		
		generate a cost invoice and to collect data extraction		
		information.[4]		
		CMS Information Exchange Agreement (IEA): "This is used to		
		modify the terms of the research DUA to allow redisclosure of		
		linked datasets by federal agencies. However, we are		
		exploring creating a research DUA addendum with standard		
		clauses for the redisclosure scenario instead. This document		
		is also used by the CMS Privacy Office for other types of		
		disclosures (other than research) or exchanges with federal		
		agencies."		
		[5]		
		IEA Template [6]		
2	Governance for data linkage, shar	ng, access, and use based on data access authorization or	applicable regulations/policies (i.e., the origin	
.2.1	Whether the data can be linked	For standard TAFs, the CMS Privacy Board authorizes linkage	CMS Privacy Board authorizes data linkage for	[1] CMS Staff Meeting
		and use of the TAFs by researchers for research purposes.	researchers for research purposes via an approved	
		Linkage cannot occur if the Privacy Board does not authorize	RIF Application that specifies the scope of linkage	
		the linkage as part of the RIF application approval.		
		[1]		

Dataset 7 -	- T-MSIS Analytic Files (TAF)			
		Raw Language	Interpretation	
4.2.2	With what other data can it be linked or can it not be linked (scope of linkage)	For standard TAFs, the CMS Privacy Board authorizes linkage and use of the TAFs by researchers for research purposes. Linkage cannot occur if the Privacy Board does not authorize the linkage as part of the RIF application approval. [1] Researchers can request linkages as part of research protocol. PII, such as SSN, are not released to researchers as part of the standard research files. o For linkages with external datasets (listed in the RIF application), the researchers must submit PII for linkages with the external datasets to CMS. o CMS facilitates the linkage (to BENE_ID) based on the PII provided. o CMS returns the crosswalk of BENE_ID to the requesting researcher. o The data that CMS releases does not contain SSN; CMS releases data with the identifier BENE_ID which is also used as the link key. [1]	CMS policy and Data Use Agreement specify that data can only be linked to external data in accordance with the RIF Application approved by the CMS Privacy Board which specifies the scope of linkage	[1] CMS Staff N
4.2.3	Whether data can be shared	Does not authorize/specify	Does not authorize/specify	
4.2.4	How data can be shared (de- identification status, disclosure review)	The Chronic Conditions Warehouse (CCW) Virtual Research Data Center (VRDC) output review process exists to help researchers protect Medicare and Medicaid beneficiaries' confidentiality. The purpose of the output review process is to help CCW VRDC users avoid accidental disclosure or the perceived disclosure of confidential information. The CCW analytical team reviews all output requested for download from the VRDC, and ensures it meets all disclosure checks before allowing the user to download it. [1]	CMS policy specifies that data shared through the VRDC: must undergo the VRDC Review Process which is disclosure review by CCW VRDC staff of analysis outputs prior to removing output data from the VRDC	[1] https://www2. 6/ccw-vrdc-dat 4/25/23) [2] CMS Staff N
		 '-ensure output containing fields representing small cell size (N > 11) to ensure beneficiary or patient information privacy. '-ensure no personal identifiers '-CMS policies prohibit individual values such as extreme observations (e.g., five smallest or five greatest values in a distribution of data). By definition, an extreme observation is a sample of size N = 1. [1] 		
		Researchers must abide by the CMS suppression policy and HIPAA. All results in the VRDC go through output review before they can be downloaded. Researchers must aggregate and de-identify results in the enclave prior to downloading the results from the VRDC. [2]		

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v2.ccwdata.org/documents/10280/1900224 data-output-review-info.pdf (Accessed:

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	Raw Language	Interpretation	
ataset 7 - T-MSIS Analytic Files (TAF) 4.2.5 How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.) IRB LOD, etc.) IRB LOD, etc.)	Raw Language CMS must ensure that all research requests for protected health information meet the requirements under the Common Rule and the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. As a result, researchers must submit the following as part of the research request packet: Common Rule If subject to the Common Rule:	Interpretation CMS specifies that for data access, a user: 1. Must submit RIF Data Use Agreement, Attachment A: RIF Application, RIF Applications Worksheet, and Data Management Plan Self- Attestation Questionnaire (DMP SAQ) 2. Must obtain review and approval from ResDAC team on the proposed research 3. Must obtain review and approval from CMS' Data Privacy Safeguard Program (DPSP) on the Data Management Plan Self-Attestation Questionnaire (DMP SAQ) 4. Must obtain IRB LOD from the requesting institution 5. Must obtain review and approval from CMS Privacy Board on the proposed research 6. Must access data through the VRDC or through encrypted shipped disks	[1] https://resda waiver-approval [2] https://resda process-timeline [3] https://resda 4/28/23) [4] CMS Staff Me

dac.org/irb-common-rule-and-hipaa-/al (Accessed: 4/25/23)

ine (Accessed: 4/25/23) ine (Accessed: 4/25/23) idac.org/request-form/dmp-saq (Accessed:

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;)		
Raw Language	Interpretation	
The DMP SAQ for Federal Agencies replaces the former Data Management Plan (DMP) requirement for CMS IDF requests. Unlike the DMP, which was specific to a single study, the DMP SAQ is an organizational-level plan and all studies using the approved environment can be covered by a single DMP SAQ.		
The Data Management Plan Self-Attestation Questionnaire (DMP SAQ) documents security and privacy controls implemented by the research organization to protect the requested Research Identifiable Files (RIF) in the environment in which the data will be stored.		
The DMP SAQ replaces the former Data Management Plan (DMP) requirement for CMS RIF requests. Unlike the DMP, which was specific to a single study, the DMP SAQ is an organizational-level plan and all studies using the approved computing environment can be covered by a single DMP SAQ.		
The DMP SAQ is based on the CMS Acceptable Risk Safeguards (ARS) security and privacy controls. Research organizations attest that the organization complies with CMS ARS security and privacy controls addressed by the questionnaire. Some questions also require additional explanation and evidence.		
The DMP SAQ recognizes information systems may vary between organizations and allows flexibility through compensating controls or alternative implementations. The important takeaway when implementing the controls is that the intent of the security and privacy control is met. For any control that cannot be met, organizations must provide justification for not being able to implement the control.		
Approved DMP SAQs are valid for one year, after which organizations will need to recertify and update the DMP SAQ to capture any changes to their environments. Any changes to the organization's environment prior to the recertification date require notification within 15 days of the change. [3]		
After CMS receives the payment for data request, the request is sent to the contractor who then pulls the requested data extracts/research files as listed in the Specification Worksheet. The data is either encrypted and shipped or made available in the VRDC. If the data is accessed in the VRDC, VRDC staff reach out to the seat holders to begin the onboarding process. This includes identity verification and security training.		
	Raw LanguageThe DMP SAQ for Federal Agencies replaces the former Data Management Plan (DMP) requirement for CMS IDF requests. Unlike the DMP, which was specific to a single study, the DMP SAQ is an organizational-level plan and all studies using the approved environment can be covered by a single DMP SAQ.The Data Management Plan Self-Attestation Questionnaire (DMP SAQ) documents security and privacy controls implemented by the research organization to protect the requested Research Identifiable Files (RIF) in the environment in which the data will be stored.The DMP SAQ replaces the former Data Management Plan (DMP) requirement for CMS RIF requests. Unlike the DMP, which was specific to a single study, the DMP SAQ is an organizational-level plan and all studies using the approved computing environment can be covered by a single DMP SAQ.The DMP SAQ is based on the CMS Acceptable Risk Safeguards (ARS) security and privacy controls. Research organizations attest that the organization complies with CMS ARS security and privacy controls addressed by the questionnaire. Some questions also require additional explanation and evidence.The DMP SAQ recognizes information systems may vary between organizations and allows flexibility through compensating controls or alternative implementations. The important takeaway when implementing the control.Approved DMP SAQs are valid for one year, after which organizations will need to recertify and update the DMP SAQ to capture any changes to their environments. Any changes to the organization's environment prior to the recertification date require notification within 15 days of the change. [3]After CMS receives the payment for data request data extracts/research files as listed in the Specification Worksheet. The data is either encrypted	Raw Language Interpretation The DMP SAQ for Federal Agencies replaces the former Data Management Plan (DMP) requirement for CMS IDF requests. Unlike the DMP, which was specific to a single study, the DMP SAQ is an organizational-level plan and all studies using the approved environment can be covered by a single DMP SAQ. The Data Management Plan Self-Attestation Questionnaire (DMP SAQ) documents security and privacy controls implemented by the research organization to protect the requested Research Identifiable Files (RIF) in the environment in which the data will be stored. The DMP SAQ replaces the former Data Management Plan (DMP) requirement for CMS RIF requests. Unlike the DMP, which was specific to a single study, the DMP SAQ is an organizational-level plan and all studies using the approved computing environment can be covered by a single DMP SAQ. The DMP SAQ is based on the CMS Acceptable Risk Safeguards (ARS) security and privacy controls. Research organizations attest that the organization complies with CMS ARS security and privacy controls addressed by the questionnaire. Some questions also require additional explanation and evidence. The DMP SAQ recognizes information systems may vary between organizations and all studies flexibility through compensating controls or alternative implementations. The important takeway when implementing the controls is that the intent of the security and privacy control is met. For any control that cannot be met, organizations must provide justification for not being able to implement the control. Approved DMP SAQs are valid for one year, after which organizations will need to recertify and update the DMP SAQ to capture any changes to their environments, Any changes to the organization's environment prior to the recert

		Pow Longuage	Interpretation	
4.2.6	How data can be used (data use	Raw Language Does not authorize/specify	Interpretation	
4.2.0	How data can be used (data use limitations)	Does not authorize/specify	Does not authorize/specify	
4.2.7	Other (specify)	Does not authorize/specify	Does not authorize/specify	
5	Data Use			
5.1	Authorizations and Applicable			
	Regulations/Policies			
5.1.1	Authorizations			
5.1.1.1	Assent	N/A	N/A	
5.1.1.2	Consent	N/A	N/A	
5.1.1.3	IRB/equivalent Privacy Board determination	Information not available/found	Information not available/found	
5.1.1.4	Local/state/federal laws	Information not available/found	Information not available/found	
5.1.1.5	Institutional Certification	Information not available/found	Information not available/found	
5.1.1.6	Data originator agreement	Information not available/found	Information not available/found	
5.1.1.7	Repository agreements/policies	Data access is authorized through CMS Privacy Board approval (the CMS Privacy Board consults with the data owner, who reviews all data requests) and under the DUA. [1]	Data Use Agreement (DUA) authorizes data use	[1] CMS Staff I
5.1.1.8	Other (specify)	Information not available/found	Information not available/found	
5.1.2	Applicable Regulations/Policies			
5.1.2.1	Local regulations/policies	Federal agencies can request TMSIS for research purposes following the standard research process (including approval by the CMS Privacy Board). Federal agencies cannot request CMS data simply to allow secondary use (e.g., to build a database for their grantees), there must be a research use to justify the initial disclosure and findings from the research must be publicly available. [1]	T-MSIS policy	[1] CMS Staff I
		For standard TAFs, the CMS Privacy Board authorizes linkage and use of the TAFs by researchers for research purposes. Linkage cannot occur if the Privacy Board does not authorize the linkage as part of the RIF application approval. [1]		
5.1.2.2	Tribal regulations/policies	Information not available/found	Information not available/found	
5.1.2.3	State regulations/policies	Information not available/found	Information not available/found	
5.1.2.4	Federal regulations/policies	CMS is a covered entity under HIPAA and is subject to the Privacy Act when collecting, using, and disclosing data. (https://www.federalregister.gov/documents/2019/02/06/20 19-01157/privacy-act-of-1974-system-of-records) [1]	 Privacy Act HIPAA Privacy Rule 	[1] CMS Staff I
5.1.2.5	International regulations/policies	Information not available/found	Information not available/found	
5.1.2.6	Contractual obligations	Information not available/found	Information not available/found	

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ataset 7 -	T-MSIS Analytic Files (TAF)			
		Raw Language	Interpretation	Source
5.1.2.7	Repository policies	The Research Identifiable File (RIF) Data Use Agreement	CMS Research Data Center (ResDAC) policy	[1] https://resdac.org/request-form/rif-data-use-
		(DUA) is a legal agreement between CMS and a requesting		agreement (also see
		organization that documents the terms and conditions under		https://resdac.org/sites/datadocumentation.resdac.org/
		which the CMS data may be used, including CMS privacy and		files/2022-10/RIF%20Data%20Use%20Agreement.pdf)
		security requirements and data release policies. [1]		(Accessed: 4/25/23))
				[2] https://resdac.org/request-form/rif-application
		The Research Identifiable File (RIF) application collects		(Accessed: 4/25/23)
		information about the requesting organization and the		[3] <u>https://resdac.org/request-form/key-personnel-</u>
		research study, including detailed study aims, data required,		supplement (Accessed: 4/25/23)
		and dissemination of findings plan. The RIF application is used		[4] https://resdac.org/request-form/rif-specifications-
		by CMS to assess the feasibility of the research and		worksheet (Accessed: 4/25/23)
		compliance with CMS data use and release policies. [2]		[5] CMS Email Communication
				[6] IEA Template
		The Key Personnel Supplement collects information about		
		each request's key contacts including the requester,		
		collaborating organizations and additional contacts who		
		should be included on notices about the project. [3]		
		The Specifications Worksheet is required for all RIF requests.		
		It collects detailed requester information, study/project data		
		extract details, shipping information, and method of		
		payment. It also includes a Part D event justification tab that		
		is required for all requests that include Part D data. The		
		Specifications Worksheet is used by the data distributor to		
		generate a cost invoice and to collect data extraction		
		information.[4]		
		CMS Information Exchange Agreement (IEA): "This is used to		
		modify the terms of the research DUA to allow redisclosure of	:	
		linked datasets by federal agencies. However, we are		
		exploring creating a research DUA addendum with standard		
		clauses for the redisclosure scenario instead. This document		
		is also used by the CMS Privacy Office for other types of		
		disclosures (other than research) or exchanges with federal		
		agencies."		
		[5]		
5.2		, access, and use based on data access authorization or a		of the governance)
5.2.1		Does not authorize/specify	Does not authorize/specify	
5.2.2	With what other data can it be linked	Does not authorize/specify	Does not authorize/specify	
	or can it not be linked (scope of			
	linkage)			
5.2.3		Does not authorize/specify	Does not authorize/specify	
5.2.4	-	Does not authorize/specify	Does not authorize/specify	
	identification status, disclosure			
	review)			
5.2.5	-	Does not authorize/specify	Does not authorize/specify	
	type, data use agreement, data			
	access committee/group approval,			
	IRB LOD, etc.)			

	T-MSIS Analytic Files (TAF)			1
		Raw Language	Interpretation	
5.2.6	How data can be used (data use	Federal agencies can request TMSIS for research purposes	1. T-MSIS policy specifies that there must be a	[1] CMS Staff
	limitations)	following the standard research process (including approval	research use to justify the initial disclosure and	[2]
		by the CMS Privacy Board). Federal agencies cannot request	findings from the research must be publicly	https://resda
		CMS data simply to allow secondary use (e.g., to build a	available.	files/2022-10
		database for their grantees), there must be a research use to	2. Data Use Agreement (DUA) specifies that data	
		justify the initial disclosure and findings from the research	will be used solely for the study described in detail	
		must be publicly available.	in the RIF Request Application	
		[1]		
		For standard TAFs, the CMS Privacy Board authorizes linkage		
		and use of the TAFs by researchers for research purposes.		
		Linkage cannot occur if the Privacy Board does not authorize		
		the linkage as part of the RIF application approval.		
		[1]		
		DATA USE AGREEMENT FOR USE OF CENTERS FOR MEDICARE		
		AND MEDICAID SERVICES (CMS) RESEARCH IDENTIFIABLE		
		FILES (RIFS):		
		a) The data files specified in Attachment A – RIF Request		
		Application, as well as any derivative data, will be used solely		
		for the study titled:, as described in detail in		
		"Attachment A – RIF Request Application", as modified, if		
		applicable, by submitting a request and receiving CMS		
		approval to amend Attachment A – RIF Request Application.		
		c) Attachment A - RIF Request Application contains a detailed		
		description of the entirety of the research to be done in the		
		above-referenced research study, the research could not		
		practicably be conducted without CMS data, and the		
		requested data is the minimum necessary to achieve the		
		stated research purpose(s).		
		d) As described in Attachment A – RIF Request Application		
		that is submitted to CMS, the researcher believes that the		
		study demonstrates the potential to improve the		
		administration of the Medicare and Medicaid programs [2]		
5.2.7	Other (specify)	Does not authorize/specify	Does not authorize/specify	
	PII Elements			

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c.org/sites/datadocumentation.resdac.org/ /RIF%20Data%20Use%20Agreement.pdf

lasel	7 - T-MSIS Analytic Files (TA			
		Raw Language	Interpretation	
6.1	PII elements collected	The eligible individual's social security number. For newborns		[1] <u>https://ww</u>
		when value is unknown it is not required. For SSN states, in	Address, City, State, Zip code, date of birth, sex	<u>elements/</u> (Acc
		instances where the social security number is not known and		
		a temporary MSIS Identification Number is used, the MSIS		
		Identification Number field should be populated with the		
		temporary MSIS Identification Number and the SSN field		
		should be space-filled, or blank. When the SSN becomes		
		known, the MSIS Identification Number field should continue		
		to be populated with the temporary MSIS Identification		
		Number and the SSN field should be populated with the		
		newly acquired SSN for at least one monthly submission of		
		the Eligible File so that T-MSIS can associated the temporary		
		MSIS Identification Number and the social security number.		
		The last name of the individual to whom the services were		
		provided. (The patients name should be captured as it		
		appears on the claim record, it does not need to be the same		
		as it appears on the eligibility file. The MSIS Identification		
		Number will be used to associate a claim record with the		
		appropriate eligibility data.)		
		The first name of the individual to whom the services were		
		provided. (The patients name should be captured as it		
		appears on the claim record, it does not need to be the same		
		as it appears on the eligibility file. The MSIS Identification		
		Number will be used to associate a claim record with the		
		appropriate eligibility data.)		

ww.medicaid.gov/tmsis/dataguide/dataccessed: 4/25/23)

Dataset 7 -	T-MSIS Analytic Files (TAF)			
		Raw Language	Interpretation	
		Individual's middle initial; middle initial component of full name (e.g. First Name, Middle Initial, Last Name).		
		The first line of a potentially multi-line physical street or mailing address for a given entity (e.g. person, organization, agency, etc.).		
		The city component of an address associated with a given entity (e.g. person, organization, agency, etc.).		
		The ANSI state numeric code for the U.S. state, Territory, or the District of Columbia code for where the individual eligible to receive healthcare services resides. (The state for the type of address indicated in Address Type.)		
		U.S. ZIP Code component of an address associated with a given entity (e.g. person, organization, agency, etc.)		
		Date of birth of the individual to whom the services were provided. A patient's age should not be greater than 112 years.		
		Either individual's biological sex or their self-identified sex. [1]		
6.2	PII elements holder (i.e., party that holds the PII)	(See data dictionary definitions in 6.1)	PII elements are part of the research identifiable dataset from TMSIS	[1] <u>https://ww</u> elements/ (Ac
6.3	Use of common data model, if any, for data collection	Information not available/found	Information not available/found	
7	Prior Data Linkages			
7.1	Dataset linked with other datasets			
7.1.1	Name of other linked dataset	NCHS survey data from participants who consented to linkage Approval for the linkage was provided by the NCHS Research Ethics Review Board (ERB). [1]	Linkage was performed only on consented data with approval from NCHS ERB	[1] <u>https://wv</u> <u>cms-tmsis-link</u>
7.1.2	Other dataset type (clinical, EHR, survey, claims, SDOH, etc.)	 NCHS has recently linked data from following surveys to 2014-2019 CMS T-MSIS enrollment and claims data: 1994-2018 National Health Interview Survey (NHIS) 1999-2018 Continuous National Health and Nutrition Examination Survey (NHANES) Third National Health and Nutrition Examination Survey (NHANES) Third National Health and Nutrition Examination Survey (NHANES III) 2004 National Nursing Home Survey (NNHS) 	Survey data from NCHS (NHIS, NHANES, and NNHS)	[1] <u>https://wv</u> cms-tmsis-link
7.1.3	Other dataset source(s)	NCHS	Source was NCHS datasets	[1] <u>https://wv</u> cms-tmsis-linl

Source www.medicaid.gov/tmsis/dataguide/data-(Accessed: 4/25/23) /www.cdc.gov/nchs/data/datalinkage/nchslinkage-methodology.pdf (Accessed: 4/25/23) www.cdc.gov/nchs/data/datalinkage/nchslinkage-methodology.pdf (Accessed: 4/25/23) /www.cdc.gov/nchs/data/datalinkage/nchslinkage-methodology.pdf (Accessed: 4/25/23)

		Development	Internetation	
		Raw Language	Interpretation	[[]]
7.1.4	Linking methodology (PPRL or non- PPRL); linkage technology	The NCHS survey participant records and the CMS T-MSIS enrollment database were linked using both deterministic	Non-PPRL method was used - both deterministic using direct identifiers and probabilistic using	[1] <u>https://www</u> cms-tmsis-linka
		and probabilistic approaches. For the probabilistic approach,	various PII	
		scoring was conducted according to the Fellegi-Sunter		
		method. Following this, a selection process was implemented		
		with the goal of selecting pairs believed to match (i.e.,		
		representing the same individual between the data sources).		
		1. Deterministic linkage joined records on exact SSN, with		
		links validated by comparing other identifying fields (i.e., first		
		name, last name, day of birth, etc.)		
		2. Probabilistic linkage identified likely matches, or links,		
		between all records. All records were probabilistically linked		
		and scored as follows:		
		a. Formed pairs via blocking		
		b. Scored pairs		
		c. Modeled probability – assigned estimated probability that		
		pairs are matches		
		3. Pairs were selected that were believed to represent the		
		same individual between data sources (i.e., they are a match).		
		Deterministic matches (from step 1) were assigned a match		
		probability of 1 and records selected from the probabilistic		
		match (step 2) were assigned the modeled match probability.		
		For each NCHS survey participant record that was linked, CMS		
		extracted the T-MSIS claims information and sent the data to		
		NCHS following secure data transfer procedures.		
		[1]		
7.1.5	PII elements used for the linkage	Linkage-eligible NCHS survey participant records were linked	Broad set of PIIs were used:	[1] <u>https://www</u>
		to the CMS T-MSIS enrollment database using the following	SSN (9 digits or last 4 digits, depending on the	cms-tmsis-linka
		identifiers: SSN (9 digits or last 4 digits, depending on the	survey and year of the survey), first name, last	
		survey and year of the survey), first name, last name, middle	name, middle initial, month of birth, day of birth,	
		initial, month of birth, day of birth, year of birth, 5-digit ZIP	year of birth, 5-digit ZIP code of residence, state of	
		code of residence, state of residence, and sex.	residence, and sex.	
		[1]		
7.1.6	Entity resolver (data originator or	NCHS	NCHS	[1] https://www
7.1.0	data linker or third party)			cms-tmsis-linka
7.1.7	Party performing the linkages	NCHS	NCHS	[1] <u>https://www</u>
				cms-tmsis-linka

Source vww.cdc.gov/nchs/data/datalinkage/nchsnkage-methodology.pdf (Accessed: 4/25/23) vww.cdc.gov/nchs/data/datalinkage/nchsnkage-methodology.pdf (Accessed: 4/25/23) vww.cdc.gov/nchs/data/datalinkage/nchsnkage-methodology.pdf (Accessed: 4/25/23) vww.cdc.gov/nchs/data/datalinkage/nchsnkage-methodology.pdf (Accessed: 4/25/23)

		Raw Language	Interpretation	
7.1.8	Linkage quality assessment	Subsequent to performing the record linkage analysis an error analysis was performed. There are two type of errors that were estimated: • Type I Error: Among pairs that are linked, what percentage of them were not true matches • Type II Error: Among true matches, how many were not linked [1]	Linkage error analysis was performed - details in the pdf file	[1] <u>https://www</u> cms-tmsis-linka
7.1.9	Linked data sharing method (linkage maps or pre-linked dataset)	To ensure confidentiality, NCHS provides safeguards including the removal of all personal identifiers from analytic linked files. Additionally, the linked data files are only made available in secure facilities for approved research projects. Researchers who wish to access the Linked NCHS-CMS T-MSIS data files must submit a research proposal to the NCHS Research Data Center (RDC) to obtain permission to access the restricted use files. All researchers must submit a research proposal to determine if their projects are feasible and to gain access to these restricted data files. The proposal provides a framework which allows RDC staff to identify potential disclosure risks. More information regarding the RDC and instructions for submitting an RDC proposal are available from: <u>https://www.cdc.gov/rdc/</u> (accessed September 19, 2022). [1]	through the RDC for approved research projects.	[1] <u>https://www</u> cms-tmsis-linka

www.cdc.gov/nchs/data/datalinkage/nchsinkage-methodology.pdf (Accessed: 4/25/23)

vww.cdc.gov/nchs/data/datalinkage/nchsnkage-methodology.pdf (Accessed: 4/25/23)

								[L		TABLE 1: USE CAS Table 1 = information n			rmed to not exist]								
	Governance	Data Collection	Data Linkage	Dataset 1 - N3C Data Sharing	Data Access	Data Use	Data Collection	Data Linkage	Dataset 2 - PEDSno Data Sharing		Data Use	Data Collection	Data Linkage	Dataset 3 - RADx-L Data Sharing	JP Data Access	Data Use	Data Collection	Data Linkage	Dataset 4 - EPA Data Sharing	Data Access	Data Use
Au .1 As	uthorization/s ssent	N/A	N/A	N/A	N/A	N/A	Assent authorizes data collection.					Assent from children authorizes data collection.	Does not authorize/ specify	Assent from children authorizes data sharing.	Does not authorize/specify	Does not authorize/specify	N/A	N/A	N/A	N/A	N/A
.2 Co	onsent	N/A	N/A	N/A	N/A	N/A	Consent authorizes data collection.	Consent (when obtained) authorizes data linkage.					Does not authorize/ specify	Consent from parents authorizes data sharing.	Does not authorize/specify	Does not authorize/specify	N/A	N/A	N/A	N/A	N/A
Pri	B/equivalent rivacy Board etermination	N/A		Two IRB determinations authorize data sharing: 1. Institutional IRB or external central IRB approval for transfer of data from participating institutions to the NCATS N3C Platform 2. NIH IRB waiver of consent for sharing through the NCATS N3C Platform	user's Insitutional IRB authorizes data	Letter of Determination from user's institutional IRB authorizes data access	approval authorizes	IRB authorizes data linkage for research conducted under a waiver of consent.		Human Subjects Review (IRB review or determination) authorizes data access in two possible paths: 1. Non-Human Subjects Research (NHSR) determination: no further review/MRA required 2. Human Subjects Research (HSR) determination: requester IRB approval with IRB reliance for site providing data (NPRA MRA or SMART IRB MRA is also required		AHARO Health Centers/Comprehens ive Health Center IRB authorizes data collection.	· · ·			Does not authorize/specify	N/A	N/A	N/A	N/A	N/A
.4 Lo lav		HIPAA authorizes health care providers to release data to N3C	N/A					PEDSnet Steering Committee approval authorizes data linkage as part of a specific study research plan.	n	Network Participation Approval (PEDSnet Executive Committee Approval) authorizes data access.	Steering Committee authorizes data use.	Hawaii DOE Data Governance and Analytics Branch authorizes data collection.		FERPA authorizes data sharing.			Clean Air Act authorizes data collection by state/local/tribal air pollution control agencies for reporting to the EPA.		Clean Air Act authorizes data sharing.		
	stitutional ertification	N/A	N/A		N/A									RADx Institutional Certification authorizes data sharing.		The RADx Institutional Certification authorize data use.		N/A	N/A	N/A	N/A
	ata originator greement		authorize data linkage: 1. The Linkage	Agreement (DTA) executed with NCATS authorizes data transfer to NCATS N3C Platform			Master Reliance Agreement authorizes data collection under one IRB.	sites authorize data linkage on a study-by-	Two agreements authorize data sharing: 1. PEDSnet Participation and DUA signed by PEDSnet members authorizes data sharing between PEDSnet members. 2. PEDSnet sites data release vote authorizes data sharing (i.e., release)	approval) authorizes data access.	Two agreements authorize data use: 1. PEDSnet Site PI written affirmation authorizes data use fo other investigators 2. PEDSnet site participation vote authorizes data use fo individual studies			Agreement For Disclosure And Transfer Of Confidential Information And Protected Health Information authorized data sharing.	5						N/A
	epository greements/policies		The External Dataset Committee in the Tools and Resource subgroup and NCATS approval authorizes data linkage		Two repository agreements authorize data access: 1. Data Use Agreement 2. Data Use Request	authorize data use: 1. Data Use Agreement			PEDSnet Master Data Use Agreement authorizes data sharing.	a Legal review (comprised of PEDSnet Data use agreement and Responsible Use of Data Agreement) authorizes data access.	Data use agreement and Responsible Use o Data Agreement)				Three repository agreements authorize data access: 1. RADx Data Use Certification (DUC) Agreement 2. Genomic Data Use Coder of Conduct 3. RADxSM Data User Code of Conduct	RADx Data Use Certification Agreement authorizes data use.	N/A	AQS being in the public domain authorizes data linkage.		AQS being in the public domain authorizes data access.	AQS being in the public domain authorizes data
8 Ot	ther (specify)		The External Dataset Committee in the Tools and Resource subgroup and NCATS approval authorizes data linkage				Waiver of consent authorizes data collection for routine delivery of health care.			Network Participation Approval (PEDSnet Executive Committee Approval) authorizes data access.	Steering Committee authorizes data use.										
	pplicable Regulati																				A second second
	ocal regulations/ olicies		N3C policy designation of external datasets	N3C policies		N3C Data User Code of Conduct			PEDSnet policy		PEDSnet policy										

										ASE 3 - DATASET O not available/found; N/		irmed to not exist]								
				120																
	Governance		Dataset 1 - I					Dataset 2 - PEDSne					Dataset 3 - RADx-					Dataset 4 - EPA		
	Tribal regulations/policies	Data Collection	Data LinkageData Sharing1. NIH Guidance of the Implementat of the HHS Tribal Consultation Poli 2. Tribal Consulta Report	on	Data Use1. NIH Guidance onthe Implementationof the HHS TribalConsultation Policy2. Tribal ConsultationReport		Data Linkage	Data Sharing	Data Access	Data Use	Data Collection	Data Linkage	Data Sharing	Data Access	Data Use	Data Collection	Data Linkage	Data Sharing	Data Access	Data Use
	State regulations/policies							State regulations												
	Federal regulations/policies	HIPAA Privacy Rule	HHS Tribal Consultation Poli	Certificate of cy Confidentiality	HHS Tribal Consultation Policy			 Federal regulation: 45 CFR 46 (Common Rule) HIPAA Privacy Rule 												
	International regulations/policies																			
2.6	Contractual Obligations			Obligations from contract between NCATS and Palantir																
2.7	Repository policies		N3C policy designation of	N3C policies, includir N3C Results	ng N3C policies	-			PEDSnet policy	PEDSnet policy			RADx Data Hub policy	RADx Data Hub policy	RADx Data Hub policy	N/A	AQS policy		AQS policy	AQS policy
3	Data Linking/Sharin		external datasets ernance Based on Authorizations and	Download Policy	/Policies															
3.1	Whether the data can be linked	n Does not authorize/specify	 1. LHBA specifies that the data can be linked 2. Participating PPRL sites specify that data can be linked with particular external datasets 2. The External Dataset Committee in the Tools and Resource subgroup and NCATS approval specifies that data can be linked 	Does not	Does not authorize/specify	linked.	 Consent (when obtained) specifies that data can be linked. PEDSnet Steering Committee approval specifies that data can be linked according to the approved research plan. Individual PEDSnet sites, through a study particpation vote, specify that the sites can participation in data linkage on a study-by-study basis. IRB specifies that PEDSnet data can be linked for research conducted under a waiver of consent. 	n b h	Does not authorize/specify	Individual PEDSnet sites, through a study particpation vote, specify participation in data linkage on a study by-study basis	do not specify linkage. Raw 'language referring to "other research studies" is interpreted by the study PI as leaving the option open for data linkage. 2. AHARO Health Centers/Comprehen	 consent and assent do not specify linkage. Raw language refering to "other research studies" is interpreted by the study PI as leaving the option open for data linkage. 2. AHARO Health Centers/Comprehen ive Health Center IRE specifices that data can be linked at an f individual level only 	 if consent and assent do not specify linkage. Raw language refering to "other research studies" is interpreted by the study PI as leaving the option open for data linkage. 	g	Does not authorize/specify	Does not authorize/specify	N/A	Does not authorize/specify		Does not authorize/specify
3.2	With what other data can it be linked or can it not be linked (scope of linkage)		1. N3C policyCommon Ruledesignation ofexternal datasets forlinking specifies that:a.a. External datasetsmust be classified asClass 0, 2, 3, or 4 tobe considered forN3C linkage. Adataset which isdataset which iscategorized as class 2can be imported butwill require hashingb. Class 1 linkages arenot permitted2. Participating PPRLsites specify linkageswith externaldatasets on a case-by-case basis3. External DatasetCommittee in theTools and Resourcesubgroup and NCATSdetermines the scopeof linkage byapproving externaldatasets for importand linkage withinN3CN3C	Does not authorize/specify	Does not authorize/specify	protocols specify that data can be linked using PPRL for research conducted under a waiver of consent.	using PPRL for research conducted under a waiver of	authorize/specify	Does not authorize/specify	Does not authorize/specify	outside of general research purposes	individual level or outside of general research purposes must be approved by	y Does not authorize/specify	Does not authorize/specify	Does not authorize/specify	Does not authorize/specify	N/A	Does not authorize/specify	Does not authorize/specify	Does not authorize/specify

										TABLE 1: USE CA	ASE 3 - DATASET	GOVERNANCE								
									[Legend: Blank cell in ⁻	Table 1 = information	not available/found; I	N/A = information cor	firmed to not exist]							
	Governance			Dataset 1 - N3C					Dataset 2 - PEDSne	et				Dataset 3 - RADx-UP				Dataset 4 - EPA		
		Data Collection	Data Linkage		Data Access	Data Use	Data Collection	Data Linkage	Data Sharing	Data Access	Data Use	Data Collection	Data Linkage	Data Sharing Data Access	Data Use	Data Collection	Data Linkage	Data Sharing	Data Access	Data Use
3.3	Whether data can be shared	e Does not authorize/specify	Does not authorize/specify	 NIH IRB waiver of consent specifies that data can be shared Data Transfer Agreement specifies that data can be shared NIH Guidance on the Implementation of the HHS Tribal Consultation Policy, the HHS Tribal Consultation Policy, and the Tribal Consultation Report specify that AI/AN data can be shared 		Does not authorize/specify	Does not authorize/specify	Does not authorize/specify	 PEDSnet sites data release vote specifies whether data can be shared (i.e., release). The PEDSnet Master DUA specifies whether data can be shared. 45 CFR 46 (Common Rule) and HIPAA Privacy Rule specifies that de- identified data can be shared. 	authorize/specify	Does not authorize/specify	Parental informed consent specifies that data will be shared with other researchers.	Parental informed consent specifies that data will be shared with other researchers.	The following specify that data can be shared:Does not authorize/specshared:1. Parental informed consent language.2. FERPA3. Agreement For Disclosure And Transfer Of Confidential Information And Protected Health Information (study data, including PHI, to be sent to Duke (CDCC) and for Duke to provide de- identified project data for the awarding agency.)4. Study registration in dbGaP.5. RADx Institutional Certification (in the RADx Data Hub by the CDCC/Duke)	RADx Institutional Certification specifies that the CDCC (Duke i the case of RADx UP) submits data to the RADx Data Hub.	authorize/specify	N/A	Clean Air Act specifies that ambient air data can be shared.		Does not authorize/specify
3.4	How data can be shared (de- identification status, disclosure review)	HIPAA specifies that N3C data partners (health care providers) car release limited EHF dataset (with no direct PII) for research purposes	3	 N3C policy specifies limited datasets (LDS), de-identified, and synthetic datasets are shared. NIH Guidance on the Implementation of the HHS Tribal Consultation Policy, the HHS Tribal Consultation Policy, and the Tribal Consultation Report specify that (a). AI/AN data will be a standalone category With this change, AI/ AN data will be available in any N3C analysis that provides race and ethnicity distribution.(b). ZIP codes must be removed entirely for all geographic units containing 20,000 or fewer people, and full five-digit ZIP codes of predominantly AI/AN community will never be shown. 	authorize/specify f /	Does not authorize/specify	Does not authorize/specify	Does not authorize/specify	 1. State and federal regulations specify that HIV-related data and reproductive and mental health health care data for minors must be removed before sharing data. 2. PEDSnet regulations specify that individual level data must be deidentified using the Safe Harbor method of de-identification of PHI before sharing data. 3. PEDSnet policy specifies that a risk review is performed on the requested datasets as well as data transformations, such as date shifts, replacement labels for free text fields and geographic information, and removing HIV/pregnancy/ mental health data prior to data sharing. 	authorize/specify f	Does not authorize/specify	Does not authorize/specify	Does not authorize/specify	CDCC/Dukey1. RADx policy specifies that the study be registered in dbGaP prior to sharing through RADx Data Hub. 2. The RADx Institutional Certification specifies that all data shared in an NIH designated repository must be de- identified. 3. The RADx DCC works with study teams to de- identify zip codes, shift dates, and adjust ages into categories for specific ages.		that ambient air data be shared through EPA's Air Quality System (AQS).	N/A	specifies that full geographic identifiers including site address, zip code,	AQS policy specifies that full geographic identifiers including site address, zip code, CBSA, county, and state are shared	authorize/specify

											SE 3 - DATASET G		firmed to not original								
											not available/found; N/	A = Information cor	infrmed to not exist]								
	Governance			Dataset 1 - N3C					Dataset 2 - PEDSne					Dataset 3 - RADx-I		D · · · ·			Dataset 4 - EPA		
3.5	How data can be	Data Collection	Data Linkage	Data Sharing for The DTA specifies that	Data Access	Data UseN3C policy specifies	Data Collection	Data Linkage Does not	Data Sharing Does not	Data Access PEDSnet human	Data Use PEDSnet policy	Data Collection Does not	Data Linkage Does not	Data SharingRADx Institutional	Data Access The dbGaP data access	Data Use RADx Institutional	Data Collection Does not	Data Linkage	Data Sharing Does not	Data AccessAQS being in the	Data Use Does not
5.5	accessed (access		data access, there	users who access the		that to access the	authorize/specify	authorize/specify	authorize/specify	subjects review,	specifies that the	authorize/specify	authorize/specify	Certification specifies		Certification specifies		N/A	authorize/specify	public domain	authorize/specify
	type, data use	data partners	must be:	data will access the		Limited Dataset, the	authorize, speeny	authonize/specify	autionze, speeny	network participation	requester:	authonize/specify	autionze/speeny	that all individual-leve		that all individual-level			authorize/speeny	specifies that the	autionize/speeny
	agreement, data	(health care	1. For N3C Class 0 c		user:	user:				review, institutional	1. Must sign DUA and			data are controlled	· · ·	data are controlled				data is open access.	
	access committee/	providers) must	Class 2 linkages:	NCATS N3C Platform	1) Must complete	1) Must complete					, RUD (Responsible Use			access.	requirements/steps	access.				·	
	group approval,	enter into a data	a. Existing		N3C registration and	N3C registration and				and legal review	of Data) (Legal Review)				specify that the user/						
	IRB LOD, etc.)	use agreement	institutional N3C Da	ata	create a N3C Data	create a N3C Data				specify that the	2. Must access the				eligible investigator:						
		with limited EHR	Use Agreement		Enclave account	Enclave account				requester:	data through a										
		dataset receipients				2) Must execute an					t workspace within the				1) Must have an eRA						
			authentication and			Institutional Data Use					PEDSnet cloud				commons or Login.go	v					
			authorization		Agreement	Agreement				the Research	enclaveORto have				account						
			c. Signed institution							Committee	the data transfered to				2) Must submit a Data						
			linkage honest brok agreement for	er		Use Request (DUR)				2. Must undergo IRB review/determination	their institution, the				Access Request (DAR). Data Use Certification						
			multiple datasets		for approval by N3C Data Access	Data Access				(Human Subjects	Approval request				(DUC) Agreement, the						
			d. Approved data us	se	Committee	Committee				Review)	should specify,				Genomic Data User						
			request (DUR) by th		4) Must complete NIH					· ·	pending approval from	n			Code of Conduct, and						
			federally staffed dat		IT training, attest to	· ·					all PEDSnet institutions				the RADx SM Data Use	r					
			access committee		-	attest to the N3C				NHSR, then no further	providing data for the				Code of Conduct are						
			(DAC)		Code of Conduct, and	Data User Code of				review/MRA required	request				signed as part of the						
			e. Local institutions		· ·	Conduct, and				4. If IRB determines					DAR process						
			IRB letter of			complete Human				the proposed study					3) Must ensure that th	e					
			determination		Protection training at					HSR, the requester					Signing Official from						
			f. Interconnect		their home institution					must provide IRB					investigator's institutio						
			agreement (for Clas 0 only)	SS	5) Must provide IRB					approval with IRB					reviews, approves, and	1					
			U UIIIY)		letter of determination for	letter of determination for				reliance for site providing data					co-signs the request 4) Must receive						
			2. For N3C Class 3		data access	data access				(NPRA MRA or SMART					approval from Data						
			and 4 linkages:			6) Must access the				IRB MRA is also					Access Committee						
			a. Approved data		data within the N3C					required)					5) Must access the						
			use request (DUR) b	ру		Enclave				5. Must sign DUA and					controlled access data						
			the federally staffed	k	7) Must abide by the					RUD (Responsible Use					through RADx Data Hu	b					
			data access		N3C Results					of Data) (Legal Review)					Jupyter Notebooks						
			committee (DAC)		Download Policy					6. Must receive											
					when downloading					prospective site PI											
					results from the N3C					approval (Institutional											
					enclave					Participation Approval) 7. Must receive											
										PEDSnet Executive											
										Committee approval											
										(Network Participation											
										Approval)											
										8. Must access the											
										data through a											
										workspace within the											
										PEDSnet cloud											
										enclaveORto have											
										the data transfered to											
										their institution, the PEDSnet Study											
										Approval request											
										should specify,											
										pending approval from											
										all PEDSnet institutions											
										providing data for the											
										request.											
L																					

											ASE 3 - DATASET (
								լլ			not available/found; N	A = information conf	firmed to not exist]								
	Governance			Dataset 1 - N3C					Dataset 2 - PEDSn	et				Dataset 3 - RADx-L	JP				Dataset 4 - EPA		
		Data Collection	Data Linkage	Data Sharing	Data Access	Data Use			Data Sharing	Data Access	Data Use	Data Collection	Data Linkage	-	Data Access	Data Use	Data Collection	Data Linkage	Data Sharing	Data Access	Data Use
	How data can be	HIPAA privacy	Does not	1. The Tribal		1. N3C DUA specifies		PEDSnet site	Does not	Does not	PEDSnet policy	Does not			Does not	RADx Institutional	Does not	N/A	Does not	Does not	No data use
			authorize/specify	Consultation Report		e that the data must be	authorize/specify	participation vote	authorize/specify	authorize/specify	specifies two data use	authorize/specify	authorize/specify	Certification specifies	authorize/specify	Certification specifies	authorize/specify		authorize/specify	authorize/specify	limitations since the
	use limitations)	that de-identified			used exclusively for			specifies data use for			limitations:			that the data can be		that the use of data is					data is open
		data can be used			the Research Project	-		individual studies.			1. Data can only be			used for general		for general research					access
		for general		attest that they		proposed, and/or					used for the purposes			research purposes.		purposes.					
		research purposes	i.								specified and approved										
				contains no Tribal	using data from	using data from					by the Steering										
				affiliation data and that use of AI/AN		individuals infected with pathogens such					Committee. Namely, using data from real-										
				data and ZIP code	as SARS, MERS, and						world clinical settings										
				information to make		H1N1 to support					for research, quality										
					comparative studies.						measurement, and										
				Tribal affiliation is not		2. N3C Data User					improvement/										
				valid or appropriate		Code of Conduct					advancement of child										
				2. The DTA specifies		specifies that N3C					health, particularly										
				that data must be		data must only be					studies that inform or										
				used only for		used for COVID-19					directly address clinica	I									
				research purposes		general research					decision making,										
				and public health		purposes.					including retrospective										
				activities related to		3. NIH Guidance on					observational studies										
				the COVID-19		the Implementation of the HHS Tribal					2. Cannot be used for commercial sale										
				pandemic		Consultation Policy,					commercial sale										
						the HHS Tribal															
						Consultation Policy,															
						and the Tribal															
						Consultation Report															
						specify that data															
						users will be asked to															
						attest that they															
						understand the N3C															
						contains no Tribal															
						affiliation data and															
						that use of AI/AN															
						data and ZIP code															
						information to make assumptions about															
						Tribal affiliation is not															
						valid or appropriate.															
						4. User must also															
						comply with the N3C															
						Community Guiding															
						Principles and the															
						Attribution and															
						Publication Principles															
3.7	Other (specify)	Does not	Does not	Does not	1. Contract between		Does not	Does not	Does not	Does not	Does not	Does not	Does not	Does not	Does not	Does not		N/A	Does not	Does not	Does not
		authorize/specify	authorize/specify	authorize/specify	NCATS and Palantir		authorize/specify	authorize/specify	authorize/specify	authorize/specify	authorize/specify	authorize/specify	authorize/specify	authorize/specify	authorize/specify	authorize/specify	authorize/specify		authorize/specify	authorize/specify	authorize/specify
					specifies that Palantin																
					contractors with																
					access to the NCATS GovCloud instance to																
					implement and																
					maintain the NCATS																
					N3C Data Enclave ar	e															
					subject to all relevant																
					NIH-specified																
					clearances, non-																
					disclosure																
					agreements, training,																
					rules and restrictions																
					and are not allowed																
					to independently																
					access NCATS N3C																
					Data Enclave data, remove it from the																
					enclave, or use it for																
					commercial purposes																
					2. Certificate of																
					Confidentiality																
					protects N3C data																
					from certain types of																
					disclosures.																

	s are restrictions on data linkage and use (e.g., dataset sharing, access, and use (e.g., user must access data in a authorization or the authorization is not available or	a physical enclave, user must sign data use agreement,		.). Authorization gaps exist when there i
	Can the datasets be linked?	What limitations do the linked datasets inherit?	What controls do the linked dataset require?	What authorization gaps exi
N3C (Dataset 1)	Yes, N3C and PEDSnet can be linked provided:	Researchers/users must:	For sharing:	No authorization gaps exist
and PEDSnet		1a. Use N3C data within the N3C Enclave [N3C]	A. N3C staff must:	
(Dataset 2) linkage	A. N3C staff:	1b. Use N3C data for COVID-19 general research	1a. Share N3C limited datasets (LDS), de-identified	
	1. Shares N3C limited datasets (LDS), de-identified	purposes [N3C]	datasets, or synthetic datasets [N3C]	
	datasets, or synthetic datasets [Control 1a]	1c. Not use AI/AN data and ZIP code information to make		
	2. Removes ZIP codes entirely for all geographic units	assumptions about Tribal affiliation [N3C]	containing 20,000 or fewer people and replace full five-	
	containing 20,000 or fewer people and replaces full five-	1d. Work with N3C staff to link Class 2 or Class 0 data	digit ZIP codes of predominantly AI/AN communities with	
	digit ZIP codes of predominantly AI/AN communities with	using PPRL [N3C]	partial ZIP codes [N3C]	
	partial ZIP codes [Control 1b]	1e. Comply with the N3C Community Guiding Principles	1c. Have waiver of consent from NIH IRB for sharing data	
	3. Has waiver of consent from NIH IRB for sharing data	and the Attribution and Publication Principles [N3C]	through the NCATS N3C Platform [N3C]	
	through the NCATS N3C Platform [Control 1c]		B. Data providers must:	
		2a. Use the data in a workspace within the PEDSnet	1d. Execute a Data Transfer Agreement (DTA) with NCATS	
	B. Data providers:	cloud enclaveORat their own institution if approved to		
	4. Execute a Data Transfer Agreement (DTA) with NCATS	have the data transferred to their institution by all	1e. Obtain institutional or external IRB approval [N3C]	
	[Control 1D]	PEDSnet institutions providing data for the request	zer ostan institutional of external ind approval [NSC]	
	5. Obtain institutional or external IRB approval [Control	[PEDSnet]	For sharing, PEDSnet staff must:	
	1E]	2b. Use the data for purposes specified and approved by	2a. Remove HIV-related data and reproductive and	
	1	participating sites and the Steering Committee, namely	mental health care data for minors [PEDSnet]	
	C. PEDSnet staff:	using data from real-world clinical settings for research,	2b. De-identify individual level data using the Safe Harbor	
	6. Removes HIV-related data and reproductive and mental	quality measurement, and improvement/advancement	method of de-identification of PHI [PEDSnet]	
	health care data for minors [Control 2a]	of child health, particularly studies that inform or	2c. Perform a risk review on the requested datasets as	
	7. De-identifies individual level data using the Safe Harbor	directly address clinical decision making, including	well as data transformations, such as date shifts,	
	method of de-identification of PHI [Control 2b]	retrospective observational studies. [PEDSnet]	replacement labels for free text fields and geographic	
	8. Performs a risk review on the requested datasets as	2c. Work with PEDSnet staff to link data conducted		
	well as data transformations, such as date shifts,	under a waiver of consent using PPRL [PEDSnet]	information, and removing HIV/pregnancy/mental health	
	replacement labels for free text fields and geographic	under a waiver of consent using FFRE [FEDShet]	data [PEDSnet]	
	information, and removing HIV/pregnancy/mental health		For accessing N3C, researchers/users must:	
	data [Control 2c]		1f. Execute Institutional Data Use Agreement (DUA) with	
			NCATS [N3C]	
	D. The researcher/user:			
	1. Uses the linked N3C and PEDSnet data for general		1g. Submit Data Use Request (DUR) for approval by N3C Data Access Committee [N3C]	
	COVID-19 research purposes specified and approved by			
	PEDSnet participating sites and the PEDSnet Steering		1h. Complete NIH IT training, attest to the N3C Data User Code of Conduct, abide by the N3C Results Download	
	Committee [Limitations 1b and 2b]		Policy, and complete Human Subjects Research Protection	
	Does not use the linked data to make assumptions		training [N3C]	
	about Tribal affiliation [Limitation 1c]		1i. Provide IRB letter of determination for data access	
	3. Complies with the N3C Community Guiding Principles		[N3C]	
	and the Attribution and Publication Principles [Limitation			
	1e]		1j. Access the data within the N3C Enclave [N3C]	
	4. Executes the Institutional Data Use Agreements (DUA)		For linking N3C data, researchers/users must:	
	with NCATS and PEDSnet and Responsible Use of Data		1k. Work with N3C staff to verify and complete the	
	Agreement (RUD) with PEDSnet [Controls 1f and 2f]		following requirements for N3C Class 0 or Class 2 linkages	
	5. Submits Data Use Request (DUR) for approval by N3C		[N3C]:	
	Data Access Committee and request form for approval by		i. Existing institutional N3C Data Use Agreement	
	the PEDSnet Research Committee [Controls 1g and 2d]		ii. Dual authentication and authorization	
	6. Completes NIH IT training, attests to the N3C Data		iii. Signed institutional linkage honest broker agreement	
	User Code of Conduct, abides by N3C Results Download		for multiple datasets	
	Policy, and completes Human Subjects Research			
	Protection training to access N3C data [Control 1h]		iv. Approved data use request (DUR) by the federally	
	7. Provides IRB letter of determination for N3C data		staffed Data Access Committee (DAC)	
	access and if determined to be Human Subjects Research,		v. Local institution's IRB letter of determination	
	provide IRB approval with IRB reliance for site providing		vi. Interconnect agreement (for Class 0 only)	
	data (NPRA Master Reliance Agreement (MRA) or SMART		1I. Have agreement from participating sites for linkage with the external dataset [N3C]	
	IRB MRA) for PEDSnet [Controls 1i and 2e]			
	8. Obtains approvals from PEDSnet prospective site PI		1m. Have approval from the External Dataset Committee	
	and PEDSnet Executive Committee on the proposed		in the Tools and Resource subgroup and NCATS for linkage	

		Can the datasets be linked?	What limitations do the linked datasets inherit?	What controls do the linked dataset require?	What authorization gaps exist?
		[Controls 2g and 2h] 9. Works with N3C staff to obtain Class 2 designation for PEDSnet data so that it can be linked using PPRL with N3C data [Limitations 1d and 2c] - Assumption 10. If PEDSnet data are designated as Class 2, uses/accesses N3C data within the N3C Enclave and obtains approval from PEDSnet staff to export PEDSnet data into the N3C Enclave [Limitations 1a and 2a, Controls 1j and 2i] - Assumption for PEDSnet 11. Ensures they have an existing institutional N3C Data Use Agreement, dual authentication and authorization, signed institutional linkage honest broker agreement for multiple datasets, an approved data use request (DUR) by the data access committee (DAC), and local institution's IRB letter of determination for N3C Class 2 or Class 0 designation for PEDSnet thage. If PEDSnet data are designated as Class 0, ensures they also have an interconnect agreement. [Control 1k] 12. Has approval from participating sites for linkage with the external dataset and the External Dataset Committee in the Tools and Resource subgroup and NCATS for PEDSnet linkage [Limitations 11 and 1m]		For accessing PEDSnet, researchers/users must: 2d. Submit request form for approval by the Research Committee (PEDSnet] 2e. Undergo IRB review/determination (Human Subjects Review, HSR) (PEDSnet] 1. If IRB determines the proposed study is NHSR, then no further review/NRA required (PEDSnet] 13. If IRB determines the proposed study HSR, the requester must provide IRB approval with IRB reliance for site providing data (NPRA MRA or SMART IRB MRA) (PEDSnet] 2f. Sign DUA (Data Use Agreement) and RUD (Responsible Use of Data) (Legal Review) (PEDSnet] 2g. Receive prospective site PI approval (Institutional Participation Approval) (PEDSnet] 2h. Receive PEDSnet Executive Committee approval (Network Participation Approval) (PEDSnet] 2i. Access the data through a workspace within the PEDSnet cloud enclave-OR-have the data transferred to their institution, the PEDSnet Study Approval request should specify, pending approval from all PEDSnet]	
2	N3C (Dataset 1) and RADx-UP (Dataset 3) linkage	Yes, N3C and RADx-UP can be linked provided: A. N3C staff: 1. Shares N3C limited datasets (LDS), de-identified datasets, or synthetic datasets [Control 1a] 2. Removes 2IP codes entirely for all geographic units containing 20,000 or fewer people and replaces full five- digit 2IP codes of predominanty AI/AN communities with partial 2IP codes of predominanty AI/AN communities with partial 2IP codes [Control 1b] 3. Has waiver of consent from NIH IR Bf or sharing data through the NCATS N3C Platform [Control 1c] 8. Data providers: 4. Execute a Data Transfer Agreement (DTA) with NCATS [Control 1D] 5. Obtain institutional or external IRB approval [Control 1E] C. RADx Data Hub staff: 6. Ensures the studies are registered in dbGaP [Control 3a] 7. Ensures that the data is de-identified by working with study teams to de-identify zip codes, shift dates, and adjust ages into categories for specific ages [Control 3b] D. The researcher/user: 1. Uses the linked N3C and RADx-UP data for general COVID-19 research purposes [Limitations 1b and 3a]	Researchers/users must: 1a. Use N3C data within the N3C Enclave [N3C] 1b. Use N3C data for COVID-19 general research purposes [N3C] 1c. Not use Al/AN data and ZIP code information to make assumptions about Tribal affiliation [N3C] 1d. Work with N3C staff to link Class 2 or Class 0 data using PPRL [N3C] 1e. Comply with the N3C community Guiding Principles and the Attribution and Publication Principles [N3C] 3a. Use RADx-UP data for general research purposes [RADx-UP]	For sharing: A. N3C staff must: 1a. Share N3C limited datasets (LDS), de-identified datasets, or synthetic datasets [N3C] 1b. Remove ZIP codes entirely for all geographic units containing 20,000 or fewer people and replace full five- digit ZIP codes of predominantly AI/AN communities with partial ZIP codes [N3C] 1c. Have waiver of consent from NIH IRB sharing data through the NCATS N3C Platform [N3C] B. Data providers must: 1d. Execute a Data Transfer Agreement (DTA) with NCATS [N3C] 1e. Obtain institutional or external IRB approval [N3C] For sharing, RADX Data Hub stuff must: 3a. Ensure that the data is de-identified by working with study teams to de-identify ip codes, shift dates, and adjust ages into categories for specific ages [RADx-UP] For accessing N3C, researchers/users must: 1f. Execute Institutional Data Use Agreement (DUA) with NCATS [N3C] 1g. Submit Data Use Request (DUR) for approval by N3C Data Committee [N3C]	No authorization gaps exist

2. Does not use the linked data to make assumptions about Tribal affiliation [Limitation 1c]	
 3. Complies with the NSC Community Guiding Principles and the Attribution and Publication Principles [Limitation 1e] 4. Executes the institutional Data Use Agreements (DUA) with NCATS [Control 1f] 5. Has an eRA commons or Login gov account [Control 3c] 6. Submits Data Use Request (DUR) for approval by NSC Data Access Committee and a Data Access Request (DAR), which includes the Data Use Certification (DUC) Agreement, the Genomic Data User Code of Conduct, and the RADx SM Data User Code of Conduct, for RADx-UP [Controls 1g and 3d] 7. Ensure the Signing Official from the investigator's institution reviews, approves, and co-signs the request [Control 3e] 8. Completes NIH IT training, attests to the N3C Data User Code of Conduct, abides by the N3C Results Download Policy, and completes Human Subjects Research Protection training to access N3C data [Control 1h] 9. Provides IRB letter of determination for N3C data access [Control 1i] 10. Obtains approvals from the AHARO Center/Comprehensive Health Center IRB and the RADx Data Hub Data Access Committee for the proposed linkage [Controls 3h and 3f] 11. Works with N3C staff to obtain Class 2 designation for RADx-UP data sort it can be linked using PRL with N3C [Limitation 1d] - Assumption 12. If RADx-UP data are designated as Class 2, uses/accesses M3C data within the N3C Enclave and obtains approval from RADx Data Hub staff to export RADx-UP data is athe and the N3C Data Use Agreement, dual authentication and authorization, signed institutional linkage honest broker agreement for multiple datasets, an approved from N3C Class 2 or Class 0 designated as Class 0, ensures they also have an Interconnect agreement. [Control 1k] 14. Has approval from participating its for linkage with the external dataset and the External Dataset Committee in the Tools and Resource subgroup and NCATS for RADx- UP linkage [Limitations 11 and 1m] 	Code of Conduct, abide by the N3C Results Download Policy, and complete Human Subjects Research Protection training [N3C] 1. Provide IRB letter of determination for data access [N3C] 7. Access the data within the N3C Enclave [N3C] For linking N3C data, researchers/users must: 14. Work with N3C staff to verify and complete the following requirements for N3C Class 0 or Class 2 linkages [N3C]: 1. Existing institutional N3C Data Use Agreement 1. Dual authentication and authorization 11. Signed institutional linkinge honest broker agreement 15. molecular institutional insige honest broker agreement 16. multiple datasets 16. Approved data use request (DUR) by the federally staffed Data Access Committee (DAC) 17. Local institutions IRB letter of determination 18. Signed Trom Participating sites for linkage 19. In Have agreement from participating sites for linkage 19. Submit a Data Access Request (DAR), which includes 19. Have agreement from participating sites for linkage 19. Submit a Data Access Request (DAR), which includes 19. Bate Gate of Conduct (RADx-UP) 36. Submit a Data Access Request (DAR), which includes 19. Bate User Code of Conduct (RADx-UP) 39. Ensure the Signing Official from the investigator's 19. Institution reviews, approve, and co-signs the request 19. Roceive approval from the Data Access Committee 19. Nork with AHARO Center/Comprehensive Health Center IRB to obtain approval

			TABLE 2: USE CASE 3 - DATASET LINKA		
				ataset must be used in a physical enclave, etc.). Control user must receive data access committee approval, etc	
501				n for various data life cycle stages (data collection, linki	
		Can the datasets be linked?	What limitations do the linked datasets inherit?	What controls do the linked dataset require?	What authorization gaps exist?
3	N3C (Dataset 1)	Yes, N3C and EPA can be linked provided:	Researchers/users must:	For sharing:	No authorization gaps exist
	and EPA (Dataset		1a. Use N3C data within the N3C Enclave [N3C]	A. N3C staff must:	
			1b. Use N3C data for COVID-19 general research purposes		
		, ,,	[N3C]	datasets, or synthetic datasets [N3C]	
		datasets, or synthetic datasets [Control 1a]	1c. Not use AI/AN data and ZIP code information to make	1b. Remove ZIP codes entirely for all geographic units	
			assumptions about Tribal affiliation [N3C]	containing 20,000 or fewer people and replace full five-	
			1d. Work with N3C staff to link Class 2 or Class 0 data	digit ZIP codes of predominantly AI/AN communities with partial ZIP codes [N3C]	
		partial ZIP codes of predominantly Al/AN communities with	using PPRL [N3C] 1e. Comply with the N3C Community Guiding Principles	1c. Have waiver of consent from NIH IRB for sharing data	
			and the Attribution and Publication Principles [N3C]	through the NCATS N3C Platform [N3C]	
		through the NCATS N3C Platform [Control 1c]	and the Attribution and Publication Principles [NSe]	B. Data providers must:	
				1d. Execute a Data Transfer Agreement (DTA) with NCATS	
		B. Data providers:		[N3C]	
		4. Execute a Data Transfer Agreement (DTA) with NCATS		1e. Obtain institutional or external IRB approval [N3C]	
		[Control 1d]			
		5. Obtain institutional or external IRB approval [Control		For sharing, EPA staff must:	
		1e]		4a. Host ambient air data, which contains full geographic	
				identifiers including site address, zip code, CBSA, county,	
		C. EPA staff:		and state, through EPA's Air Quality System (AQS) [EPA]	
		Hosts ambient air data, containing full geographic			
		identifiers including site address, zip code, CBSA, county		For accessing N3C, researchers/users must:	
		and state, through EPA's Air Quality System (AQS) [Control		1f. Execute Institutional Data Use Agreement (DUA) with	
		4a]		NCATS [N3C]	
				1g. Submit Data Use Request (DUR) for approval by N3C	
		C. The researcher/user:		Data Access Committee [N3C]	
		1. Uses the linked N3C and EPA data for general COVID-19		1h. Complete NIH IT training, attest to the N3C Data User	
		research purposes [Limitation 1b] 2. Does not use the linked data to make assumptions		Code of Conduct, abide by the N3C Results Download Policy, and complete Human Subjects Research Protection	
		about Tribal affiliation [Limitation 1c]		training [N3C]	
		3. Complies with the N3C Community Guiding Principles		1i. Provide IRB letter of determination for data access	
		and the Attribution and Publication Principles [Limitation		[N3C]	
		1e]		1j. Access the data within the N3C Enclave [N3C]	
		 Uses/accesses the linked N3C and EPA data within the 		-,	
		N3C enclave [Limitation 1a, Control 1j]		For linking N3C data, researchers/users must:	
		5. Executes the Institutional Data Use Agreements (DUA)		1k. Work with N3C staff to verify and complete the	
		with NCATS [Controls 1f]		following requirements for N3C Class 0 or Class 2 linkages	
		6. Submits Data Use Request (DUR) for approval by N3C		[N3C]:	
		Data Access Committee [Control 1g]		i. Existing institutional N3C Data Use Agreement	
		7. Completes NIH IT training, attests to the N3C Data User		ii. Dual authentication and authorization	
		Code of Conduct, abides by the N3C Results Download		iii. Signed institutional linkage honest broker agreement	
		Policy, and completes Human Subjects Research		for multiple datasets	
		Protection training to access N3C data [Control 1h]		iv. Approved data use request (DUR) by the federally	
		8. Provides IRB letter of determination for N3C data		staffed Data Access Committee (DAC)	
		access [Control 1i]		v. Local institution's IRB letter of determination	
		9. Has approval from participating sites for linkage with		vi. Interconnect agreement (for Class 0 only)	
		the external dataset and the External Dataset Committee		1. Have agreement from participating sites for linkage	
		in the Tools and Resource subgroup and NCATS for EPA		with the external dataset [N3C]	
		linkage [Limitations 1l and 1m]		1m. Have approval from the External Dataset Committee	
		Note: Controls 1k, 4a, and 4c are not required for this		in the Tools and Resource subgroup and NCATS for linkage [N3C]	
		linkage as EPA Air Quality Data has already been brought		[NOC]	
		into the N3C Enclave and is already available for linkage to		For accessing EPA data, researchers/users can:	
		N3C.		4c. Obtain data from AQS, an open access repository	
				set obtain data nom Aqo, an open access repository	

		Can the datasets be linked?	What limitations do the linked datasets inherit?	What controls do the linked dataset require?	What authorization gaps exist?
4	PEDSnet (Dataset	Yes, PEDSnet and RADx-UP can be linked provided:	Researchers/users must:	For sharing, PEDSnet staff must:	No authorization gaps exist
	2) and RADx-UP		2a. Use the data in a workspace within the PEDSnet cloud		
	(Dataset 3) linkage		enclaveORat their own institution if approved to have	mental health care data for minors [PEDSnet]	
			the data transferred to their institution by all PEDSnet	2b. De-identify individual level data using the Safe Harbor	
			institutions providing data for the request [PEDSnet]	method of de-identification of PHI [PEDSnet]	
		2. De-identifies individual level data using the Safe Harbor		2c. Perform a risk review on the requested datasets as	
		method of de-identification of PHI [Control 2b] 3. Performs a risk review on the requested datasets as	participating sites and the Steering Committee, namely using data from real-world clinical settings for research,	well as data transformations, such as date shifts, replacement labels for free text fields and geographic	
		well as data transformations, such as date shifts,	quality measurement, and improvement/advancement of	information, and removing HIV/pregnancy/ mental health	
		replacement labels for free text fields and geographic	child health, particularly studies that inform or directly	data [PEDSnet]	
			address clinical decision making, including retrospective		
		data [Control 2c]	observational studies. [PEDSnet]	For sharing, RADx Data Hub staff must:	
				3a. Ensure the studies are registered in dbGaP [RADx-UP]	
			a waiver of consent using PPRL [PEDSnet]	3b. Ensure that the data is de-identified by working with	
		4. Ensures the studies are registered in dbGaP [Control	• • •	study teams to de-identify zip codes, shift dates, and	
		3a]	3a. Use RADx-UP data for general research purposes	adjust ages into categories for specific ages [RADx-UP]	
		5. Ensures that the data is de-identified by working with	[RADx-UP]		
		study teams to de-identify zip codes, shift dates, and		For accessing PEDSnet, researchers/users must:	
		adjust ages into categories for specific ages [Control 3b]		2d. Submit request form for approval by the Research	
		0.71		Committee [PEDSnet]	
		C. The researcher/user:		2e. Undergo IRB review/determination (Human Subjects	
		1. Uses the linked PEDSnet and RADx-UP data for general research purposes specified and approved by PEDSnet		Review, HSR) [PEDSnet]	
		participating sites and the PEDSnet Steering Committee		i. If IRB determines the proposed study is NHSR, then no	
		[Limitations 2b and 3a]		further review/MRA required [PEDSnet]	
		 Has an eRA commons or Login.gov account [Control 3c] 		ii. If IRB determines the proposed study HSR, the	
		3. Submits request form for approval by the Research		requester must provide IRB approval with IRB reliance for	
		Committee and submits a Data Access Request (DAR),		site providing data (NPRA MRA or SMART IRB MRA) [PEDSnet]	
		which includes the Data Use Certification (DUC)		2f. Sign DUA (Data Use Agreement) and RUD (Responsible	
		Agreement, the Genomic Data User Code of Conduct, and		Use of Data) (Legal Review) [PEDSnet]	
		the RADx SM Data User Code of Conduct [Controls 2d and		2g. Receive prospective site PI approval (Institutional	
		3d]		Participation Approval) [PEDSnet]	
		Ensures that the Signing Official from investigator's		2h. Receive PEDSnet Executive Committee approval	
		institution reviews, approves, and co-signs the request		(Network Participation Approval) [PEDSnet]	
		[Control 3e]		2i. Access the data through a workspace within the	
		5. Undergoes IRB review to receive a letter of		PEDSnet cloud enclaveORhave the data transferred to	
		determination for data access and if determined to be		their institution, the PEDSnet Study Approval request	
		Human Subjects Research, provide IRB approval with IRB reliance for site providing data (NPRA Master Reliance		should specify, pending approval from all PEDSnet	
		Agreement (MRA) or SMART IRB MRA is also required) for		institutions providing data for the request [PEDSnet]	
		PEDSnet [Control 2e]			
		6. Signs PEDSnet DUA and Responsible Use of Data		For accessing RADx-UP data, researchers/users must:	
		Agreement (RUD) with PEDSnet [Control 2f]		3c. Have an eRA commons or Login.gov account [RADx- UP]	
		7. Receives PEDSnet prospective site PI approval and		UPJ 3d. Submit a Data Access Request (DAR), which includes	
		PEDSnet Executive Committee approval, AHARO Center/		the Data Use Certification (DUC) Agreement, the Genomic	
		Comprehensive Health Center IRB and RADx Data Access		Data User Code of Conduct, and the RADx SM Data User	
		Committee approval for the proposed PPRL linkage		Code of Conduct [RADx-UP]	
		[Limitation 2c; Controls 2g, 2h, 3h, and 3f]		3e. Ensure the Signing Official from the investigator's	
		8. Works with PEDSnet staff and RADx Data Hub staff to		institution reviews, approves, and co-signs the request	
		determine whether RADx-UP data downloaded through		[RADx-UP]	
		Jupyter Notebooks can be transferred to the PEDSnet		3f. Receive approval from the Data Access Committee	
		cloud enclave workspaceOR obtains approval to have		[RADx-UP]	
		PEDSnet data transferred to the user's institution to use		3g. Access the data through RADx Data Hub Jupyter	
		with the downloaded RADx-UP data [Controls 2i and 3g]		Notebooks [RADx-UP]	
		Assumption			
		9. Uses the linked PEDSnet and RADx-UP data within the		For linking RADx-UP data, researchers/users must:	
		PEDSnet cloud enclave workspace or at the user's institution with approval [Limitation 2a] - Assumption		3h. Work with AHARO Center/Comprehensive Health	
		instruction with approval [Emitation 2a] Assumption		Center IRB to obtain approval for individual level data	
				linkages [RADx-UP]	
<u> </u>					

			TABLE 2: USE CASE 3 - DATASET LINKA	GE DETERMINATION	
				ataset must be used in a physical enclave, etc.). Control	
go	ernance for data s			user must receive data access committee approval, etc.	
		authorization or the authorization is not available or	r found in the information collected by the project tean	n for various data life cycle stages (data collection, linki	ng, sharing, access and use).
		Can the datasets be linked?	What limitations do the linked datasets inherit?	What controls do the linked dataset require?	What authorization gaps exist?
5	PEDSnet (Dataset	Yes, PEDSnet and EPA can be linked provided:	Researchers/users must:	For sharing, PEDSnet staff must:	No authorization gaps exist
	2) and EPA		2a. Use the data in a workspace within the PEDSnet cloud	2a. Remove HIV-related data and reproductive and	
	(Dataset 4) linkage	A. PEDSnet staff:	enclaveORat their own institution if approved to have	mental health care data for minors [PEDSnet]	
		1. Removes HIV-related data and reproductive and	the data transferred to their institution by all PEDSnet	2b. De-identify individual level data using the Safe Harbor	
			institutions providing data for the request [PEDSnet]	method of de-identification of PHI [PEDSnet]	
				2c. Perform a risk review on the requested datasets as	
			participating sites and the Steering Committee, namely	well as data transformations, such as date shifts,	
			using data from real-world clinical settings for research,	replacement labels for free text fields and geographic	
				information, and removing HIV/pregnancy/ mental health	
			child health, particularly studies that inform or directly	data [PEDSnet]	
			address clinical decision making, including retrospective	Free should be FDA at all south	
			observational studies. [PEDSnet] 2c. Work with PEDSnet staff to link data conducted under	For sharing, EPA staff must:	
			2C. Work with PEDSnet staff to link data conducted under a waiver of consent using PPRL [PEDSnet]	4a. Host ambient air data, which contains full geographic identifiers including site address, zip code, CBSA, county,	
		4. Hosts ambient air data, containing full geographic	a waiver of consent using PPRE [PEDShet]	and state, through EPA's Air Quality System (AQS) [EPA]	
		identifiers including site address, zip code, CBSA, county			
		and state, through EPA's Air Quality System (AQS) [Control		For accessing PEDSnet, researchers/users must:	
		4a]		2d. Submit request form for approval by the Research	
				Committee [PEDSnet]	
		C. The researcher/user:		2e. Undergo IRB review/determination (Human Subjects	
		1. Uses the linked PEDSnet and EPA data for purposes		Review) [PEDSnet]	
		specified and approved by PEDSnet participating sites and		i. If IRB determines the proposed study is NHSR, then	
		the PEDSnet Steering Committee [Limitation 2b]		no further review/MRA required [PEDSnet]	
		Obtains the EPA data from AQS, an open access		ii. If IRB determines the proposed study HSR, the	
		repository [Control 4c]		requester must provide IRB approval with IRB reliance for	
		3. Submits request form for approval by the Research		site providing data (NPRA MRA or SMART IRB MRA)	
		Committee [Control 2d]		[PEDSnet]	
		 Undergoes IRB review to receive a letter of determination for data access and if determined to be 		2f. Sign DUA (Data Use Agreement) and RUD (Responsible Use of Data) (Legal Review) [PEDSnet]	
		Human Subjects Research, provide IRB approval with IRB		2g. Receive prospective site PI approval (Institutional	
		reliance for site providing data (NPRA Master Reliance		Participation Approval) [PEDSnet]	
		Agreement (MRA) or SMART IRB MRA is also required) for		2h. Receive PEDSnet Executive Committee approval	
		PEDSnet [Control 2e]		(Network Participation Approval) [PEDSnet]	
		5. Signs PEDSnet DUA and Responsible Use of Data		2i. Access the data through a workspace within the	
		Agreement (RUD) with PEDSnet [Control 2f]		PEDSnet cloud enclaveORhave the data transferred to	
		6. Receives prospective site PI approval and PEDSnet		their institution, the PEDSnet Study Approval request	
		Executive Committee approval for the proposed linkage		should specify, pending approval from all PEDSnet	
		[Controls 2g and 2h]		institutions providing data for the request [PEDSnet]	
		7. Works with PEDSnet staff to determine whether EPA		Francisco FRA data anno 1990 (1990)	
		data can be transferred to the PEDSnet cloud enclave		For accessing EPA data, researchers/users can:	
		workspaceOR obtain approval to have PEDSnet data transferred to the user's institution to use with the EPA		4c. Obtain data from AQS, an open access repository	
		data [Control 2i] Assumption			
		8. Uses the linked PEDSnet and EPA data within the			
		PEDSnet cloud enclave workspace or at the user's			
		institution with approval [Limitation 2a] – Assumption			
		Note: Limitation 2c is not required as EPA data is location			
		based and would not be linked through PPRL			

			TABLE 2: USE CASE 3 - DATASET LINKA		
				ataset must be used in a physical enclave, etc.). Contro	
goveri	nance for data s			user must receive data access committee approval, etc n for various data life cycle stages (data collection, linki	
		Can the datasets be linked?	What limitations do the linked datasets inherit?	What controls do the linked dataset require?	What authorization gaps exist?
D A	Dx UB (Datacot	Yes, RADx-UP and EPA can be linked provided:	Researchers/users must:	For sharing, RADx Data Hub staff must:	No authorization gaps exist
	and EPA	res, RADX-OP and EPA can be linked provided:	3a. Use RADx-UP data for general research purposes	3a. Ensure the studies are registered in dbGaP [RADx-UP]	No autionzation gaps exist
		A. RADx Data Hub staff:	[RADx-UP]	3b. Ensure that the data is de-identified by working with	
(0)		1. Ensures the studies are registered in dbGaP [Control	[in the off	study teams to de-identify zip codes, shift dates, and	
		3a]		adjust ages into categories for specific ages [RADx-UP]	
		2. Ensures that the data is de-identified by working with			
		study teams to de-identify zip codes, shift dates, and		For sharing, EPA staff must:	
		adjust ages into categories for specific ages [Control 3b]		4a. Host ambient air data, which contains full geographic	
				identifiers including site address, zip code, CBSA, county,	
		B. EPA staff:		and state, through EPA's Air Quality System (AQS) [EPA]	
		3. Hosts ambient air data, containing full geographic identifiers including site address, zip code, CBSA, county			
		and state, through EPA's Air Quality System (AQS) [Control		For accessing RADx-UP data, researchers/users must:	
		4a]		3c. Have an eRA commons or Login.gov account [RADx-	
				UP]	
		C. The researcher/user:		3d. Submit a Data Access Request (DAR), which includes	
		1. Uses the linked RADx-UP and EPA data for general		the Data Use Certification (DUC) Agreement, the Genomic	
		research purposed [Limitation 3a]		Data User Code of Conduct, and the RADx SM Data User Code of Conduct [RADx-UP]	
		2. Obtains the EPA data from AQS, an open access			
		repository [Control 4c]		3e. Ensure the Signing Official from the investigator's institution reviews, approves, and co-signs the request	
		3. Has an eRA commons or Login.gov account [Control 3c]		[RADx-UP]	
		4. Submits a Data Access Request (DAR), which includes		3f. Receive approval from the Data Access Committee	
		the Data Use Certification (DUC) Agreement, the Genomic		[RADx-UP]	
		Data User Code of Conduct, and the RADx SM Data User		3g. Access the data through RADx Data Hub Jupyter	
		Code of Conduct [Control 3d]		Notebooks [RADx-UP]	
		5. Ensures the Signing Official from the investigator's			
		institution reviews, approves, and co-signs the request		For linking RADx-UP data, researchers/users must:	
		[Control 3e]		3h. Work with AHARO Center/Comprehensive Health	
		6. Receives approval from the AHARO		Center IRB to obtain approval for individual level data	
		Center/Comprehensive Health Center IRB and the Data Access Committee for the proposed linkage [Controls 3h		linkages [RADx-UP]	
		and 3f]			
		7. Access the linked data through RADx Data Hub Jupyter		For accessing EPA data, researchers/users can:	
		Notebooks [Control 3g]		4c. Obtain data from AQS, an open access repository	
All	l datasets (N3C,	Yes, N3C, PEDSnet, RADx-UP, and EPA can be linked	Researchers/users must:	For sharing:	No authorization gaps exist
PE	DSnet, RADx-	provided:	1a. Use N3C data within the N3C Enclave [N3C]	A. N3C staff must:	
UF	P, EPA)		1b. Use N3C data for COVID-19 general research purposes	1a. Share N3C limited datasets (LDS), de-identified	
		A. N3C/PEDSnet/RADx Data Hub/EPA staff:	[N3C]	datasets, or synthetic datasets [N3C]	
		1. Shares N3C, PEDSnet, and RADx data de-identified of all			
		direct identifers	assumptions about Tribal affiliation [N3C]	containing 20,000 or fewer people and replace full five-	
			1d. Work with N3C staff to link Class 2 or Class 0 data	digit ZIP codes of predominantly AI/AN communities with	
		be shared; ZIP codes entirely for all geographic units	using PPRL [N3C]	partial ZIP codes [N3C]	
		containing 20,000 or fewer people should be removed;	1e. Comply with the N3C Community Guiding Principles	1c. Have waiver of consent from NIH IRB for sharing data	
		and full five-digit ZIP codes of predominantly AI/AN	and the Attribution and Publication Principles [N3C]	through the NCATS N3C Platform [N3C]	
		communities should be replaced with partial ZIP codes - for PEDSnet, HIV-related data and reproductive and	22. Use the data in a workspace within the BEDSpot cloud	B. Data providers must: 1d. Execute a Data Transfer Agreement (DTA) with NCATS	
			enclaveORat their own institution if approved to have	[N3C]	
		 for EPA, full geographic identifiers including site address, 		1e. Obtain institutional or external IRB approval [N3C]	
		zip code, CBSA, county, and state are shared	institutions providing data for the request [PEDSnet]		
		[Controls 1a, 1b, 2a, 2b, 3b, and 4a]	2b. Use the data for purposes specified and approved by	For sharing, PEDSnet staff must:	
		2. Has waiver of consent from NIH IRB for sharing data	participating sites and the Steering Committee, namely	2a. Remove HIV-related data and reproductive and	
		through the NCATS N3C Platform [Control 1c]	using data from real-world clinical settings for research,	mental health care data for minors [PEDSnet]	
		3. Performs risk review prior to sharing of PEDSnet data		2b. De-identify individual level data using the Safe Harbor	
		(data transformations, such as date shifts, replacement	child health, particularly studies that inform or directly	method of de-identification of PHI [PEDSnet]	
			address clinical decision making, including retrospective	2c. Perform a risk review on the requested datasets as	
		removing HIV/pregnancy/mental health data) [Control 2c]	observational studies. [PEDSnet]	well as data transformations, such as date shifts,	
		Ensures the RADx studies are registered in dbGaP	2c. Work with PEDSnet staff to link data conducted under	replacement labels for free text fields and geographic	
		[Control 3a]	a waiver of consent using PPRL [PEDSnet]	information, and removing HIV/pregnancy/mental health	
				data [PEDSnet]	
		B. N3C Data Providers:	3a. Use RADx-UP data for general research purposes	data [PEDSnet] For sharing, RADx Data Hub stuff must:	

	ntrol 1d]		
6. Ob		3a. Ensure the studies are registered in dbGaP [RADx-UP]	
	Obtain institutional or external IRB approval [Control	3b. Ensure that the data is de-identified by working with	
1e]		study teams to de-identify zip codes, shift dates, and	
		adjust ages into categories for specific ages [RADx-UP]	
C. Th	he researcher/user:		
1. Us	Jses the linked N3C and PEDSnet data for general	For sharing, EPA staff must:	
COV	VID-19 research purposes specified and approved by	4a. Host ambient air data, which contains full geographic	
the F	PEDSnet participating sites and PEDSnet Steering	identifiers including site address, zip code, CBSA, county,	
Com	nmittee [Limitations 1b, 2b, and 3a]	and state, through EPA's Air Quality System (AQS) [EPA]	
2. Dr	Does not use the linked data to make assumptions		
abou	out Tribal affiliation [Limitation 1c]	For accessing N3C, researchers/users must:	
3. Cc	Complies with the N3C Community Guiding Principles	1f. Execute Institutional Data Use Agreement (DUA) with	
and	the Attribution and Publication Principles [Limitation	NCATS [N3C]	
1e]		1g. Submit Data Use Request (DUR) for approval by N3C	
4. Ha	as an eRA commons or Login.gov account [Control 3c]	Data Access Committee [N3C]	
5. Ex	executes the Institutional Data Use Agreements (DUA)	1h. Complete NIH IT training, attest to the N3C Data User	
with	h NCATS and PEDSnet and Responsible Use of Data	Code of Conduct, abide by the N3C Results Download	
Agre	eement (RUD) with PEDSnet [Controls 1f and 2f]	Policy, and complete Human Subjects Research Protection	
6. Su	submits Data Use Request (DUR) for approval by N3C	training [N3C]	
Data	a Access Committee, request form for approval by the	1i. Provide IRB letter of determination for data access	
PEDS	Snet Research Committee, and Data Access Request	[N3C]	
(DAF	R), which includes the Data Use Certification (DUC)	1i. Access the data within the N3C Enclave [N3C]	
Agre	eement, the Genomic Data User Code of Conduct, and		
the F	RADx SM Data User Code of Conduct [Controls 1h, 2d,	For accessing PEDSnet, researchers/users must:	
and	i 3d]	2d. Submit request form for approval by the Research	
7. En	nsures the Signing Official from the investigator's	Committee [PEDSnet]	
instit	titution reviews, approves, and co-signs the request	2e. Undergo IRB review/determination (Human Subjects	
[Con	ntrol 3e]	Review) [PEDSnet]	
8. Cc	Completes NIH IT training, attests to the N3C Data User	i. If IRB determines the proposed study is NHSR, then no	
Code	le of Conduct, and completes Human Subjects	further review/MRA required [PEDSnet]	
Rese	earch Protection training to access N3C data [Control	ii. If IRB determines the proposed study HSR, the	
1i]		requester must provide IRB approval with IRB reliance for	
9. Pr	Provides IRB letter of determination for N3C data	site providing data (NPRA MRA or SMART IRB MRA)	
acce	ess and if determined to be Human Subjects Research,	[PEDSnet]	
prov	vide IRB approval with IRB reliance for site providing	2f. Sign DUA (Data Use Agreement) and RUD (Responsible	
data	a (NPRA Master Reliance Agreement (MRA) or SMART	Use of Data) (Legal Review) [PEDSnet]	
IRB M	MRA) for PEDSnet [Controls 1k and 2e]	2g. Receive prospective site PI approval (Institutional	
	Obtains approvals from PEDSnet prospective site PI	Participation Approval) [PEDSnet]	
appr	proval and PEDSnet Executive Committee, the AHARO	2h. Receive PEDSnet Executive Committee approval	
Cent	nter/Comprehensive Health Center IRB and RADx Data	(Network Participation Approval) [PEDSnet]	
Hub	b Data Access Committee on the proposed linkage	2i. Access the data through a workspace within the	
[Con	ntrols 2g, 2h, 3h, and 3f]	PEDSnet cloud enclaveORhave the data transferred to	
11. 1	Works with N3C staff to obtain Class 2 or Class 0	their institution, the PEDSnet Study Approval request	
desig	ignation for PEDSnet and RADx-UP so that all three	should specify, pending approval from all PEDSnet	
data	asets can be linked using PPRL [Limitations 1d and 2c] -	institutions providing data for the request [PEDSnet]	
Assu	umption		
12. If	If non-N3C data are designated as Class 2,	For accessing RADx-UP data, researchers/users must:	
uses.	s/accesses N3C data within the N3C Enclave and	3c. Have an eRA commons or Login.gov account [RADx-	
obta	ains approval from PEDSnet staff to export PEDSnet	UP]	
data	a into the N3C Enclave and RADx Data Hub staff to	3d. Submit a Data Access Request (DAR), which includes	
expo	ort RADx-UP data into the N3C Enclave [Limitations 1a	the Data Use Certification (DUC) Agreement, the Genomic	
and 2	2a; Controls 1j, 2i, and 3g] - Assumption for PEDSnet	Data User Code of Conduct, and the RADx SM Data User	
and	RADx-UP	Code of Conduct [RADx-UP]	

Can the datasets be linked?	What limitations do the linked datasets inherit?	What controls do the linked dataset require?	What authorization gaps exis
13. Ensures they have an existing institutional N3C Data		3e. Ensure the Signing Official from the investigator's	
Use Agreement, dual authentication and authorization,		institution reviews, approves, and co-signs the request	
signed institutional linkage honest broker agreement for		[RADx-UP]	
multiple datasets, an approved data use request (DUR) by		3f. Receive approval from the Data Access Committee	
the data access committee (DAC), and local institutions		[RADx-UP]	
IRB letter of determination for N3C Class 2 or Class 0		3g. Access the data through RADx Data Hub Jupyter	
designation for PEDSnet and RADx-UP linkage. If non-N3C		Notebooks [RADx-UP]	
data are designated as Class 0, ensures they also have an		Francisco FRA data anticipation data anticipaticipation data anticipation data anticipation data antic	
Interconnect agreement. [Control 1k]		For accessing EPA data, researchers can:	
14. Has approval from participating sites for linkage with		4c. Obtain data from AQS, an open access repository	
the external dataset and the External Dataset Committee		For linking N3C data, researchers/users must:	
in the Tools and Resource subgroup and NCATS for EPA		1k. Work with N3C staff to verify and complete the	
linkage [Limitations 1I and 1m]		following requirements for N3C Class 0 or Class 2 linkages	
		[N3C]:	
Note: Controls 4a and 4c are not required for this linkage		i. Existing institutional N3C Data Use Agreement	
as EPA Air Quality Data has already been brought into the		ii. Dual authentication and authorization	
N3C Enclave and is already available for linkage to N3C.		iii. Signed institutional linkage honest broker agreement	
		for multiple datasets	
		iv. Approved data use request (DUR) by the federally	
		staffed Data Access Committee (DAC)	
		v. Local institution's IRB letter of determination	
		vi. Interconnect agreement (for Class 0 only)	
		1l. Have agreement from participating sites for linkage	
		with the external dataset [N3C]	
		1m. Have approval from the External Dataset Committee	
		in the Tools and Resource subgroup and NCATS for linkage	
		[N3C]	
		For Pather PAD, UD data and the former	
		For linking RADx-UP data, researchers/users must:	
		3h. Work with AHARO Center/Comprehensive Health	
		Center IRB to obtain approval for individual level data linkages [RADx-UP]	

	GOVERNANCE INFORMATION	ted School Absonce Dees SARS CoV 2 vassingtion result in reduced asthma re	lated school absonces at 2/6/12, ma	nthe next vacai
	N3C (Limited Data Set)	ted School Absence - Does SARS-CoV-2 vaccination result in reduced asthma-re	stated school absences at 5/6/12+ mo	nths post-vacch
	Dataset Source	National COVID Cohort Collaborative (N3C)		
	Dataset Source Agency	NIH, NCATS		
	Dataset Type (Clinical, EHR, Survey, SDOH,	Clinical, EHR Data		
	etc.)			
	Information Sources	Website, NCATS's Responses to N3C Questions, Information from predecessor repo	I rt, NCATS staff email communication and	meeting
				0
Dataset 8 -	N3C			
		Raw Language	Interpretation	
1	Data Collection			
1.1	Authorizations and Applicable Regulatio	ons/Policies		
	Authorizations		1. HIPAA	
1.1.1.1	Assent	N/A	N/A	
1.1.1.2	Consent	N/A Participating institutions do not obtain consent from individual patients for	N/A	[1] https://ncats
		the data they send to the N3C. The 1996 Health Insurance Portability and		(Accessed 4/21/
		Accountability Act (HIPAA) allows medical and health care institutions to release		
		data for research without obtaining an individual's authorization if direct identifying	5	
		information is removed and appropriate oversight and agreements are in place.		
		Under the HIPAA Privacy Rule requirements, these institutions can release what is		
		called a Limited Data Set. This is what participating health sites send to the N3C. [1]		
1.1.1.3	IRB/equivalent Privacy Board	N/A	N/A	
	determination			
1.1.1.4	Local/state/federal laws	The 1996 Health Insurance Portability and Accountability Act (HIPAA) allows	HIPAA authorizes health care providers	[1] https://ncats
		medical and health care institutions to release data for research without obtaining	to release data to N3C	(Accessed 4/21/
		an individual's authorization if direct identifying information is removed and		[2]
		appropriate oversight and agreements are in place. [1]		https://ncats.ni
				m-faq#use-the-
		Under the HIPAA privacy regulations for a Limited Data Set, de-identified health		
		information may be used and disclosed for research purposes. [2]		
1.1.1.5	Institutional Certification	N/A	N/A	
1.1.1.6	Data originator agreement	N/A	N/A	
1.1.1.7	Repository agreements/policies	N/A	N/A	
1.1.1.8	Other (specify)	Information not available/found	Information not available/found	
1.1.2	Applicable Regulations/Policies			
1.1.2.1	Local regulations/policies	Information not available/found	Information not available/found	
1.1.2.2	Tribal regulations/policies	Information not available/found	Information not available/found	
1.1.2.3	State regulations/policies	Information not available/found	Information not available/found	
1.1.2.4	Federal regulations/policies	Under the HIPAA privacy regulations for a Limited Data Set, de-identified health	HIPAA Privacy Rule	[1]
		information may be used and disclosed for research purposes. [1]		https://ncats.ni
				<u>m-faq#use-the-</u>
		Data-contributing sites abide by the HIPAA Privacy Rule; Data are provided as a		[2] NCATS Emai
		HIPAA-defined limited data set [2]		
1.1.2.5	International regulations/policies	Information not available/found	Information not available/found	
1.1.2.6	Contractual obligations	Information not available/found	Information not available/found	
1.1.2.7	Repository policies	Information not available/found	Information not available/found	

6/12+ months post-vaccination?		
ication and	meeting	
	Source	
	[1] <u>https://ncats.nih.gov/n3c/about</u> (Accessed 4/21/23)	
e providers	 [1] <u>https://ncats.nih.gov/n3c/about</u> (Accessed 4/21/23) [2] <u>https://ncats.nih.gov/n3c/about/progra</u> <u>m-faq#use-the-data</u> (Accessed 4/21/23) 	
und		
und		
und		
und		
	 [1] <u>https://ncats.nih.gov/n3c/about/progra</u> <u>m-faq#use-the-data</u> (Accessed 4/21/23) [2] NCATS Email Communication 	
und		
und		
und		

Dataset 8 -	N3C			
		Raw Language	Interpretation	Source
1.2	Governance for data linkage, sharing, access, and use based on data collection authorization or applicable regulations/policies (i.e., the origin of the governance)			
1.2.1	Whether the data can be linked	Does not authorize/specify	Does not authorize/specify	
1.2.2	With what other data can it be linked or	Does not authorize/specify	Does not authorize/specify	
	can it not be linked (scope of linkage)			
1.2.3	Whether data can be shared	Does not authorize/specify	Does not authorize/specify	
1.2.4	How data can be shared (de-identification	The 1996 Health Insurance Portability and Accountability Act (HIPAA) allows	HIPAA specifies that N3C data partners	[1] <u>https://ncats.nih.gov/n3c/about</u>
	status, disclosure review)	medical and health care institutions to release data for research without obtaining	(health care providers) can release	(Accessed 4/21/23)
		an individual's authorization if direct identifying information is removed and	limited EHR dataset (with no direct PII)	[2]
		appropriate oversight and agreements are in place. [1]	for research purposes	https://ncats.nih.gov/n3c/about/progra
				m-faq#use-the-data (Accessed 4/21/23)
		Under the HIPAA privacy regulations for a Limited Data Set, de-identified health		
		information may be used and disclosed for research purposes. [2]		
1.2.5	How data can be accessed (access type,	"Under the HIPAA Privacy Rule "A covered entity may use or disclose a limited data	HIPAA Privacy Rule specifies that N3C	[1]
	data use agreement, data access	set that meets the requirements of paragraphs (e)(2) and (e)(3) of this section, if	data partners (health care providers)	https://www.hhs.gov/sites/default/files/
	_	the covered entity enters into a data use agreement with the limited data set	must enter into a data use agreement	ocr/privacy/hipaa/administrative/combin
		recipient, in accordance with paragraph (e)(4) of this sectionA covered entity may	with limited EHR dataset receipients	ed/hipaa-simplification-201303.pdf
		use or disclose a limited data set under paragraph (e)(1) of this section only for the		(Accessed 11/9/23)
		purposes of research, public health, or health care operations." [1]		
1.2.6	How data can be used (data use	The 1996 Health Insurance Portability and Accountability Act (HIPAA) allows	HIPAA privacy regulations specify that	[1] https://ncats.nih.gov/n3c/about
	limitations)	medical and health care institutions to release data for research without obtaining	de-identified data can be used for	(Accessed 4/21/23)
		an individual's authorization if direct identifying information is removed and	general research purposes.	[2]
		appropriate oversight and agreements are in place. [1]		https://ncats.nih.gov/n3c/about/progra
				m-faq#use-the-data (Accessed 4/21/23)
		Under the HIPAA privacy regulations for a Limited Data Set, de-identified health		
		information may be used and disclosed for research purposes. [2]		
4 2 7				
1.2.7	Other (specify)	Does not authorize/specify	Does not authorize/specify	
2	Data Linkage			
2.1	Authorizations and Applicable Regulations	s/Policies		
2.1.1	Authorizations		1. Linkage Honest Broker Agreement	
			2. External Dataset Committee in the	
			Tools and Resource subgroup and	
			NCATS	
2.1.1.1		N/A	N/A	
2.1.1.2	Consent	N/A	N/A	
2.1.1.3	IRB/equivalent Privacy Board	Information not available/found	Information not available/found	
	determination			
2.1.1.4		N/A	N/A	
2.1.1.5	Institutional Certification	N/A	N/A	

Dataset 8 -	N3C		
		Raw Language	Interpretation
2.1.1.6	Data originator agreement	All organizations contributing data to the N3C Data Enclave must have an approved Data Transfer Agreement (DTA). In addition to the DTA, these organizations have the option of signing the Linkage Honest Broker Agreement (LHBA) to participate in the PPRL pilot. The LHBA is an agreement between the organization, NCATS and The Regenstrief Institute, which serves as the linkage honest broker. A linkage honest broker in the PPRL's infrastructure is a party that holds de-identified tokens and operates a service that matches tokens generated across disparate data sets to formulate a single Match ID for a specific use case. The data remains under the complete control of the organizations that provide data to N3C and is never accessible by or under the control of the linkage honest broker. PPRL enables three functions within N3C: Deduplication of patient records, linkage of a patient's records from different sources and cohort discovery. Deduplication is a requirement for any organization that participates in the LHBA because of its importance to the data quality of the N3C Data Enclave and its scientific mission. Organizations participating in the LHBA have the option of participating in linking multiple data sets and cohort discovery as well. [1] Data partners who choose to participate in PPRL with external datasets must agree to link to the given external dataset PPRL Site Permissions Dashboard [2]	Two data originator agreements authorize data linkage: 1. The Linkage Honest Broker Agreement (LHBA) authorizes data linkage 2. Participating PPRL sites authorize data linkage for particular external datasets
2.1.1.7	Repository agreements/policies	Users that need to utilize an external dataset will first request the external dataset for consideration to be imported. Once the request is received, the External Dataset Committee in the Tools and Resource subgroup and NCATS will review external database requests to include in the N3C Dataset. This review process will be done in three phases: Initial Review Process Overall Dataset Review Process External Dataset Importation [1]	NCATS approval authorizes data linkage
2.1.1.8	Other (specify)	Information not available/found	Information not available/found
2.1.2	Applicable Regulations/Policies		
2.1.2.1	Local regulations/policies	Information not available/found	Information not available/found
2.1.2.2	Tribal regulations/policies	Information not available/found	Information not available/found
2.1.2.3	State regulations/policies	Information not available/found	Information not available/found
2.1.2.4	Federal regulations/policies	Information not available/found	Information not available/found
2.1.2.5	International regulations/policies	Information not available/found	Information not available/found
2.1.2.6	Contractual obligations	Information not available/found	Information not available/found

	Source
nts	[1] https://ncats.nih.gov/n3c/about/data-
	overview#privacy-preserving-record-
	linkage (Accessed 4/21/23)
data	[2] Predecessor report
	(https://www.nichd.nih.gov/sites/default
horize	<u>/files/inline-</u>
ernal	files/NICHD_ODSS_PPRL_for_Pediatric_C
	OVID-
	19 Studies_Public_Final_Report_508.pdf
)
tee in the	[1]
and	https://docs.google.com/document/d/1
and Ita linkage	QJi_sNiOwnZFV3ghTBubI7d3kFLtdkVfQws
	LQJOFil8/edit (Accessed: 11/17/23)
nd	
nd	

Dataset 8 - N3C			
	Raw Language	Interpretation	Source
2.1.2.7 Repository policies	All External Datasets under consideration are given a classification code, which defines a dataset's risk for re-identification. The current classes are defined below: Class 0: Linkage is not available at this time, but defined in anticipation of the implementation of a Privacy-Preserving Record Linkage (PPRL e.g., hashed identifiers) managed by a third-party honest broker. O The assumption here is that Enclave data for a given patient has an internally generated ID, the external team has their own ID, and the honest broker has both (but nothing else), and only shares a hash of the other ID with each team. O Examples here include connecting Enclave data with separate repositories (at the individual patient level) of sequence data, imaging, etc. Class 1: Linkages leading to immediate re-identification of patients. O Linked datasets directly containing data that increases the risk or the reality of re- identification. A simple example here is a table of HIPAA-sensitive variables matching against Limited Dataset records. O Data fitting this class will not be permitted in the N3C Data Enclave, but we define it for sake of completeness. Class 2: Linkages leading to high-confidence heuristic re-identification of patients. O Example: a linkage of zip code and age (plus or minus an approximate data of infection) potentially leading to high-confidence heuristic reidentification of nursing home residents. Class 3: Linkages leading to data sufficiently aggregated to reasonably mitigate the risk of re-identification. O Example: a patient with a specific comorbidity known to be associated with a given genetic defect, knowing the pool of persons with that genetic defect fails to provide sufficient discrimination (assuming that that pool is of a sufficient cardinality.) Note that any additional linkage information (e.g., a person's height) might provide additional discriminating power in a sparse information space to allow re-identification.	N3C policy designation of external datasets	[1] NCATS Response to N3C Questions

Dataset 8 -	N3C			
		Raw Language	Interpretation	Source
2.2.1	Whether the data can be linked	All organizations contributing data to the N3C Data Enclave must have an approved Data Transfer Agreement (DTA). In addition to the DTA, these organizations have the option of signing the Linkage Honest Broker Agreement (LHBA) to participate in the PPRL pilot. The LHBA is an agreement between the organization, NCATS and The Regenstrief Institute, which serves as the linkage honest broker. A linkage honest broker in the PPRL's infrastructure is a party that holds de-identified tokens and operates a service that matches tokens generated across disparate data sets to formulate a single Match ID for a specific use case. The data remains under the complete control of the organizations that provide data to N3C and is never accessible by or under the control of the linkage honest broker. PPRL enables three functions within N3C: Deduplication of patient records, linkage of a patient's records from different sources and cohort discovery. Deduplication is a requirement for any organization that participates in the LHBA because of its importance to the data quality of the N3C Data Enclave and its scientific mission. Organizations participating in the LHBA have the option of participating in linking multiple data sets and cohort discovery as well. [1] Data partners who choose to participate in PPRL with external datasets must agree to link to the given external dataset PPRL Site Permissions Dashboard [2] Users that need to utilize an external dataset will first request the external dataset for consideration to be imported. Once the request is received, the External Dataset Committee in the Tools and Resource subgroup and NCATS will review external database requests to include in the N3C Dataset. This review process will be done in three phases: Initial Review Process Overall Dataset Review Process External Dataset Importation [3]	 LHBA specifies that the data can be linked Participating PPRL sites specify that data can be linked with particular external datasets The External Dataset Committee in the Tools and Resource subgroup and NCATS approval specifies that data can be linked 	 [1] NCATS Response to N3C Questions [2] Predecessor report (https://www.nichd.nih.gov/sites/default /files/inline- files/NICHD_ODSS_PPRL_for_Pediatric_C OVID- 19 Studies_Public_Final_Report_508.pdf

Dataset 8 - N	13C			
		Raw Language	Interpretation	Source
2.2.2	With what other data can it be linked or	Linking Multiple Datasets:	1. N3C policy designation of external	[1] https://zenodo.org/record/5165257
	can it not be linked (scope of linkage)	Though there are many types of datasets and ways to link to them, the Linkage	datasets for linking specifies that:	(Accessed 4/19/23)
		Honest Broker Agreement applies only to datasets that are within N3C Data Enclave	a. External datasets must be classified	[2] NCATS Response to N3C Questions
		and requires linkage using the hash/PPRL.N3C has developed an external dataset	as Class 0, 2, 3, or 4 to be considered	[3]
		classification system (See description below Multi-Dataset Linkage Classification)	for N3C linkage. A dataset which is	https://docs.google.com/document/d/1
		the LHBA only applies to datasets classified as class "0" and Class "2". Linkages to	categorized as class 2 can be imported	QJi_sNi0wnZFV3ghTBubI7d3kFLtdkVfQws
		external datasets that do not require the hash or PPRL are not covered by this	but will require hashing	LQJOFil8/edit (Accessed: 11/17/23)
		agreement. The difference between Class 0 datasets and Class 2 datasets is Class 0	b. Class 1 linkages are not permitted	
		datasets originate from different enclaves and allows for a temporary extension of	2. Participating PPRL sites specify	
		the N3C Data Enclave to accommodate this requirement. If additional	linkages with external datasets on a	
		computational resources are required for large datasets, the N3C Data Enclave will	case-by-case basis	
		utilize NCATS High PC Performance Computing (HPC) services for data processing.	3. External Dataset Committee in the	
		Multi-Dataset Linkage Classification Summary	Tools and Resource subgroup and	
		• Class 0: Linkages using cryptographic hash codes (tokens) managed by a third-	NCATS determines the scope of linkage	
		party linkage honest broker to connect multiple Enclaves.	by approving external datasets for	
		• Class 1: Linkages leading to immediate re-identification of patients and is not permitted with the N3C	import and linkage within N3C	
		• Class 2: Linkages using cryptographic hash codes (tokens)within a single enclave		
		leading to higher confidence re-identification of patients.		
		Class 3: Linkages leading to data sufficiently aggregated to reasonably mitigate		
		the risk of re-identification		
		 Class 4: Linkages or use of data not involving individual persons. 		
		[1]		
		All External Datasets under consideration are given a classification code, which		
		defines a dataset's risk for re-identification. The current classes are defined below:		
		Class 0: Linkage is not available at this time, but defined in anticipation of the		
		implementation of a Privacy-Preserving Record Linkage (PPRL e.g., hashed		

aset 8 -		Raw Language	Interpretation
			interpretation
		identifiers) managed by a third-party honest broker.	
		• The assumption here is that Enclave data for a given patient has an internally	
		generated ID, the external team has their own ID, and the honest broker has both	
		(but nothing else), and only shares a hash of the other ID with each team.	
		• Examples here include connecting Enclave data with separate repositories (at	
		the individual patient level) of sequence data, imaging, etc.	
		Class 1: Linkages leading to immediate re-identification of patients.	
		• Linked datasets directly containing data that increases the risk or the reality of	
		re-identification. A simple example here is a table of HIPAA-sensitive variables	
		matching against Limited Dataset records.	
		• Data fitting this class will not be permitted in the N3C Data Enclave, but we	
		define it for sake of completeness.	
		Class 2: Linkages leading to high-confidence heuristic re-identification of patients.	
		• Example: a linkage of zip code and age (plus or minus an approximate data of	
		infection) potentially leading to high-confidence heuristic re-identification of	
		nursing home residents.	
		Class 3: Linkages leading to data sufficiently aggregated to reasonably mitigate the risk of re-identification.	
		• Example: a patient with a specific co-morbidity known to be associated with a	
		given genetic defect knowing the pool of persons with that genetic defect fails to	
		provide sufficient discrimination (assuming that that pool is of a sufficient	
		cardinality.) Note that any additional linkage information (e.g., a person's height	
		provide additional discriminating power in a sparse information space to allow re- identification.	
		Class 4: Linkages or use of data not involving individual persons.	
		• Examples: a dataset mapping zip code to the climate zone or a dataset mapping	
		drugs to known side effects. Data sources that would extend specific value sets,	
		such as ClinVar data for specific genomic mutations are another example.	
		[2]	
		Users that need to utilize an external dataset will first request the external dataset	
		for consideration to be imported. Once the request is received, the External Dataset	
		Committee in the Tools and Resource subgroup and NCATS will review external	
		database requests to include in the N3C Dataset. This review process will be done in	
		three phases:	
		Initial Review Process	
		Overall Dataset Review Process	
		External Dataset Importation [3]	
2.2.3	Whether data can be shared	Does not authorize/specify	Does not authorize/specify
2.2.4	How data can be shared (de-identification	Does not authorize/specify	Does not authorize/specify
	status, disclosure review)		

Source

Dataset 8 -	N3C		
		Raw Language	Interpretation
2.2.5	How data can be accessed (access type,	Class 1 (not allowed). Linkages leading to immediate re-identification of patients.	N3C specifies that for data access, th
	data use agreement, data access committee/group approval, IRB LOD, etc.)	Access to various classes of data require sets of agreements to be in place for the	must be: 1. For N3C Class 0 or Class 2 linkages
		data requesters. All datasets that use the PPRL (Class 0 and 2) are considered level 3	
		data and as such must work through their institutional policies and require a letter	Agreement
		of determination when submitting an N3C Data Use Request (DUR).	b. Dual authentication and
			authorization
		Class 2 dataset linkages require existing institutional N3C Data Use Agreement, Dual	
		authentication and authorization, a signed institutional linkage honest broker	broker agreement for multiple datas
		agreement for multiple datasets, an approved data use request (DUR) by the	d. Approved data use request (DUR)
		federally staffed data access committee (DAC), and local institutions IRB letter of	the federally staffed data access
		determination. IRBs must clearly have reviewed the DURs proposed protocol and	committee (DAC)
		the specific use of multiple datasets beyond N3C EHR-derived data. Class 2 dataset	e. Local institutions IRB letter of
		linkage are contained within the single N3C Data Enclave. An example of a class 2	determination
		multiple linkage datasets would be if N3C data is linked to Mortality data that was	f. Interconnect agreement (for Class
		sent to N3C.	only)
		For class 0 dataset linkages, that connect more than one enclave, an additional	2. For N3C Class 3 and 4 linkages:
		interconnect agreement will be in place. The interconnect agreement will be	a. Approved data use request (DUR)
		agreement between two trusted enclaves in order to instantiate what is referred to	the federally staffed data access
		as a temporary virtual or ephemeral workbench. The workbench is ephemeral	committee (DAC)
		because it is short-lived for a specific task and then destroyed when an	
		investigator's work is completed.	
		Classes 3 and 4 require a DUR for the study approved by the DAC.	
		[1]	
2.2.6	How data can be used (data use limitations)	Does not authorize/specify	Does not authorize/specify
2.2.7	Other (specify)	Does not authorize/specify	Does not authorize/specify
3	Data Sharing		
3.1	Authorizations and Applicable Regulation	s/Policies	
3.1.1	Authorizations		1. Institutional IRB or external centra
			IRB approval
			2. Waiver of consent
			3. Data Transfer Agreement
3.1.1.1	Assent	N/A	N/A
3.1.1.2	Consent		N/A
3.1.1.3	IRB/equivalent Privacy Board	The N3C does not contain direct identifying information, and additional measures	Two IRB determinations authorize da
	determination	have been put in place to protect patient privacy. As a result, NCATS received a waiver of consent from an NIH Institutional Review Board, conforming to the	sharing: 1. Institutional IRB or external centra
		Federal Policy for the Protection of Human Subjects ("Common Rule"). [1]	IRB approval for transfer of data fror
		rederal Policy for the Protection of Human Subjects (Common Rule). [1]	participating institutions to the NCAT
		Transfer of data from participating institutions to the NCATS N3C platform covered	N3C Platform
		under a cIRB, unless an institution chose to utilize their own IRB for data transfer to	2. NIH IRB waiver of consent for shar
		NCATS [2]	through the NCATS N3C Platform
	Local/state/federal laws	Information not available/found	Information not available/found

	Source
here	[1] https://covid.cd2h.org/PPRL
	(Accessed 4/28/23)
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R) by	
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lata	[1] https://ncats.nih.gov/n3c/about_
	(Accessed 4/21/23)
al	[2] NCATS Email Communication
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aring	
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Dataset 8 -	N3C		
		Raw Language	Interpretation
3.1.1.5	Institutional Certification	Information not available/found	Information not available/found
3.1.1.6	Data originator agreement	Participating partners and other collaborators provide data to the N3C after they execute a Data Transfer Agreement with NCATS. [1]	Data Transfer Agreement (DTA) executed with NCATS authorizes dat transfer to NCATS N3C Platform
		"Recipient shall not use the Data except as authorized under this Agreement. The Data will be deposited in the NIH COVID-19 Data Warehouse and made accessible to users under a separate data use agreement to support the response to the COVID-19 pandemic." [2]	
		Institutions that wish to contribute data to the N3C must execute a Data Transfer Agreement (DTA) with NCATS. The DTA provides terms and conditions for data transfer and outlines the general terms of data use. [3] The NCATS Data Transfer Agreement: is under the stewardship of NCATS and is an agreement between NCATS and participating institutions that are willing to provide de-identified data to the N3C Data Enclave. [4]	
3.1.1.7	Repository agreements/policies	Information not available/found	Information not available/found
3.1.1.8	Other	Information not available/found	Information not available/found
3.1.2	Applicable Regulations/Policies		
3.1.2.1	Local regulations/policies	 NCATS asks medical institutions and health care organizations to contribute this information as a limited data set, pursuant to the requirements in the HIPAA Privacy Rule. A limited data set is defined as protected health information that excludes certain direct identifiers of an individual or of relatives, employers or household members of the individual — but may include city, state, ZIP code and elements of dates. A limited data set can be disclosed only for purposes of research, public health or health care operations. Three levels of data are available for analysis: Limited Data Set (LDS): Consists of patient data that retain the following protected health information — dates of service patient ZIP code De-identified Data Set: Consists of patient data from the LDS with the following changes — Dates of service are algorithmically shifted to protect patient privacy. Patient ZIP codes are truncated to the first three digits or removed entirely if the ZIP code represents fewer than 20,000 individuals or represents Tribal lands. Synthetic Data Set: Consists of data that are computationally derived from the LDS and that resemble patient information statistically but are not actual patient data. 	N3C policies

	Source
ta	 [1] <u>https://ncats.nih.gov/n3c/about</u> (Accessed 4/21/23) [2] <u>https://ncats.nih.gov/sites/default/files/</u> <u>NCATS_Data_Transfer_Agreement_508.p</u> <u>df</u> (Accessed 4/21/23) [3] <u>https://ncats.nih.gov/n3c/resources/data-contribution</u> (Accessed 4/21/23) [4] NCATS's Responses to N3C Questions
	[1] <u>https://ncats.nih.gov/n3c/about/data- overview</u> (Accessed 8/9/23)

Dataset 8 -	· N3C			
		Raw Language	Interpretation	Source
3.1.2.2	Tribal regulations/policies		 NIH Guidance on the Implementation of the HHS Tribal Consultation Policy Tribal Consultation Report 	
3.1.2.3	State regulations/policies	Information not available/found	Information not available/found	

Dataset 8 -	N3C			
		Raw Language	Interpretation	Source
3.1.2.4	Federal regulations/policies	In alignment with the National Institutes of Health Guidance on the Implementation of the HHS Tribal Consultation Policy, NCATS sought input from Tribal Nations on whether and how to provide AI/AN data within the N3C. Now that the Tribal Consultation has been conducted, AI/AN data is available for research in a manner that reflects the input that NIH received through the consultation process. The Tribal Consultation report (PDF-1.3MB) details how this data is now being made available. [1]	HHS Tribal Consultation Policy	[1] https://ncats.nih.gov/n3c/about/progra m-faq# (Accessed 4/21/23)
3.1.2.5	International regulations/policies	Information not available/found	Information not available/found	
3.1.2.6	Contractual obligations	Information not available/found	Information not available/found	
3.1.2.7	Repository policies	Information not available/found	Information not available/found	
3.2	1 1 11	ess, and use based on data sharing authorization or applicable regulations/po		ce)
3.2.1	Whether the data can be linked	Does not authorize/specify	Does not authorize/specify	
3.2.2	With what other data can it be linked or can it not be linked (scope of linkage)	the N3C platform is subject to the common rule. [1] The N3C does not contain direct identifying information, and additional measures have been put in place to protect patient privacy. As a result, NCATS received a waiver of consent from an NIH Institutional Review Board, conforming to the Federal Policy for the Protection of Human Subjects ("Common Rule"). [2]	Common Rule	 [1] NCATS Email Communication [2] <u>https://ncats.nih.gov/n3c/about</u> (Accessed 4/21/23)
3.2.3	Whether data can be shared	The N3C does not contain direct identifying information, and additional measures have been put in place to protect patient privacy. As a result, NCATS received a waiver of consent from an NIH Institutional Review Board, conforming to the Federal Policy for the Protection of Human Subjects ("Common Rule"). [1] Participating partners and other collaborators provide data to the N3C after they execute a Data Transfer Agreement with NCATS. [1] "Recipient shall not use the Data except as authorized under this Agreement. The Data will be deposited in the NIH COVID-19 Data Warehouse and made accessible to users under a separate data use agreement to support the response to the COVID-19 pandemic." [2] In alignment with the National Institutes of Health Guidance on the Implementation of the HHS Tribal Consultation Policy, NCATS sought input from Tribal Nations on whether and how to provide AI/AN data within the N3C. Now that the Tribal Consultation report (PDF-1.3MB) details how this data is now being made available. [3] Based on the feedback from Tribal Consultation, NCATS will take the following steps to make AI/AN data available for research through its standard Data Use Request (DUR) process:	of the HHS Tribal Consultation Policy, the HHS Tribal Consultation Policy, and the Tribal Consultation Report specify that AI/AN data can be shared	<pre>[1] https://ncats.nih.gov/n3c/about (Accessed 4/21/23) [2] https://ncats.nih.gov/sites/default/files/ NCATS_Data_Transfer_Agreement_508.p df (Accessed 4/21/23) [3] https://ncats.nih.gov/n3c/about/progra m-faq# (Accessed 4/21/23) [4] https://ncats.nih.gov/n3c/about/tribal- consultation (Accessed 4/21/23) [5] https://dpcpsi.nih.gov/sites/default/files/ N3C-Consultation-Report-508.pdf (Accessed 4/21/23)</pre>

Dataset 8 - N3C		
	Raw Language	Interpretation
	 Al/AN data will be moved back to a standalone category. With this change, Al/AN data will be available in any N3C analysis that provides race and ethnicity distribution. IP codes that overlap with Tribal communities will be available for research in the following manner: ZIP codes for all geographic units containing 20,000 or fewer people are removed entirely. This is standard practice for all geographic units and will be applied the same way when Al/AN data are restored to a separate category. For example, if a ZIP code of "01234" represents a community of 20,000 or fewer individuals, the user will see a ZIP code of "00000." Currently, specific ZIP codes representing rural populations predominantly with Al/AN-identifying individuals are hidden. These will now be visible in both the limited data set and de-identified data. This means that Al/AN data will be managed as others are managed, with the exception that the full five-digit ZIP codes are never shown. For example, if a ZIP code of "01234" represents a predominantly Al/AN community, the user will see only a partial ZIP code of "012." The N3C Data User Code of Conduct will be modified so that data users will be asked to attest that they understand the N3C contains no Tribal affiliation data and that use of Al/AN data and ZIP code information to make assumptions about Tribal affiliation is not valid or appropriate. This statement will be included as a reminder when a DUR is received, a Data Use Agreement is executed, and data are accessed in the N3C platform and during publication processes. The N3C vill continue to engage NIH's Tribal Health Research Office and Tribal Nations as issues for discussion arise. It is important to note that the N3C does not have EHR data from the Indian Health Service, nor does it contain information about Tribal affiliation. 	

Source

Dataset 8 -	N3C		
		Raw Language	Interpretation
3.2.4	How data can be shared (de-identification status, disclosure review)	Three levels of data are available for analysis: Limited Data Set (LDS): Consists of patient data that retain the following protected health information — dates of service patient ZIP code De-identified Data Set: Consists of patient data from the LDS with the following changes — Dates of service are algorithmically shifted to protect patient privacy. Patient ZIP codes are truncated to the first three digits or removed entirely if the ZIP code represents fewer than 20,000 individuals or represents Tribal lands. Synthetic Data Set: Consists of data that are computationally derived from the LDS and that resemble patient information statistically but are not actual patient data. [1] In alignment with the National Institutes of Health Guidance on the Implementation of the HHS Tribal Consultation Policy, NCATS sought input from Tribal Nations on whether and how to provide AI/AN data within the N3C. Now that the Tribal Consultation has been conducted, AI/AN data is available for research in a manner that reflects the input that NIH received through the consultation process. The Tribal Consultation report (PDF-1.3MB) details how this data is now being made available. [2]	 N3C policy specifies limited dataset (LDS), de-identified, and synthetic datasets are shared. NIH Guidance on the Implementat of the HHS Tribal Consultation Policy, and the Tribal Consultation Policy, and the Tribal Consultation Report specific that (a). AI/AN data will be a standalone category. With this change, AI/AN data will be available in any N3C analysis that provides race and ethnicity distribution. (b). ZIP codes must be removed entire for all geographic units containing 20,000 or fewer people, and full five-digit ZIP codes of predominantly AI/A community will never be shown.
		 Based on the feedback from Tribal Consultation, NCATS will take the following steps to make Al/AN data available for research through its standard Data Use Request (DUR) process: 1. Al/AN data will be moved back to a standalone category. With this change, Al/AN data will be available in any N3C analysis that provides race and ethnicity distribution. 2. ZIP codes that overlap with Tribal communities will be available for research in the following manner: ZIP codes for all geographic units containing 20,000 or fewer people are removed entirely. This is standard practice for all geographic units and will be applied the same way when Al/AN data are restored to a separate category. For example, if a ZIP code of "01234" represents a community of 20,000 or fewer individuals, the user will see a ZIP code of "00000." Currently, specific ZIP codes representing rural populations predominantly with Al/AN-identifying individuals are hidden. These will now be visible in both the limited data set and de-identified data. This means that Al/AN data will be managed as others are managed, with the exception that the full five-digit ZIP codes are never shown. For example, if a ZIP code of "01234" represents a predominantly Al/AN community, the user will see only a partial ZIP code of "012." 	

	Source
sets	[1] https://ncats.nih.gov/n3c/about/data-
	overview (Accessed 4/21/23)
	[2]
	https://ncats.nih.gov/n3c/about/progra
-	<u>m-faq#</u> (Accessed 4/21/23)
and	[3]
ify	https://ncats.nih.gov/n3c/about/tribal-
	consultation (Accessed 4/21/23)
lata	https://dpcpsi.nih.gov/sites/default/files/
)	N3C-Consultation-Report-508.pdf
	(Accessed 4/21/23)
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Dataset 8 -	N3C		
		Raw Language	Interpretation
		 3. The N3C Data User Code of Conduct will be modified so that data users will be asked to attest that they understand the N3C contains no Tribal affiliation data and that use of AI/AN data and ZIP code information to make assumptions about Tribal affiliation is not valid or appropriate. This statement will be included as a reminder when a DUR is received, a Data Use Agreement is executed, and data are accessed in the N3C platform and during publication processes. 4. The N3C will continue to engage NIH's Tribal Health Research Office and Tribal Nations as issues for discussion arise. [3] It is important to note that the N3C does not have EHR data from the Indian Health Service, nor does it contain information about Tribal affiliation. [4] 	
3.2.5	How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.)	Recipient shall not use the Data except as authorized under this Agreement. The Data will be deposited in the NIH COVID-19 Data Warehouse and made accessible to usersNCATS Data Transfer Agreement FINAL 4-7-2021 2 under a separate data use agreement to support the response to the COVID-19 pandemic. Users who access the Data will: • only analyze the Data within the NIH COVID-19 Data Warehouse platform. • not be able to download or remove the Data from the NIH COVID-19 Warehouse in any form. • share the results of analyses within the platform to the extent possible • make no effort to contact or identify individuals who are or may be the sources or subjects of the Data • agree to acknowledge the NIH COVID-19 Data Warehouse in all publications and oral disclosures that rely on the Data • be used only for research purposes and public health activities related to the COVID-19 pandemic [1]	The DTA specifies that users who ac the data will access the data within NCATS N3C Plaform

	Source
the	[1] <u>https://ncats.nih.gov/sites/default/files/</u> <u>NCATS_Data_Transfer_Agreement_508.p</u> <u>df</u> (Accessed 4/21/23)

Dataset 8 -	- N3C		
		Raw Language	Interpretation
3.2.6	How data can be used (data use limitations)	 3. The N3C Data User Code of Conduct will be modified so that data users will be asked to attest that they understand the N3C contains no Tribal affiliation data and that use of Al/AN data and ZIP code information to make assumptions about Tribal affiliation is not valid or appropriate. This statement will be included as a reminder when a DUR is received, a Data Use Agreement is executed, and data are accessed in the N3C platform and during publication processes. [1] Recipient shall not use the Data except as authorized under this Agreement. The Data will be deposited in the NIH COVID-19 Data Warehouse and made accessible to users NCATS Data Transfer Agreement FINAL 4-7-2021 2 under a separate data use agreement to support the response to the COVID-19 pandemic. Users who access the Data will: only analyze the Data within the NIH COVID-19 Data Warehouse platform. not be able to download or remove the Data from the NIH COVID-19 Warehouse in any form. share the results of analyses within the platform to the extent possible make no effort to contact or identify individuals who are or may be the sources or subjects of the Data agree to acknowledge the NIH COVID-19 Data Warehouse in all publications and oral disclosures that rely on the Data be used only for research purposes and public health activities related to the COVID-19 pandemic [2] 	 The Tribal Consultation Report specifies that data users will be asked to attest that they understand the N3C contains no Tribal affiliation data and that use of AI/AN data and ZIP code information to make assumptions about Tribal affiliation is not valid or appropriate The DTA specifies that data must be used only for research purposes and public health activities related to the COVID-19 pandemic
3.2.7	Other (specify)	Does not authorize/specify	Does not authorize/specify
4	Data Access		
4.1	Authorizations and Applicable Regula	tions/Policies	
4.1.1	Authorizations		 Letter of Determination Data Use Agreement Data Use Request
4.1.1.1	Assent	N/A	N/A
4.1.1.2 4.1.1.3	Consent IRB/equivalent Privacy Board determination	N/A Local IRB letter of determination is required for accessing data (see Appendix Table 2) [1] If requesting access to the Limited Data Set, researchers will need to provide a copy of their institution's Human Research Protection Program IRB determination letter. [2]	N/A Letter of Determination from user's Insitutional IRB authorizes data access
4.1.1.4 4.1.1.5	Local/state/federal laws Institutional Certification	Information not available/found N/A	Information not available/found N/A
4.1.1.6	Data originator agreement	Information not available/found	Information not available/found

	Source
sked e N3C and ode s d or ust be and the	 [1] <u>https://ncats.nih.gov/n3c/about/tribal-</u> <u>consultation</u> (Accessed 4/21/23) [2] <u>https://ncats.nih.gov/sites/default/files/</u> <u>NCATS_Data_Transfer_Agreement_508.p</u> <u>df</u> (Accessed 4/21/23)
er's ccess	 [1] Predecessor report (<u>https://www.nichd.nih.gov/sites/default</u>/<u>files/inline-</u> <u>files/NICHD_ODSS_PPRL_for_Pediatric_C</u> <u>OVID-</u> <u>19_Studies_Public_Final_Report_508.pdf</u>) [2] <u>https://ncats.nih.gov/n3c/about/applyin</u> <u>g-for-access</u> (Accessed 4/21/23)

	Raw Language	Interoreiation	
		Interpretation	Sc [1]
Repository agreements/policies	Before researchers can request access to the data, their institutions must execute a	Two repository agreements authorize	[1] https://ncats.nih.go
	Data Use Agreement (DUA) with NCATS. Once a DUA is in place, researchers can submit a Data Use Request (DUR) through the N3C Data Enclave. In the DUR,	data access:	-
		1. Data Use Agreement	<u>g-for-access</u> (Acces
		2. Data Use Request	[2] <u>https://ncats.ni</u>
			<u>files/</u>
			NCATS_N3C_Data_
			(Accessed 4/21/23)
	The N3C Data Access Committee reviews and approves DURs. [1]		
	Data Access Committee (DAC), referred to as the NCATS N3C DAC, is composed of		
	representatives from the NIH or other Federal Agencies and is responsible for		
	reviewing Data Use Requests (DUR) and verifying that conditions for accessing Data		
	are met. [2]		
	Data Lise Request (DLIR) a document that Liser(s) must complete and submit to the		
Other (specify)	Information not available/found	Information not available/found	
	Information not available/found	Information not available/found	
		-	
			[1]
rederal regulations/policies			
			https://grants.nih.g
			e-files/NOT-OD-17
			10/23/23)
	NIH Policy for Issuing Certificates of Confidentiality [1]		
International regulations/policies	Information not available/found	Information not available/found	
Contractual obligations	NCATS uses Palantir for its software and expertise in the platform's execution.	Obligations from contract between	[1] NCATS Email Co
	Palantir is hosted by NCATS within this instance, and no data can leave this enclave	NCATS and Palantir	
	or be accessed by the company for its use. All contractors with access to the NCATS		
		representatives from the NIH or other Federal Agencies and is responsible for reviewing Data Use Requests (DUR) and verifying that conditions for accessing Data are met. [2] Data Use Request (DUR) a document that User(s) must complete and submit to the DAC for review prior to accessing the NCATS N3C Data Enclave. For each individual project, the DUR, outlined in Appendix A, will contain overarching use objectives and designs, scientific goals, any testable hypotheses, and an outline of plans for using the Data. [2] Other (specify) Information not available/found Applicable Regulations/Policies Information not available/found Tribal regulations/policies Information not available/found State regulations/policies Information not available/found Federal regulations/policies Data residing in NCATS N3C Data Enclave is protected by a Certificate of Confidentiality pursuant to section 301(d) of the Public Health Service Act. The Certificate of Confidentiality prohibits disclosure, including in any federal, state, or local criminal, civil, administrative, legislative, or other proceeding, of identifiable, sensitive information collected or used during research unless disclosure is made pursuant to a statutory exception. The Certificate of Confidentiality also protects all copies of Data from the NCATS N3C Data Enclave in perpetuty as explained in the NIH Policy for Issuing Certificates of Confidentiality as explained in the NIH Policy for Issuing Certificates of Confidentiality as explained in the NIH Policy for Issuing Certificates of Confidentiality [1] International regulations/policies Information not available/found NCATS uses Palantir for its software and expertise in the platform's execution. Palantir is hosted by NCATS within this instance, and no data can leave this enclave or be accessed by the company for its use. All contractors with access to the NCATS GovCloud instance to implement and maintain the NCATS N3C Data Enclave are subject to all relevant NIH-specified clearances, non-disclosure agreements,	title, names of project personnel, a non-confidential research statement, the project proposal and the requested data access level. Additional DUR requirements include reviewing and agreeing to comply with the N3C Data User Code of Conduct. The N3C Data Access Committee reviews and approves DURs. [1] Data Access Committee (DAC), referred to as the NCATS N3C DAC, is composed of representatives from the N1H or other Federal Agencies and is responsible for reviewing Data Use Requests (DUR) and verifying that conditions for accessing Data are met. [2] Data Use Request (OUR) a document that User(s) must complete and submit to the ACTS N3C DATE finders, for each individual project, the DUR, outlined in Appendix A, will contain overarching use objectives and designs, scientific goals, any testable hypotheses, and an outline of plans for using the Data. [2] Other (specify) Information not available/found Information not available/found Tribal regulations/Policies Information not available/found Information not available/found Tribal regulations/policies Information not available/found Information not available/found Tribal regulations/policies Information not available/found Information not available/found Federal regulations/policies Information not available/found Information not available/found Federal regulations/policies Information not available/found Information not available/found Federal regulations/policies Information not available/found Information not available/found

terpretation	Source
reement quest	[1] https://ncats.nih.gov/n3c/about/applyin g-for-access (Accessed 4/21/23) [2] https://ncats.nih.gov/sites/default/ files/ NCATS_N3C_Data_Use_Agreement.pdf (Accessed 4/21/23)
t available/found	
t available/found	
t available/found	
t available/found	
onfidentiality	 [1] <u>https://grants.nih.gov/grants/guide/notic</u> <u>e-files/NOT-OD-17109.html</u> (Accessed 10/23/23)
t available/found	
m contract between antir	[1] NCATS Email Communication

	- N3C	Pour Longuago	Interpretation
4.1.2.7	Repository policies	Raw LanguageBefore researchers can request access to the data, their institutions must execute aData Use Agreement (DUA) with NCATS. Once a DUA is in place, researchers cansubmit a Data Use Request (DUR) through the N3C Data Enclave. In the DUR,researchers will need to include, among other information, the project researchtitle, names of project personnel, a non-confidential research statement, theproject proposal and the requested data access level. Additional DUR requirementsinclude reviewing and agreeing to comply with the N3C Data User Code of Conduct.The N3C Data Access Committee reviews and approves DURs. [1]Data Access Committee (DAC), referred to as the NCATS N3C DAC, is composed ofrepresentatives from the NIH or other Federal Agencies and is responsible forreviewing Data Use Requests (DUR) and verifying that conditions for accessing Dataare met. [2]Data Use Request (DUR) a document that User(s) must complete and submit to theDAC for review prior to accessing the NCATS N3C Data Enclave. For each individualproject, the DUR, outlined in Appendix A, will contain overarching use objectivesand designs, scientific goals, any testable hypotheses, and an outline of plans forusing the Data. [2]Investigators using the rich data compiled in the N3C Data Enclave are expected togenerate quantitative results in the forms of tables, figures, parameter estimates,and aggregated statistics. These results may have broad impact and will be shared,typically in the form of manuscripts, reports, and visualizations for websites andseminars. Additionally, many artifacts such as workflows, value sets, andph	
4.2 4.2.1	Governance for data linkage, sharing, acc Whether the data can be linked	ess, and use based on data access authorization or applicable regulations/poli Does not authorize/specify	icies (i.e., the origin of the governa Does not authorize/specify
4.2.1	With what other data can it be linked or can it not be linked (scope of linkage)	Does not authorize/specify	Does not authorize/specify
4.2.3	Whether data can be shared	Does not authorize/specify	Does not authorize/specify
4.2.4	How data can be shared (de-identification status, disclosure review)	Does not authorize/specify	Does not authorize/specify
4.2.5	How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.)	An N3C Data Use Agreement (DUA) is executed by NCATS and a research institution (or directly with a researcher in the case of a citizen scientist who is not affiliated with an institution). To submit a DUA to NCATS, institutions can download this form and email it to <u>NCATSPartnerships@mail.nih.gov</u> (link sends e-mail). Note: DUAs can only be signed by Authorized Institutional Officials who have the	N3C policies specify that to access th Limited Dataset, the user: 1) Must complete N3C registration an create a N3C Data Enclave account 2) Must execute an Institutional Data Use Agreement

	Source
	[1] https://ncats.nih.gov/n3c/about/applyin g-for-access (Accessed 4/21/23) [2] https://ncats.nih.gov/sites/default/files/ NCATS_N3C_Data_Use_Agreement.pdf (Accessed 4/21/23) [3] https://zenodo.org/record/7942069 (Accessed 10/23/23)
ance	2)
he	[1] https://ncats.nih.gov/n3c/resources/data-
and	access (Accessed 4/21/23) [2]
a	https://ncats.nih.gov/n3c/about/applyin g-for-access (Accessed 4/21/23)

Dataset 8 - N3C			
	Raw Language	Interpretation	Source
	Raw Language authority to bind all users at their institution to the terms of the DUA. With the exception of citizen scientists not associated with institutions, individual researchers cannot sign their own DUAs with NCATS. It is strongly recommended that researchers ensure that their home institution has executed a DUA with NCATS before they begin the process of applying for data access. See the list of institutions(link is external) with active DUAs. DUAs will remain in effect for five years from the DUA Effective Date. They will automatically expire at the end of this period unless terminated or renewed. [1] In order to access N3C data, researchers must submit an online Data Use Request (DUR) through the NCATS N3C Data Enclave for each project they want to start or join. Information researchers need to provide in the DUR includes: The project title Names of project personnel A non-confidential research statement The project proposal The requested data access level The N3C Data Access Committee (DAC) reviews and approves DURs. Once the DAC approves a DUR, access to the N3C Data Enclave workspace will be effective for one year starting from the date access is granted. A DUA must be in place for the entire term of a DUR. DURs will be renewable. When users renew their DURs, they will need to attest at that time that their training for access to the N3C Data Enclave is	 3) Must submit Data Use Request (DUR) for approval by N3C Data Access Committee 4) Must complete NIH IT training, attest to the N3C Data User Code of Conduct, and complete Human Subjects Research Protection training at their home institution 5) Must provide IRB letter of determination for data access 6) Must access the data within the N3C Enclave 7) Must abide by the N3C Results Download Policy when downloading results from the N3C enclave 	
	 up to date. N3C Data User Code of Conduct The N3C Data User Code of Conduct states core activities of data users and prohibitions on certain activities involving data or other resources accessible through the N3C Data Enclave. Researchers must agree to the N3C Data User Code of Conduct when they apply to access and use N3C data. NIH Information Security and Information Management Training The N3C Data Enclave is hosted by NCATS, and all researchers must complete the "Information Security, Counterintelligence, Privacy Awareness, Records Management Refresher, Emergency Preparedness Refresher" course, which can be accessed at NIH's information security training website, before submitting a DUR. It will take approximately 60-90 minutes to complete the entire course and users should save evidence of completion for their records (a screenshot or copy of the certificate of completion). [1] If requesting access to the Limited Data Set, researchers will need to provide a copy of their institution's Human Research Protection Program IRB determination letter. [2] 		

Dataset 8 -	N3C		
		Raw Language	Interpretation
		Data are not allowed to leave the Enclave; analyses must be done within the platform and analysis results can be shared broadly. [3]	
		Local IRB letter of determination is required for accessing data (see Appendix Table 2) [4]	
		Researchers who request access to de-identified data or to the Limited Data Set must have completed their home institution's human subjects research training requirements. Researchers will be required to provide the date they completed training in their Data Use Request. [5]	
		Investigators using the rich data compiled in the N3C Data Enclave are expected to generate quantitative results in the forms of tables, figures, parameter estimates, and aggregated statistics. These results may have broad impact and will be shared, typically in the form of manuscripts, reports, and visualizations for websites and seminars. Additionally, many artifacts such as workflows, value sets, and phenotyping algorithms may be developed in the Enclave and made useful to others by being exported for presentation on public websites such as GitHub, or incorporated as supplementary materials to publications. The purpose of this policy is to establish a process to permit the download of quantitative artifacts used in analyses that are necessary for sharing results, while at the same time ensuring protection and security of the data in the Enclave and compliance with the NCATS Data Transfer and Data Use Agreements. [6]	
4.2.6	How data can be used (data use limitations)	User(s) agree(s) to use the Data exclusively for the Research Project proposed, and/or comparative studies using data from individuals infected with pathogens such as SARS, MERS, and H1N1 to support comparative studies, described in the DUR. Any other use of the Data is prohibited. [1]	N3C DUA specifies that the data must be used exclusively for the Research Project proposed, and/or comparative studies using data from individuals infected with pathogens such as SARS MERS, and H1N1 to support comparative studies.

	Source
must arch arative als SARS,	[1] https://ncats.nih.gov/sites/default/files/ NCATS_N3C_Data_Use_Agreement.pdf (Accessed 4/21/23)

Dataset 8 -	N3C			
		Raw Language	Interpretation	Source
4.2.7	Other (specify)	 NCATS uses Palantir for its software and expertise in the platform's execution. Palantir is hosted by NCATS within this instance, and no data can leave this enclave or be accessed by the company for its use. All contractors with access to the NCATS GovCloud instance to implement and maintain the NCATS N3C Data Enclave are subject to all relevant NIH-specified clearances, non-disclosure agreements, training, rules and restrictions. Contractors are not allowed to independently access NCATS N3C Data Enclave data, remove it from the enclave or use it for commercial purposes. [1] Data residing in NCATS N3C Data Enclave is protected by a Certificate of Confidentiality pursuant to section 301(d) of the Public Health Service Act. The Certificate of Confidentiality prohibits disclosure, including in any federal, state, or local criminal, civil, administrative, legislative, or other proceeding, of identifiable, sensitive information collected or used during research unless disclosure is made pursuant to a statutory exception. The Certificate of Confidentiality also protects all copies of Data from the NCATS N3C Data Enclave in perpetuity as explained in the NIH Policy for Issuing Certificates of Confidentiality [2] 	1. Contract between NCATS and Palantir specifies that Palantir contractors with access to the NCATS GovCloud instance to implement and maintain the NCATS N3C Data Enclave	
-	Data Usa			
5	Data Use			
5.1	Authorizations and Applicable Regul Authorizations	ations/Policies	1. Letter of Determination	
5.1.1			2. Data Use Agreement 3. Data Use Request	
5.1.1.1	Assent	N/A	N/A	
5.1.1.2	Consent	N/A	N/A	
5.1.1.3	IRB/equivalent Privacy Board determination	Local IRB letter of determination is required for accessing data (see Appendix Table 2) [1] If requesting access to the Limited Data Set, researchers will need to provide a copy of their institution's Human Research Protection Program IRB determination letter. [2]	Letter of Determination from user's institutional IRB authorizes data access	 [1] Predecessor report (https://www.nichd.nih.gov/sites/default /files/inline- files/NICHD_ODSS_PPRL_for_Pediatric_C OVID- 19_Studies_Public_Final_Report_508.pdf) [2] https://ncats.nih.gov/n3c/about/applyin g-for-access (Accessed 4/21/23)
5.1.1.4	Local/state/federal laws	Information not available/found	Information not available/found	
5.1.1.5	Institutional Certification	Information not available/found	Information not available/found	
5.1.1.6	Data originator agreement	Information not available/found	Information not available/found	

Dataset 8 -	N3C			
		Raw Language	Interpretation	Source
5.1.1.7	Repository agreements/policies	 Before researchers can request access to the data, their institutions must execute a Data Use Agreement (DUA) with NCATS. Once a DUA is in place, researchers can submit a Data Use Request (DUR) through the N3C Data Enclave. In the DUR, researchers will need to include, among other information, the project research title, names of project personnel, a non-confidential research statement, the project proposal and the requested data access level. Additional DUR requirements include reviewing and agreeing to comply with the N3C Data User Code of Conduct. The N3C Data Access Committee reviews and approves DURs. [1] Data Access Committee (DAC), referred to as the NCATS N3C DAC, is composed of representatives from the NIH or other Federal Agencies and is responsible for reviewing Data Use Requests (DUR) and verifying that conditions for accessing Data are met. [2] Data Use Request (DUR) a document that User(s) must complete and submit to the DAC for review prior to accessing the NCATS N3C Data Enclave. For each individual project, the DUR, outlined in Appendix A, will contain overarching use objectives and designs, scientific goals, any testable hypotheses, and an outline of plans for using the Data. [2] User(s) agree(s) to use the Data exclusively for the Research Project proposed, and/or comparative studies using data from individuals infected with pathogens such as SARS, MERS, and H1N1 to support comparative studies, described in the DUR. Any other use of the Data is prohibited. [2] 		<pre>[1] https://ncats.nih.gov/n3c/about/applyin g-for-access (Accessed 4/21/23) [2] https://ncats.nih.gov/sites/default/ files/ NCATS_N3C_Data_Use_Agreement.pdf (Accessed 4/21/23)</pre>
5.1.1.8	Other (specify)	Information not available/found	Information not available/found	
5.1.2	Applicable Regulations/Policies			
5.1.2.1	Local regulations/policies	N3C data may be used only for COVID-19 research purposes. [1] Use data only for the COVID-19-related research projects or comparative studies defined in the Data Use Request (DUR) approved by the N3C DAC for public health purposes and research to inform decision making. [2]	N3C Data User Code of Conduct	 [1] NCATS Response to N3C Questions [2] <u>https://ncats.nih.gov/n3c/resources/data-user-code-of-conduct</u> (Accessed 4/21/23)

Dataset 8 - N3C			
		Raw Language	Interpretation
5.1.2.2	Tribal regulations/policies	In alignment with the National Institutes of Health Guidance on the Implementation of the HHS Tribal Consultation Policy, NCATS sought input from Tribal Nations on whether and how to provide AI/AN data within the N3C. Now that the Tribal Consultation has been conducted, AI/AN data is available for research in a manner that reflects the input that NIH received through the consultation process. The Tribal Consultation report (PDF-1.3MB) details how this data is now being made available. [1] Based on the feedback from Tribal Consultation, NCATS will take the following	 NIH Guidance on the Implementation of the HHS Tribal Consultation Policy Tribal Consultation Report
		steps to make AI/AN data available for research through its standard Data Use Request (DUR) process: 1. AI/AN data will be moved back to a standalone category. With this change,	
		 AI/AN data will be available in any N3C analysis that provides race and ethnicity distribution. 2. ZIP codes that overlap with Tribal communities will be available for research in the following manner: ZIP codes for all geographic units containing 20,000 or fewer people are removed 	
		entirely. This is standard practice for all geographic units and will be applied the same way when AI/AN data are restored to a separate category. For example, if a ZIP code of "01234" represents a community of 20,000 or fewer individuals, the user will see a ZIP code of "00000."	
		Currently, specific ZIP codes representing rural populations predominantly with AI/AN-identifying individuals are hidden. These will now be visible in both the limited data set and de-identified data. This means that AI/AN data will be managed as others are managed, with the exception that the full five-digit ZIP codes are never shown.	
		 For example, if a ZIP code of "01234" represents a predominantly AI/AN community, the user will see only a partial ZIP code of "012." 3. The N3C Data User Code of Conduct will be modified so that data users will be asked to attest that they understand the N3C contains no Tribal affiliation data and that use of AI/AN data and ZIP code information to make assumptions about 	
		 Tribal affiliation is not valid or appropriate. This statement will be included as a reminder when a DUR is received, a Data Use Agreement is executed, and data are accessed in the N3C platform and during publication processes. 4. The N3C will continue to engage NIH's Tribal Health Research Office and Tribal Nations as issues for discussion arise. [2] 	
		It is important to note that the N3C does not have EHR data from the Indian Health Service, nor does it contain information about Tribal affiliation. [3]	
5.1.2.3	State regulations/policies	Information not available/found	Information not available/found

Source			
 [1] https://ncats.nih.gov/n3c/about/progra m-faq# (Accessed 4/21/23) [2] https://ncats.nih.gov/n3c/about/tribal- consultation (Accessed 4/21/23) [3] 			
https://dpcpsi.nih.gov/sites/default/files/ /N3C-Consultation-Report-508.pdf (Accessed 4/21/23)			

Dataset 8 -	N3C			
		Raw Language	Interpretation	Source
5.1.2.4	Federal regulations/policies	In alignment with the National Institutes of Health Guidance on the Implementation of the HHS Tribal Consultation Policy, NCATS sought input from Tribal Nations on whether and how to provide AI/AN data within the N3C. Now that the Tribal Consultation has been conducted, AI/AN data is available for research in a manner that reflects the input that NIH received through the consultation process. The Tribal Consultation report (PDF-1.3MB) details how this data is now being made available. [1]	HHS Tribal Consultation Policy	[1] <u>https://ncats.nih.gov/n3c/about/progra</u> <u>m-faq#</u> (Accessed 4/21/23)
5.1.2.5	International regulations/policies	Information not available/found	Information not available/found	
5.1.2.6	Contractual obligations	Information not available/found	Information not available/found	
5.1.2.7	Repository policies	 Information not available/Joind Before researchers can request access to the data, their institutions must execute a Data Use Agreement (DUA) with NCATS. Once a DUA is in place, researchers can submit a Data Use Request (DUR) through the N3C Data Enclave. In the DUR, researchers will need to include, among other information, the project research title, names of project personnel, a non-confidential research statement, the project proposal and the requested data access level. Additional DUR requirements include reviewing and agreeing to comply with the N3C Data User Code of Conduct. The N3C Data Access Committee reviews and approves DURs. [1] Data Access Committee (DAC), referred to as the NCATS N3C DAC, is composed of representatives from the NIH or other Federal Agencies and is responsible for reviewing Data Use Requests (DUR) and verifying that conditions for accessing Data are met. [2] Data Use Request (DUR) a document that User(s) must complete and submit to the DAC for review prior to accessing the NCATS N3C Data Enclave. For each individual project, the DUR, outlined in Appendix A, will contain overarching use objectives and designs, scientific goals, any testable hypotheses, and an outline of plans for using the Data. [2] This Community Guiding Principles document outlines expectations of every N3C community member, which includes, institutions and individuals who use N3C resources, expertise, and data. The N3C community is committed to providing a welcoming and inspiring environment for all community members. These principles were established by the N3C community in an unprecedented effort to encourage and enable a highly collaborative research environment to address one of the worst health crises of our time. As such, we expect these guiding principles to be honored by each community member. [3] Purpose: This document provides community-driven guidelines and approaches that all users within the N3C research environment to addresses attribution and p	N3C policies	[1] https://ncats.nih.gov/n3c/about/applyin g-for-access (Accessed 4/21/23) [2] https://ncats.nih.gov/sites/default/ files/ NCATS_N3C_Data_Use_Agreement.pdf (Accessed 4/21/23) [3] https://zenodo.org/record/3979610 (Accessed 10/23/23) [4] https://zenodo.org/record/7787523 (Accessed 10/23/23)

Dataset 8 -	N3C			
		Raw Language	Interpretation	Source
5.2	Governance for data linkage, sharing, acce	ess, and use based on data access authorization or applicable regulations/poli	cies (i.e., the origin of the governance	e)
5.2.1	Whether the data can be linked	Does not authorize/specify	Does not authorize/specify	
5.2.2	With what other data can it be linked or can it not be linked (scope of linkage)	Does not authorize/specify	Does not authorize/specify	
5.2.3	Whether data can be shared	Does not authorize/specify	Does not authorize/specify	
5.2.4	How data can be shared (de-identification status, disclosure review)	Does not authorize/specify	Does not authorize/specify	
5.2.5	How data can be accessed (access type,	An N3C Data Use Agreement (DUA) is executed by NCATS and a research institution	N3C policy specifies that to access the	[1]
	data use agreement, data access	(or directly with a researcher in the case of a citizen scientist who is not affiliated	Limited Dataset, the user:	https://ncats.nih.gov/n3c/resources/data
	committee/group approval, IRB LOD, etc.)	with an institution). To submit a DUA to NCATS, institutions can download this form	1) Must complete N3C registration and	access (Accessed 4/21/23)
		and email it to <u>NCATSPartnerships@mail.nih.gov</u> (link sends e-mail).	create a N3C Data Enclave account	[2]
			2) Must execute an Institutional Data	https://ncats.nih.gov/n3c/about/applyin
		Note: DUAs can only be signed by Authorized Institutional Officials who have the	Use Agreement	g-for-access (Accessed 4/21/23)
		authority to bind all users at their institution to the terms of the DUA. With the	3) Must submit Data Use Request	[3] NCATS Response to N3C Questions
		exception of citizen scientists not associated with institutions, individual	(DUR) for approval by N3C Data Access	[4] Predecessor report
		researchers cannot sign their own DUAs with NCATS.	Committee	(https://www.nichd.nih.gov/sites/default
			4) Must complete NIH IT training,	/files/inline-
		It is strongly recommended that researchers ensure that their home institution has	attest to the N3C Data User Code of	files/NICHD_ODSS_PPRL_for_Pediatric_C
		executed a DUA with NCATS before they begin the process of applying for data	Conduct, and complete Human	OVID-
		access. See the list of institutions(link is external) with active DUAs.	Subjects Research Protection training	19 Studies_Public_Final_Report_508.pdf
			5) Must provide IRB letter of)
		DUAs will remain in effect for five years from the DUA Effective Date. They will	determination for data access	
		automatically expire at the end of this period unless terminated or renewed. [1]	6) Must access the data within the N3C	
			Enclave	
		If requesting access to the Limited Data Set, researchers will need to provide a copy		
		of their institution's Human Research Protection Program IRB determination letter.		
		[2]		
		In order to access N3C data, researchers must submit an online Data Use Request		
		(DUR) through the NCATS N3C Data Enclave for each project they want to start or		
		join.		
		Information researchers need to provide in the DUR includes:		
		The project title		
		Names of project personnel		

Dataset 8 - N3C		
	Raw Language	Interpretation
Dataset 8 - N3C	A non-confidential research statement The project proposal The requested data access level The N3C Data Access Committee (DAC) reviews and approves DURs. Once the DAC approves a DUR, access to the N3C Data Enclave workspace will be effective for one year starting from the date access is granted. A DUA must be in place for the entire term of a DUR. DURs will be renewable. When users renew their DURs, they will need to attest at that time that their training for access to the N3C Data Enclave is up to date. N3C Data User Code of Conduct The N3C Data User Code of Conduct states core activities of data users and prohibitions on certain activities involving data or other resources accessible through the N3C Data Enclave. Researchers must agree to the N3C Data User Code of Conduct when they apply to access and use N3C data. NIH Information Security and Information Management Training The N3C Data Enclave is hosted by NCATS, and all researchers must complete the "Information Security. Counterintelligence, Privacy Awareness, Records Management Refresher, Emergency Preparedness Refresher" course, which can be accessed at NIH's information security training website, before submitting a DUR. It will take approximately 60-90 minutes to complete the entire course and users should save evidence of completion for their records (a screenshot or copy of the certificate of completion). [1] Data are not allowed to leave the Enclave; analyses must be done within the platform and analysis results can be shared broadly. [3]	
	Local IRB letter of determination is required for accessing data (see Appendix Table 2) [4]	

Source			

Dataset 8 - N3C				
		Raw Language	Interpretation	Source
5.2.6	How data can be used (data use	User(s) agree(s) to use the Data exclusively for the Research Project proposed,	1. N3C DUA specifies that the data must	[1] https://ncats.nih.gov/sites/default/
	limitations)	and/or comparative studies using data from individuals infected with pathogens	be used exclusively for the Research	files/
		such as SARS, MERS, and H1N1 to support comparative studies, described in the	Project proposed, and/or comparative	NCATS_N3C_Data_Use_Agreement.pdf
		DUR. Any other use of the Data is prohibited.	studies using data from individuals	(Accessed 4/21/23)
		[1]	infected with pathogens such as SARS,	[2] NCATS Response to N3C Questions
			MERS, and H1N1 to support	[3]
		N3C data may be used only for COVID-19 research purposes. [2]	comparative studies.	https://ncats.nih.gov/n3c/resources/data-
			2. N3C Data User Code of Conduct	user-code-of-conduct (Accessed 4/21/23)
		Use data only for the COVID-19-related research projects or comparative studies	specifies that N3C data must only be	[4]
		defined in the Data Use Request (DUR) approved by the N3C DAC for public health	used for COVID-19 general research	https://ncats.nih.gov/n3c/about/tribal-
		purposes and research to inform decision making. [3]	purposes.	consultation (Accessed 4/21/23)
			3. NIH Guidance on the Implementation	
		Based on the feedback from Tribal Consultation, NCATS will take the following steps	of the HHS Tribal Consultation Policy,	https://dpcpsi.nih.gov/sites/default/files/
		to make AI/AN data available for research through its standard Data Use Request	the HHS Tribal Consultation Policy, and	N3C-Consultation-Report-508.pdf
		(DUR) process:	the Tribal Consultation Report specify	(Accessed 4/21/23)
			that data users will be asked to attest	[6] <u>https://zenodo.org/record/3979610</u>
		1. AI/AN data will be moved back to a standalone category. With this change,	that they understand the N3C contains	(Accessed 10/23/23)
		AI/AN data will be available in any N3C analysis that provides race and ethnicity	no Tribal affiliation data and that use of	[7] <u>https://zenodo.org/record/7787523</u>
		distribution.	AI/AN data and ZIP code information to	(Accessed 10/23/23)
		2. ZIP codes that overlap with Tribal communities will be available for research in	make assumptions about Tribal	
		the following manner:	affiliation is not valid or appropriate.	
		ZIP codes for all geographic units containing 20,000 or fewer people are removed	4. User must also comply with the N3C	
		entirely. This is standard practice for all geographic units and will be applied the	Community Guiding Principles and the	
		same way when AI/AN data are restored to a separate category.	Attribution and Publication Principles.	
		For example, if a ZIP code of "01234" represents a community of 20,000 or fewer		
		individuals, the user will see a ZIP code of "00000."		
		Currently, specific ZIP codes representing rural populations predominantly with		
		AI/AN-identifying individuals are hidden. These will now be visible in both the		

Raw Language	Interpretation
 limited data set and de-identified data. This means that Al/AN data will be managed as others are managed, with the exception that the full five-digit ZIP codes are never shown. For example, if a ZIP code of "01234" represents a predominantly Al/AN community, the user will see only a partial ZIP code of "012." 3. The N3C Data User Code of Conduct will be modified so that data users will be asked to attest that they understand the N3C contains no Tribal affiliation data and that use of Al/AN data and ZIP code information to make assumptions about Tribal affiliation is not valid or appropriate. This statement will be included as a reminder when a DUR is received, a Data Use Agreement is executed, and data are accessed in the N3C platform and during publication processes. 4. The N3C will continue to engage NIH's Tribal Health Research Office and Tribal Nations as issues for discussion arise. [4] It is important to note that the N3C does not have EHR data from the Indian Health Service, nor does it contain information about Tribal affiliation. [5] This Community Guiding Principles document outlines expectations of every N3C community member, which includes, institutions and individuals who use N3C resources, expertise, and data. The N3C community is committed to providing a welcoming and inspiring environment for all community members. These principles were established by the N3C Community in an unprecedented effort to encourage and enable a highly collaborative research environment to address one of the worst health crises of our time. As such, we expect these guiding principles to be honored by each community member. [6] Purpose: This document provides community-driven guidelines and approaches that all users within the N3C research community disemination of research. These publication principles regarding N3C Community disemination of research. These publication principles regarding N3C community disemination of research. These publ	
Does not authorize/specify	Does not authorize/specify
Combinations of PII elements to generate 18 tokens per record (last name, first name, DOB, gender, SSN, email, zip5/9, cell phone) [1]	Last name, first name, DOB, gende SSN, email, zip5/9, cell phone number are collected
	 as others are managed, with the exception that the full five-digit ZIP codes are never shown. For example, if a ZIP code of "01234" represents a predominantly AI/AN community, the user will see only a partial ZIP code of "012." 3. The N3C Data User Code of Conduct will be modified so that data users will be asked to attest that they understand the N3C contains no Tribal affiliation data and that use of AI/AN data and ZIP code information to make assumptions about Tribal affiliation is not valid or appropriate. This statement will be included as a reminder when a DUR is received, a Data Use Agreement is executed, and data are accessed in the N3C platform and during publication processes. 4. The N3C will continue to engage NIH's Tribal Health Research Office and Tribal Nations as issues for discussion arise. [4] It is important to note that the N3C does not have EHR data from the Indian Health Service, nor does it contain information about Tribal affiliation. [5] This Community Guiding Principles document outlines expectations of every N3C community member, which includes, institutions and individuals who use N3C resources, expertise, and data. The N3C community is committed to providing a welcoming and inspiring environment for all community members. These principles were established by the N3C Community in an unprecedented effort to encourage and enable a highly collaborative research environment to address one of the worst health crises of our time. As such, we expect these guiding principles to be honored by each community member. [6] Purpose: This document provides community-driven guidelines and approaches that all users within the N3C research community uphold, and it addresses attribution and publication principles regarding N3C Community dissemination of research. These publication and attribution principles apply to N3C analysis reports, data, resources, abstracts, presentations, preprints, manuscripts, and other publicatio

	Source
	Source
der,	 [1] Predecessor report (<u>https://www.nichd.nih.gov/sites/default</u>/<u>files/inline-</u> <u>files/NICHD ODSS PPRL for Pediatric C</u> <u>OVID-</u> <u>19 Studies Public Final Report 508.pdf</u>)

Dataset 8	- N3C		
		Raw Language	Interpretation
6.2	PII elements holder (i.e., party that holds the PII)	The data remains under the complete control of the organizations that provide data to N3C and is never accessible by or under the control of the linkage honest broker.	-
6.3	Use of common data model, if any, for data collection	COVID-19 Clinical Data Warehouse Data Dictionary Based on OMOP Common Data Model Specifications Version 5.3 [1]	N3C data uses OMOP.
7	Prior Data Linkages		
7.1	Dataset linked with other datasets		
7.1.1	Name of other dataset linked to this dataset	Information not available/found	Information not available/found
7.1.2	Other dataset type (clinical, EHR, survey, claims, SDOH, etc.)	N3C Class 2 External Data Linkage • Description: The N3C Data Enclave is a centralized, secure, national clinical data resource with powerful analytics capabilities that the research community can use to study COVID-19, including potential risk factors, protective factors and long-term health consequences. The N3C collects data derived from the EHRs of people who were tested for COVID-19 or who had related symptoms, as well as data from individuals infected with pathogens that can support comparative studies, such as SARS 1, MERS and H1N1. N3C facilitates the linking of external datasets with EHR data available in the N3C enclave using PPRL to generate a richer dataset that can answer new questions about COVID-19. The details below specifically pertain to PPRL linkage with two examples of external data linkages that fall under Class 2 and are currently performed within N3C—viral variant data and mortality data. • Data sources: EHR data in the N3C enclave (submitted by N3C data partners) and the following external datasets: o Viral variant data: Collected by N3C data partners but stored in NIH's National Center for Biotechnology Information (NCBI) Sequence Read Archive (SRA); currently only viral variant summary data provided by the N3C data partners are linked. When the viral variant sequence data use case is ready, it will be imported into N3C. o Mortality data: The mortality data sources include government mortality sources (death certificates and person-reporting), ObituaryData.com, and private obituary sites) [1]	

[1] <u>https://ncats.nih.gov/n3c/about/data-overview</u> (Accessed: 4/19/23)

[1] <u>https://ncats.nih.gov/sites/default/</u> <u>files/OMOP_CDM_COVID.pdf</u> (Accessed 4/19/23)

[1] Predecessor report
https://www.nichd.nih.gov/sites/default/
files/inline-
files/NICHD_ODSS_PPRL_for_Pediatric_C
OVID-
19 Studies Public Final Report 508.pdf

ataset 8 -	N3C			
		Raw Language	Interpretation	Source
7.1.3	Other dataset source(s)	 N3C Class 2 External Data Linkage Description: The N3C Data Enclave is a centralized, secure, national clinical data resource with powerful analytics capabilities that the research community can use to study COVID-19, including potential risk factors, protective factors and long-term health consequences. The N3C collects data derived from the EHRs of people who were tested for COVID-19 or who had related symptoms, as well as data from individuals infected with pathogens that can support comparative studies, such as SARS 1, MERS and H1N1. N3C facilitates the linking of external datasets with EHR data available in the N3C enclave using PPRL to generate a richer dataset that can answer new questions about COVID-19. The details below specifically pertain to PPRL linkage with two examples of external data linkages that fall under Class 2 and are currently performed within N3C—viral variant data and mortality data. Data sources: EHR data in the N3C enclave (submitted by N3C data partners) and the following external datasets: o Viral variant data: Collected by N3C data partners but stored in NIH's National Center for Biotechnology Information (NCBI) Sequence Read Archive (SRA); currently only viral variant sequence data use case is ready, it will be imported into N3C. o Mortality data: The mortality data sources include government mortality sources (death certificates and person-reporting), ObituaryData.com, and private obituary sites) [1] 	 N3C Data partners Government mortality sources (death certificates and person-reporting), ObituaryData.com, and private obituary sites 	[1] Predecessor report https://www.nichd.nih.gov/sites/defaul files/inline- files/NICHD_ODSS_PPRL_for_Pediatric_ OVID- 19_Studies_Public_Final_Report_508.pd
7.1.4	Linking methodology (PPRL or non-PPRL); linkage technology	N3C facilitates the linking of external datasets with EHR data available in the N3C enclave using PPRL to generate a richer dataset that can answer new questions about COVID-19. [1] From Table 12: PPRL Vendors and Tools "Datavant: Used by N3C and for NIH funded studies in PEDSnet" [1]	PPRL, Datavant	[1] Predecessor report https://www.nichd.nih.gov/sites/defaul files/inline- files/NICHD_ODSS_PPRL_for_Pediatric_ OVID- 19_Studies_Public_Final_Report_508.pd
7.1.5	PII elements used for the linkage	Combinations of PII elements to generate 18 tokens per record (last name, first name, DOB, gender, SSN, email, zip5/9, cell phone) [1]	Combinations of PII elements to generate 18 tokens per record (last name, first name, DOB, gender, SSN, email, zip5/9, cell phone)	[1] Predecessor report https://www.nichd.nih.gov/sites/default files/inline- files/NICHD_ODSS_PPRL_for_Pediatric_C OVID- 19_Studies_Public_Final_Report_508.pd
7.1.6	Entity resolver (data originator or data linker or third party)	In all three cases, entity resolution is performed by a linkage honest broker (LHB), Regenstrief, based on matching the hashed tokens generated by N3C EHR data partners and external enclaves/data sources (for Class 0 and 2) [1]	Regenstrief (Honest Broker)	 [1] Predecessor report <u>https://www.nichd.nih.gov/sites/default</u> <u>files/inline-</u> <u>files/NICHD_ODSS_PPRL_for_Pediatric_OOVID-</u> <u>19_Studies_Public_Final_Report_508.pd</u>

Dataset 8 -	N3C			
		Raw Language	Interpretation	Source
7.1.7	Party performing the linkages	Entity resolution is performed by the LHB, and data linkage is done within N3C enclave by requesting researchers. [1]	Researchers	[1] Predecessor report https://www.nichd.nih.gov/sites/default/ files/inline- files/NICHD ODSS PPRL for Pediatric C OVID- 19 Studies_Public_Final_Report_508.pdf
7.1.8	Linkage quality assessment	A linkage quality assessment report is being prepared by N3C. In general, the linkage quality measures will depend on the linkage use case—for example: the linkage quality for EHR data linkage is stringent to support academic research but could be less stringent for recruitment use cases (what N3C calls "cohort discovery") [1]	Linkage quality measures depend on the linkage use case	[1] Predecessor report https://www.nichd.nih.gov/sites/default/ files/inline- files/NICHD ODSS PPRL for Pediatric C OVID- 19 Studies Public Final_Report_508.pdf
7.1.9	Linked data sharing method (linkage maps or pre-linked dataset)	All three N3C PPRL implementations —internal EHR to EHR linkage and external Class 0 and Class 2 linkages —follow the linked database model where entity resolution occurs as the data are received by N3C and tokens are sent to the linkage honest broker from the data partners and the external sources. [1]	Linked dataset	[1] Predecessor report https://www.nichd.nih.gov/sites/default/ files/inline- files/NICHD ODSS PPRL for Pediatric C OVID- 19 Studies Public Final Report 508.pdf

USE CASE 3	- GOVERNANCE INFORMATION			
		a-Related School Absence - Does SARS-CoV-2 vaccination result in redu	uced asthma-related school absences at	: 3/6/12+
Dataset 9 -	- PEDSnet Limited Data Sets (LI	DS) with Exact Dates		
	Dataset Source	PCORnet		
	Dataset Source Agency	PCORI		
	Dataset Type (Clinical, EHR, Survey, SDOH, etc.)	EHR		
	Information Sources	Website, Information from predecessor report, CHOP/PEDSnet Interview (a Questions	as part of the predecessor report), Master I	RB Protoc
Dataset 9 -	- PEDSnet Limited Data Sets (LI	DS)		
		Raw Language	Interpretation	
1	Data Collection			
1.1	Authorizations and Applicable Regulations/Policies			
1.1.1	Authorizations		 Assent Consent CHOP or local/site-level IRB approval Master Reliance Agreement Waiver of consent 	
1.1.1.1	Assent	 Please confirm our understanding that PEDSnet data are collected either under a waiver of consent (large observational studies) or under consent/assent (specific studies)? [1, 2] "This is substantially correct. Data from routine delivery of health care are collected under waiver; collection of study-specific data from patients and families is with consent/assent." [2] 	Assent authorizes data collection.	[1] CHC report) [2] Res
1.1.1.2	Consent	 Please confirm our understanding that PEDSnet data are collected either under a waiver of consent (large observational studies) or under consent/assent (specific studies)? [1, 2] "This is substantially correct. Data from routine delivery of health care are collected under waiver; collection of study-specific data from patients and families is with consent/assent." [2] 	Consent authorizes data collection.	[1] CHC report) [2] Res

2+ months post-vaccination?
ocol provided by PEDSnet, Responses to PEDSnet
Source
HOP/PEDSnet Interview (as part of predecessor rt)
esponses to PEDSnet Questions
HOP/PEDSnet Interview (as part of predecessor rt)
esponses to PEDSnet Questions

		Raw Language	Interpretation	
1.1.1.3	IRB/equivalent Privacy Board determination	Raw LanguageAll PEDSnet institutional members are required to endorse the PEDSnetSingle IRB policy by becoming a participating institution of the NCATSsponsored SMART IRB Agreement.Participation in these agreements allows an institution to choose on a case-by-case protocol basis whether to participate in a ceded review, as arelying or reviewing institution, or perform its own IRB review. Given thenetwork's underlying principle of collaboration, PEDSnet expects that IRBreliance opt-out will be a rare occurrence, and would require anappropriate justification.[1]This project will use the PEDSnet Reciprocal Single IRB Master RelianceAgreement with CHOP acting as the IRB of record and the other 13institutions relying on the CHOP IRB.[2]PEDSnet centers currently capture a wide variety of data as part of clinicaloperations obtained from primary care, Emergency Department (ED),specialty care, and inpatient settings. Participating sites will collect data forPEDSnet by extraction and transformation to the network data model ofthese data collected as part of standard clinical and business operations.The specific capaendices to approved protocol #14-011242, for sitesusing the CHOP IRB as the IRB of record for these activities, or in separateprotocols reviewed by the local IRB.[2]EHR data collection and de-identification at sites is governed by site-levelIRB oversight.[3]		[1] <u>http</u> (Access [2] Mas [3] Res
1.1.1.4 1.1.1.5	Local/state/federal laws Institutional Certification	Information not available/found Information not available/found	Information not available/found Information not available/found	
1.1.1.6	Data originator agreement	 From the launch the network, PEDSnet adapted and executed a Master Reliance Agreement among all its members, which set forth the respective authorities, roles, and responsibilities of each party when a ceded review arrangement is determined to be acceptable. [1] Does the Master Reliance Agreement executed among PEDSnet partners 	Master Reliance Agreement authorizes data collection under one IRB.	[1] <u>http</u> 4/18/2: [2] Res
		authorize EHR data collection by the partners? [1, 2] "There is a master protocol with reliance by all PEDSnet members that authorizes observational research using EHR data" [2]		
1.1.1.7	Repository agreements/policies	Information not available/found	Information not available/found	

ttps://pedsnet.org/resources/governance/ essed: 4/18/23) Aaster IRB Protocol esponses to PEDSnet Questions

ttps://pedsnet.org/resources/irb/ (Accessed: 5/23)

esponses to PEDSnet Questions

	PEDSnet Limited Data Sets (LDS		Interpretation	
4440		Raw Language	Interpretation	[4] CU
1.1.1.8	Other (specify)	Please confirm our understanding that PEDSnet data are collected either	Waiver of consent authorizes data	[1] CH
		under a waiver of consent (large observational studies) or under	collection for routine delivery of health	report
		consent/assent (specific studies)? [1, 2] "This is substantially correct. Data from routine delivery of health care are	care.	[2] Res
		collected under waiver; collection of study-specific data from patients and		
		families is with consent/assent." [2]		
	Annihashla Dagulatiana (Dalisiaa	Tamines is with consent/assent. [2]		
1.1.2	Applicable Regulations/Policies	Information action in the formal		
1.1.2.1	Local regulations/policies	Information not available/found	Information not available/found	
1.1.2.2	Tribal regulations/policies	Information not available/found	Information not available/found	
1.1.2.3	State regulations/policies	Information not available/found	Information not available/found	
1.1.2.4	Federal regulations/policies	Information not available/found Information not available/found	Information not available/found	
1.1.2.5	International regulations/policies		Information not available/found	
1.1.2.6	Contractual obligations	Information not available/found	Information not available/found Information not available/found	
	Repository policies	Information not available/found	-	+
1.2		g, access, and use based on data collection authorization or applicabl		
1.2.1	Whether the data can be linked	Consent for data linking is embedded in the broad study consent (when	Consent (when obtained) specifies that	[1] CH(
		obtained).	data can be linked.	report
		[1]		
1.2.2	With what other data can it be	We also understand that consent for data linking is embedded in the broad	Governing IRB protocols specify that data	[1] CH0
	linked or can it not be linked (scope	study consent (when obtained). Are there any other authorizations for	can be linked using PPRL for research	report
	of linkage)	data linkages? [1, 2]	conducted under a waiver of consent.	[2] Res
		Authorization for privacy-preserving record linkage is part of governing IRB		
		protocols for research conducted under waiver of consent. [2]		
1.2.3	Whether data can be shared	Does not authorize/specify	Does not authorize/specify	
1.2.4	How data can be shared (de-	Does not authorize/specify	Does not authorize/specify	
	identification status, disclosure			
	review)			
1.2.5	How data can be accessed (access	Does not authorize/specify	Does not authorize/specify	
	type, data use agreement, data			
	access committee/group approval,			
	IRB LOD, etc.)			
1.2.6	How data can be used (data use	Does not authorize/specify	Does not authorize/specify	
	limitations)			
1.2.7	Other (specify)	Does not authorize/specify	Does not authorize/specify	
2	Data Linkage			
2.1	Authorizations and Applicable			
2.1				
2 1 1	Regulations/Policies Authorizations		1. Consent	1
2.1.1	Authorizations		2. IRB	
			3. PEDSnet Steering Committee approval	
			4. Individual PEDSnet sites/study	
			participation vote	
7111	Assant	Information not available /found	Information not available /found	_
2.1.1.1	Assent	Information not available/found	Information not available/found	[1] CU
2.1.1.1 2.1.1.2	Assent Consent	Information not available/found Consent for data linking is embedded in the broad study consent (when obtained).	Information not available/found Consent (when obtained) authorizes data linkage.	[1] CH(report)

HOP/PEDSnet Interview (as part of predecessor ort)

esponses to PEDSnet Questions

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HOP/PEDSnet Interview (as part of predecessor ort)

HOP/PEDSnet Interview (as part of predecessor ort) esponses to PEDSnet Questions

HOP/PEDSnet Interview (as part of predecessor ort)

	PEDSnet Limited Data Sets (LD		hat a supervised at 2 a second	
		Raw Language	Interpretation	
2.1.1.3	IRB/equivalent Privacy Board determination	We also understand that consent for data linking is embedded in the broad study consent (when obtained). Are there any other authorizations for data linkages? [1, 2]	IRB authorizes data linkage for research conducted under a waiver of consent.	[1] CH(report) [2] Res
		Authorization for privacy-preserving record linkage is part of governing IRB protocols for research conducted under waiver of consent. [2]		
2.1.1.4	Local/state/federal laws	Linkage is determined by the PEDSnet sites based on the particular use	PEDSnet Steering Committee approval	[1] Pre
		case/research study. When sites sign up to be part of the PEDSnet	authorizes data linkage as part of a specific	
			study research plan.	files/N
		study sites can decide whether to participate in data linkages on a study-by study basis once the PEDSnet Steering Committee approves the data linkage as part of a specific study research plan. [1]	*	<u>19_Stu</u>
2.1.1.5	Institutional Certification	Information not available/found	Information not available/found	
2.1.1.6	Data originator agreement	Linkage is determined by the PEDSnet sites based on the particular use	Individual PEDSnet sites authorize data	[1] Pre
		case/research study. When sites sign up to be part of the PEDSnet	linkage on a study-by-study basis.	(https:
		network, they must agree to hash their data; however, individual PEDSnet		files/N
		study sites can decide whether to participate in data linkages on a study-by	+	<u>19_Stu</u>
		study basis once the PEDSnet Steering Committee approves the data		[2] Res
		linkage as part of a specific study research plan. [1]		
		Is the decision to participate in data linking documented via the 'written		
		affirmation from the study site PI' or how is it authorized/documented?		
		Where the need for linkage is known at the inception of the study		
		(preferred), it is part of the study participation vote. Where an		
		opportunity for linkage arises during conduct of a study (e.g. new dataset		
		becomes available for linkage), a separate authorization is obtained.		
		[2]		
2.1.1.7	Repository agreements/policies	Information not available/found	Information not available/found	
2.1.1.8	Other (specify)	Information not available/found	Information not available/found	
2.1.2	Applicable Regulations/Policies			
2.1.2.1	Local regulations/policies	Information not available/found	Information not available/found	
2.1.2.2	Tribal regulations/policies	Information not available/found	Information not available/found	
2.1.2.3	State regulations/policies	Information not available/found	Information not available/found	
2.1.2.4	Federal regulations/policies	Information not available/found	Information not available/found	
2.1.2.5	International regulations/policies	Information not available/found	Information not available/found	_
2.1.2.6	Contractual obligations	Information not available/found	Information not available/found	
2.1.2.7	Repository policies	Information not available/found	Information not available/found	
.2	Governance for data linkage, sharin	ng, access, and use based on data linkage authorization or applicable r	egulations/policies (i.e., the origin of the	e gover

HOP/PEDSnet Interview (as part of predecessor rt)

esponses to PEDSnet Questions

redecessor report os://www.nichd.nih.gov/sites/default/files/inline-/NICHD_ODSS_PPRL_for_Pediatric_COVID-Studies_Public_Final_Report_508.pdf)

redecessor report os://www.nichd.nih.gov/sites/default/files/inline-/NICHD_ODSS_PPRL_for_Pediatric_COVIDotudies_Public_Final_Report_508.pdf) esponses to PEDSnet Questions

ernance)

		Raw Language	Interpretation	
2.2.1	Whether the data can be linked	Kaw Language Consent for data linking is embedded in the broad study consent (when obtained). [1] Linkage is determined by the PEDSnet sites based on the particular use case/research study. When sites sign up to be part of the PEDSnet network, they must agree to hash their data; however, individual PEDSnet study sites can decide whether to participate in data linkages on a study-by study basis once the PEDSnet Steering Committee approves the data linkage as part of a specific study research plan. [2] Is the decision to participate in data linking documented via the 'written affirmation from the study site PI' or how is it authorized/documented? Where the need for linkage is known at the inception of the study (preferred), it is part of the study participation vote. Where an opportunity for linkage arises during conduct of a study (e.g. new dataset becomes available for linkage), a separate authorization is obtained. [3] We also understand that consent for data linking is embedded in the broad study consent (when obtained). Are there any other authorizations for data linkages? [1, 3] Authorization for privacy-preserving record linkage is part of governing IRB protocols for research conducted under waiver of consent. [3]	 Consent (when obtained) specifies that data can be linked. PEDSnet Steering Committee approval specifies that data can be linked according to the approved research plan. Individual PEDSnet sites, through a study participation vote, specify that the sites can participation in data linkage on a study-by- study basis. IRB specifies that PEDSnet data can be linked for research conducted under a waiver of consent. 	[3] Re
2.2.2	With what other data can it be linked or can it not be linked (scope of linkage)	We also understand that consent for data linking is embedded in the broad study consent (when obtained). Are there any other authorizations for data linkages? [1, 2] Authorization for privacy-preserving record linkage is part of governing IRB protocols for research conducted under waiver of consent. [2] Linkage is determined by the PEDSnet sites based on the particular use case/research study. When sites sign up to be part of the PEDSnet network, they must agree to hash their data; however, individual PEDSnet study sites can decide whether to participate in data linkages on a study-by study basis once the PEDSnet Steering Committee approves the data	using PPRL for research conducted under a waiver of consent. 2. Individual PEDSnets study sites specify the scope of data linkage on a study-by- study basis.	[1] CH report [2] Res [3] Pre (<u>https:</u> <u>files/N</u> <u>19_Stu</u>
2.2.3 2.2.4	Whether data can be shared How data can be shared (de-	linkage as part of a specific study research plan. [3] Does not authorize/specify Does not authorize/specify	Does not authorize/specify Does not authorize/specify	
2.2.5	identification status, disclosure review) How data can be accessed (access type, data use agreement, data access committee/group approval,	Does not authorize/specify	Does not authorize/specify	
2.2.6	IRB LOD, etc.) How data can be used (data use limitations)	Each site must authorize use of their data and resources in a particular study via a participation vote. [1]	PEDSnet site participation vote specifies data use for individual studies.	[1] Res

HOP/PEDSnet Interview (as part of predecessor rt)

redecessor report

os://www.nichd.nih.gov/sites/default/files/inline-/NICHD_ODSS_PPRL_for_Pediatric_COVID-

tudies_Public_Final_Report_508.pdf)

esponses to PEDSnet Questions

HOP/PEDSnet Interview (as part of predecessor rt)

esponses to PEDSnet Questions

redecessor report

os://www.nichd.nih.gov/sites/default/files/inline-/NICHD_ODSS_PPRL_for_Pediatric_COVID-Studies_Public_Final_Report_508.pdf)

esponses to PEDSnet Questions

		Raw Language	Interpretation	
2.2.7	Other (specify)	Does not authorize/specify	Does not authorize/specify	
3	Data Sharing			1
3.1	Authorizations and Applicable			
•	Regulations/Policies			
3.1.1	Authorizations		1. Data release vote	
			2. PEDSnet Participation and DUA	
			3. PEDSnet Master Data Use Agreement	
3.1.1.1	Assent	Information not available/found	Information not available/found	
3.1.1.2	Consent	Information not available/found	Information not available/found	
3.1.1.3	IRB/equivalent Privacy Board determination	Information not available/found	Information not available/found	
3.1.1.4	Local/state/federal laws	Information not available/found	Information not available/found	
3.1.1.5	Institutional Certification	Information not available/found	Information not available/found	
3.1.1.6	Data originator agreement	Institutional members will be required to sign:	Two agreements authorize data sharing:	[1 <u>] htt</u> r
		Participation and Data Use Agreement, which an institutional official	1. PEDSnet Participation and DUA signed	Policies
		must sign [1]	by PEDSnet members authorizes data	[2] Res
		In addition, each institution must develop and submit a data governance	sharing between PEDSnet members. 2. PEDSnet sites data release vote	
		process and procedures for reviewing and approving release of	authorizes data sharing (i.e., release).	
		institutional data.	authorizes data sharing (i.e., release).	
		[1]		
		In addition, if the study involves release of a dataset beyond the PEDSnet		
		data center, each site must authorize the release of their data in a dataset release vote.		
		[2]		
3.1.1.7	Repository agreements/policies	The PEDSnet Master DUA authorizes sharing of limited data sets for use in	PEDSnet Master Data Use Agreement	[1] Res
		studies. [1]	authorizes data sharing.	
3.1.1.8	Other	Information not available/found	Information not available/found	
3.1.2	Applicable Regulations/Policies			
3.1.2.1	Local regulations/policies	Note that access to individual-level data, whether meeting the Privacy Rule	PEDSnet policy	[1] Res
		Safe Harbor standard or the definition of a Limited Data Set, is governed		
		by the policies for Limited Data Sets, due to the potential for pattern-		
		based reidentification in highly detailed data.		
		[1]		
		Limited data sets with and without actual dates:		
		This is the typical case. Information about standard privacy risk reduction		
		measures, including date shifting, can be found in PEDSnet Policies on our		
		web site.		
		[1]		
3.1.2.2	Tribal regulations/policies	Information not available/found	Information not available/found	
			-	

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		Raw Language	Interpretation	
3.1.2.3	State regulations/policies	All PEDSnet member systems are based in states that legislate specific	State regulations	[1] Re
		protections for minor patients accessing reproductive and mental health		[2] <u>ht</u>
		care, and state and federal regulations affect the privacy of HIV-related		(Acce
		data. [1]		
		Removal of data relating to testing or care for HIV, pregnancy, and mental		
		health, excluding educational performance.		
		[2]		
3.1.2.4	Federal regulations/policies	All PEDSnet member systems are based in states that legislate specific	1. Federal regulations	[1] Re
		protections for minor patients accessing reproductive and mental health	2. 45 CFR 46 (Common Rule)	[2] <u>htt</u>
		care, and state and federal regulations affect the privacy of HIV-related	3. HIPAA Privacy Rule	(Acce
		data.		[3] M
		[1]		
		Access to individual-level data is governed by the policies described above,		
		and appropriate regulatory oversight as defined in the Common Rule (or		
		equivalent) and HIPAA. [1]		
		Removal of data relating to testing or care for HIV, pregnancy, and mental		
		health, excluding educational performance.		
		[2]		
		This study will be conducted in full accordance with all applicable		
		Children's Hospital of Philadelphia Research Policies and Procedures and		
		all applicable Federal and state laws and regulations including 45 CFR 46,		
		and the HIPAA Privacy Rule. [3]		
3.1.2.5	International regulations/policies	Information not available/found	Information not available/found	
3.1.2.6	Contractual obligations	Information not available/found	Information not available/found	
3.1.2.7	Repository policies	Information not available/found	Information not available/found	
3.2		g, access, and use based on data sharing authorization or applicable		ne gove
3.2.1	Whether the data can be linked	Does not authorize/specify	Does not authorize/specify	
3.2.2	With what other data can it be	Does not authorize/specify	Does not authorize/specify	
	linked or can it not be linked (scope			
	of linkage)			

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Responses to PEDSnet Questions https://pedsnet.org/resources/governance/ ress: 4/18/23) Master IRB Protocol

ernance)

Jalasel 9 -	PEDSnet Limited Data Sets (LI		· · · · ·	1
		Raw Language	Interpretation	
3.2.3	Whether data can be shared	 In addition, if the study involves release of a dataset beyond the PEDSnet data center, each site must authorize the release of their data in a dataset release vote. [1] The PEDSnet Master DUA authorizes sharing of limited data sets for use in 	 PEDSnet sites data release vote specifies whether data can be shared (i.e., release). The PEDSnet Master DUA specifies whether data can be shared. 45 CFR 46 (Common Rule) and HIPAA Privacy Rule specifies that de-identified 	[1] Resp [2] Mas
		studies. [1]	data can be shared.	
		Access to individual-level data is governed by the policies described above, and appropriate regulatory oversight as defined in the Common Rule (or equivalent) and HIPAA. [1]		
		This study will be conducted in full accordance with all applicable Children's Hospital of Philadelphia Research Policies and Procedures and all applicable Federal and state laws and regulations including 45 CFR 46, and the HIPAA Privacy Rule. [2]		
3.2.4	How data can be shared (de- identification status, disclosure review)	All PEDSnet member systems are based in states that legislate specific protections for minor patients accessing reproductive and mental health care, and state and federal regulations affect the privacy of HIV-related data. Accounting for these needs is part of the PEDSnet study review process and the privacy risk reduction procedures described above. Institutional policies regarding prudential use of data are incorporated into the site's study participation review and dataset release processes. [1] Access to individual-level data is governed by the policies described above,	using the Safe Harbor method of de- identification of PHI before sharing data.	[1] Resp [2] <u>http</u> (Access [3] <u>http</u> (Access [4] Prec (<u>https://</u> <u>files/Nit</u> 19 Stud
		and appropriate regulatory oversight as defined in the Common Rule (or equivalent) and HIPAA. Note that access to individual-level data, whether meeting the Privacy Rule Safe Harbor standard or the definition of a Limited Data Set, is governed by the policies for Limited Data Sets, due to the potential for pattern-based reidentification in highly detailed data. [1]	review is performed on the requested datasets as well as data transformations, such as date shifts, replacement labels for free text fields and geographic information, and removing HIV/pregnancy/ mental health data prior to data sharing.	
		DE-IDENTIFIED INDIVIDUAL LEVEL DATA (according to the Safe Harbor guidelines). Patient-level data sets may be released to investigators within or outside of the institution of origin with an IRB determination of non- human subjects research (NHSR). The receipt of NHSR determination is for documentation purposes. For the purposes of PEDSnet, to be considered de-identified, the data set must use the safe harbor method for De- identification of Protected Health Information. [2]		
		Datasets containing any person-level records that are not synthetic, or have a k-anonymity of ≤10, (i.e. have any records that are identical for 10		

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NICHD ODSS PPRL for Pediatric COVID-
tudies_Public_Final_Report_508.pdf)

Dataset 9 -	PEDSnet Limited Data Sets (LDS	5)		
		Raw Language	Interpretation	Source
		or fewer persons), are subject to the following, unless specifically waived during the PEDSnet review process:		
		6. Replacement of stable identifiers with study-specific identifiers.		
		7. Shifting of dates within a one-year window centered on the actual date.		
		8. Replacement of free-text fields with single-use labels.		
		9. Replacement of geographic information with single-use labels. [3]		
		A risk review is done for each proposed study, but no separate deductive disclosure review of the linked data is performed. Data use agreement prohibits reidentification and re-use for other studies. All members must agree to the PEDSnet standard policies when joining the Network; additional terms of data use are stipulated on a case-by-case basis. [4]		
3.2.5	How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.)	Does not authorize/specify	Does not authorize/specify	
3.2.6	How data can be used (data use limitations)	Does not authorize/specify	Does not authorize/specify	
3.2.7	Other (specify)	Does not authorize/specify	Does not authorize/specify	
4	Data Access			
4.1	Authorizations and Applicable			
	Regulations/Policies			
4.1.1	Authorizations		1. Human Subjects Review (Letter of	
			determination)	
			 IRB approval for requester if HSR IRB reliance agreement (NPRA MRA or 	
			SMART IRB MRA) if HSR	
			4. Legal Review (DUA and RUD)	
			5. Network Participation Approval	
			(PEDSnet Executive Committee)	
			6. Institutional Participation Approval	
			(Prospective Site Pl Approval)	
<u>л 1 1 1</u>	Assent	Information not available/found		
4.1.1.1		Information not available/found	Information not available/found	
4.1.1.2	Consent	Information not available/found	Information not available/found	

alasel 9 -	PEDSnet Limited Data Sets (LDS			
		Raw Language	Interpretation	-
4.1.1.3	IRB/equivalent Privacy Board determination	Human Subjects Review: IRB Determination/Approval required by PEDSnet site -If NHSR/Exempt: no further review/MRA required -If HSR: IRB approval with IRB reliance for sites providing data (NPRA MRA or SMART IRB MRA) [1]	Human Subjects Review (IRB review or determination) authorizes data access in two possible paths: 1. Non-Human Subjects Research (NHSR) determination: no further review/MRA required 2. Human Subjects Research (HSR) determination: requester IRB approval with IRB reliance for site providing data (NPRA MRA or SMART IRB MRA is also required	[1] <u>http</u> (Access
4.1.1.4	Local/state/federal laws	Information not available/found	Information not available/found	
4.1.1.5	Institutional Certification	Information not available/found	Information not available/found	
4.1.1.6	Data originator agreement	Institutional Participation Approval: Prospective Site PI Approval for all data requests regardless of the de-identification status of the dataset being requested. [1]	Institutional participation approval (prospective site PI approval) authorizes data access.	[1 <u>] http</u> (Access
4.1.1.7	Repository agreements/policies	Legal Review: PEDSnet DUA and RUD [1]	Legal review (comprised of PEDSnet Data use agreement and Responsible Use of Data Agreement) authorizes data access.	[1 <u>] http</u> (Access
4.1.1.8	Other (specify)	Network Participation Approval: Executive Committee Approval [1]	Network Participation Approval (PEDSnet Executive Committee Approval) authorizes data access.	[1 <u>] http</u> (Access
4.1.2	Applicable Regulations/Policies			
4.1.2.1	Local regulations/policies	Information not available/found	Information not available/found	
4.1.2.2	Tribal regulations/policies	Information not available/found	Information not available/found	
4.1.2.3	State regulations/policies	Information not available/found	Information not available/found	
4.1.2.4	Federal regulations/policies	Information not available/found	Information not available/found	
4.1.2.5	International regulations/policies	Information not available/found	Information not available/found	
4.1.2.6	Contractual obligations	Information not available/found	Information not available/found	
4.1.2.7	Repository policies	Legal Review: PEDSnet DUA and RUD [1]	PEDSnet policy	[1] <u>http</u> (Access
4.2	Governance for data linkage, sharing	g, access, and use based on data access authorization or applicable re	egulations/policies (i.e., the origin of the	governa
4.2.1	Whether the data can be linked	Does not authorize/specify	Does not authorize/specify	
4.2.2	With what other data can it be linked or can it not be linked (scope of linkage)	Does not authorize/specify	Does not authorize/specify	
4.2.3	Whether data can be shared	Does not authorize/specify	Does not authorize/specify	
4.2.4	How data can be shared (de- identification status, disclosure review)	Does not authorize/specify	Does not authorize/specify	

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		Raw Language	Interpretation	
4.2.5	How data can be accessed (access	Investigators or sponsors that would like to conduct a study within	PEDSnet human subjects review, network	[1
	type, data use agreement, data	PEDSnet will complete a request form and submit that to the Coordinating	participation review, institutional	()
	access committee/group approval,	Center. The Coordinating Center will ensure that the request is complete.	participation approval, and legal review	[
	IRB LOD, etc.)	The Research Committee will vote on study concepts. Approval allows the	specify that the requester:	
		Coordinating Center to assist the requestor in the development of study	1. Must submit request form for approval	
		proposals.	by the Research Committee	
		[1]	2. Must undergo IRB review/determination	
			(Human Subjects Review)	
		Human Subjects Review: IRB Determination/Approval required by PEDSnet	3. If IRB determines the proposed study is	
		site	NHSR, then no further review/MRA	
		-If NHSR/Exempt: no further review/MRA required	required	
		-If HSR: IRB approval with IRB reliance for sites providing data (NPRA MRA	4. If IRB determines the proposed study	
		or SMART IRB MRA)	HSR, the requester must provide IRB	
		[1]	approval with IRB reliance for site	
		Legal Review: PEDSnet DUA and RUD [1]	providing data (NPRA MRA or SMART IRB	
		Network Participation Approval: Executive Committee Approval [1]	MRA is also required)	
		Institutional Participation Approval: Prospective Site PI Approval for all	5. Must sign DUA and RUD (Responsible	
		data requests regardless of the de-identification status of the dataset	Use of Data) (Legal Review)	
		being requested.[1]	6. Must receive prospective site PI approval	1
			(Institutional Participation Approval)	
		Due to its size and the corresponding charges by cloud service providers,	7. Must receive PEDSnet Executive	
		the main PEDSnet database is located in a physical datacenter. Project-	Committee approval (Network	
		related data is sometimes located in cloud enclaves to facilitate	Participation Approval)	
		collaborative research. [2]	8. Must access the data through a	
			workspace within the PEDSnet cloud	
		In general, research using the database will be done within the secure	enclaveORto have the data transfered	
		PEDSnet database environment that is managed by the Coordinating	to their institution, the PEDSnet Study	

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Dataset 9 -	PEDSnet Limited Data Sets (LD	DS)		
		Raw Language	Interpretation	
		Center. This approach generally precludes the need to share patient-level data outside the secure PEDSnet network environment. Investigators, data analysts, and statisticians who need to access the database will first apply to be an authorized user. For approved PEDSnet studies, a certified user either at the Coordinating Center or PEDSnet institution will set up a workspace within the PEDSnet database environment and transfer the minimum necessary data for the research project to the workspace. The workspace will support database and statistical applications allowing the team to conduct data analyses. [1]	Approval request should specify, pending approval from all PEDSnet institutions providing data for the request.	
		Investigators who would like to have a de-identified or limited (as defined by HIPAA) patient-level dataset transferred to their institution make this request at the time of seeking PEDSnet Study Approval. Each institution that supplies data for the dataset must affirm its approval during the Steering Committee voting process. At each site's discretion, either the PEDSnet Site PI or Site Informatics Lead may approve dataset release votes, obtaining approval from appropriate institutional officials as needed. Approved requests will be processed by the Coordinating Center, which will provide the minimum data necessary to answer study questions. The Coordinating Center will maintain procedures to reduce risk of individual patient reidentification from datasets released to investigators. Data provided by PEDSnet can be used only for the purposes specified and approved by the Steering Committee. [1]		
4.2.6	How data can be used (data use limitations)	Does not authorize/specify	Does not authorize/specify	
4.2.7	Other (specify)	Does not authorize/specify	Does not authorize/specify	
5	Data Use			
5.1	Authorizations and Applicable			
	Regulations/Policies			
5.1.1	Authorizations		 PEDSnet Steering Committee approval PEDSnet site PIs written affirmation PEDSnet site participation vote 	
5.1.1.1	Assent	Information not available/found	Information not available/found	
5.1.1.2	Consent	Information not available/found	Information not available/found	
5.1.1.3	IRB/equivalent Privacy Board determination	Information not available/found	Information not available/found	
5.1.1.4	Local/state/federal laws	Information not available/found	Information not available/found	
5.1.1.5	Institutional Certification	Information not available/found	Information not available/found	

Source

		Raw Language	Interpretation	
5.1.1.6	Data originator agreement	Participation by an Institution in a particular PEDSnet study is voluntary. A	Two agreements authorize data use:	[1] <u>h</u>
		written affirmation is required by the Site Principal Investigator for all	1. PEDSnet Site PI written affirmation	Polic
		studies. However, the expectation is that participating institutions allow	authorizes data use for other investigators	[2] F
		their data to be used for retrospective observational studies that do not	2. PEDSnet site participation vote	
		require contact with human subjects unless there is a compelling reason to		
		not participate.		
		[1]		
		Each site must authorize use of their data and resources in a particular		
		study via a participation vote.		
		[2]		
5.1.1.7	Repository agreements/policies	Legal Review: PEDSnet DUA and RUD	Legal review (comprised of PEDSnet Data	[1] <u>h</u>
		[1]	use agreement and Responsible Use of	(Acc
			Data Agreement) authorizes data use.	(
5.1.1.8	Other (specify)	Data provided by PEDSnet can be used only for the purposes specified and	Steering Committee authorizes data use.	[1] <u>h</u>
		approved by the Steering Committee. [1]		(Acce
.1.2	Applicable Regulations/Policies			
5.1.2.1	Local regulations/policies	Requests for patient level data will be assessed for research concept	PEDSnet policy	[1] <u>h</u>
		fitness and will undergo a formal vote by the Research Committee.		[2] R
		PEDSnet will seek to prioritize studies that will inform or directly address		
		clinical decision making among diagnostic or treatment alternatives		
		available to parents, patients and providers or by health care delivery		
		systems. [1]		
		The expectation is that participating institutions allow their data to be		
		used for retrospective observational studies that do not require contact		
		with human subjects unless there is a compelling reason to not		
		participate. [1]		
		In order to support a learning health system, PEDSnet fosters the use of		
		data from real-world clinical settings for research, quality measurement,		
		and improvement of child health. Use of these data make it possible to		
		reach conclusions that more accurately reflect actual health and medical		
		care than simulated or idealized data. [1]		
		PEDSnet data are not available for commercial sale; other uses are		
		reviewed for their alignment with advancement of child health. When		
		released for a study, data use is limited to the conduct of that study;		
		blanket releases of datasets are not made. [2]		
5.1.2.2	Tribal regulations/policies	Information not available/found	Information not available/found	
5.1.2.3	State regulations/policies	Information not available/found	Information not available/found	
5.1.2.4	Federal regulations/policies	Information not available/found	Information not available/found	
5.1.2.5	International regulations/policies	Information not available/found	Information not available/found	
5.1.2.6	Contractual obligations	Information not available/found	Information not available/found	
5.1.2.7	Repository policies	Legal Review: PEDSnet DUA and RUD	PEDSnet policy	[1] <u>h</u>
		[1]		(Acc

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		Raw Language	Interpretation	
5.2.1	Whether the data can be linked	Linkage is determined by the PEDSnet sites based on the particular use case/research study. When sites sign up to be part of the PEDSnet	Individual PEDSnet sites, through a study particpation vote, specify participation in data linkage on a study-by-study basis	[1] Prec (<u>https:/</u> <u>files/NI</u> <u>19_Stuc</u> [2] Resp
		Is the decision to participate in data linking documented via the 'written affirmation from the study site PI' or how is it authorized/documented? Where the need for linkage is known at the inception of the study (preferred), it is part of the study participation vote. Where an opportunity for linkage arises during conduct of a study (e.g. new dataset becomes available for linkage), a separate authorization is obtained. [2]		
5.2.2	With what other data can it be linked or can it not be linked (scope of linkage)	Does not authorize/specify	Does not authorize/specify	
5.2.3	Whether data can be shared	Does not authorize/specify	Does not authorize/specify	
5.2.4	How data can be shared (de- identification status, disclosure review)	Does not authorize/specify	Does not authorize/specify	
5.2.5	How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.)	Legal Review: PEDSnet DUA and RUD [1] Network Participation Approval: Executive Committee Approval [1] Institutional Participation Approval: Prospective Site PI Approval for all data requests regardless of the de-identification status of the dataset being requested.[1] Due to its size and the corresponding charges by cloud service providers, the main PEDSnet database is located in a physical datacenter. Project- related data is sometimes located in cloud enclaves to facilitate collaborative research. [2] In general, research using the database will be done within the secure PEDSnet database environment that is managed by the Coordinating Center. This approach generally precludes the need to share patient-level	PEDSnet policy specifies that the requester 1. Must sign DUA and RUD (Responsible Use of Data) (Legal Review) 2. Must access the data through a workspace within the PEDSnet cloud enclaveORto have the data transfered to their institution, the PEDSnet Study Approval request should specify, pending approval from all PEDSnet institutions providing data for the request	: [1] <u>http</u> (Access [2] Res _j
		data outside the secure PEDSnet network environment. Investigators, data analysts, and statisticians who need to access the database will first apply to be an authorized user. For approved PEDSnet studies, a certified user either at the Coordinating Center or PEDSnet institution will set up a workspace within the PEDSnet database environment and transfer the minimum necessary data for the research project to the workspace. The workspace will support database and statistical applications allowing the team to conduct data analyses. [1]		
		Investigators who would like to have a de-identified or limited (as defined by HIPAA) patient-level dataset transferred to their institution make this request at the time of seeking PEDSnet Study Approval. Each institution that supplies data for the dataset must affirm its approval during the		

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s://www.nichd.nih.gov/sites/default/files/inline-
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tudies_Public_Final_Report_508.pdf)
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ataset 9 -	PEDSnet Limited Data Sets (LI	DS)		
		Raw Language	Interpretation	Source
		Steering Committee voting process. At each site's discretion, either the PEDSnet Site PI or Site Informatics Lead may approve dataset release votes, obtaining approval from appropriate institutional officials as needed. Approved requests will be processed by the Coordinating Center, which will provide the minimum data necessary to answer study questions. The Coordinating Center will maintain procedures to reduce risk of individual patient reidentification from datasets released to investigators. Data provided by PEDSnet can be used only for the purposes specified and approved by the Steering Committee. [1]		
5.2.6	How data can be used (data use limitations)	Requests for patient level data will be assessed for research concept fitness and will undergo a formal vote by the Research Committee.PEDSnet will seek to prioritize studies that will inform or directly address clinical decision making among diagnostic or treatment alternatives available to parents, patients and providers or by health care delivery systems. [1]The expectation is that participating institutions allow their data to be used for retrospective observational studies that do not require contact with human subjects unless there is a compelling reason to not participate. [1]In order to support a learning health system, PEDSnet fosters the use of data from real-world clinical settings for research, quality measurement, and improvement of child health. Use of these data make it possible to reach conclusions that more accurately reflect actual health and medical care than simulated or idealized data. [1]PEDSnet data are not available for commercial sale; other uses are reviewed for their alignment with advancement of child health. When released for a study, data use is limited to the conduct of that study; blanket releases of datasets are not made. [2]Data provided by PEDSnet can be used only for the purposes specified and approved by the Steering Committee. [1]	PEDSnet policy specifies two data use limitations: 1. Data can only be used for the purposes specified and approved by the Steering Committee. Namely, using data from real- world clinical settings for research, quality measurement, and improvement/advancement of child health, particularly studies that inform or directly address clinical decision making, including retrospective observational studies 2. Cannot be used for commercial sale	 [1] <u>https://pedsnet.org/resources/data-governance/</u> (Accessed: 4/19/23) [2] Responses to PEDSnet Questions
5.2.7	Other (specify)	Does not authorize/specify	Does not authorize/specify	
6	PII Elements			

	9 - PEDSnet Limited Data Sets (LE		•••	1
		Raw Language	Interpretation	
6.1	PII elements collected	All sites collect a variety of PII, including demographic, familial, and insurance data, for the purposes of health care treatment, payment, and operations. PII other than dates and geocodes at the census block group level are removed from PEDSnet data, with the goal of producing a limited dataset for core use and best-effort deidentification for study specific activities (<i>e.g.</i> text for NLP, chart reviews). [1]	PEDSnet collects first name, last name, sex, and date of birth.	[1] Res [2] CHC report)
		 PEDSnet uses the following PII elements to generate five different hashed codes, which are all salted: 1. Last name, first name, sex, DOB: Gives best match with over 93% accuracy. 2. Last name, first three letters of first name, sex, DOB: 87% accuracy The more the name is truncated, less accurate it is. 3. Last name, first initial, sex and DOB: overall accuracy is 62%. 4. Last name, first name, DOB and zip3: does not perform as well as sex and DOB. 5. Soundex of last name, Soundex of first name, sex, and DOB (in children populations, PEDSnet would use trigraphs instead of Soundex). [2] 		
6.2	PII elements holder (i.e., party that holds the PII)	 Institutions contributing data to the PEDSnet Database will retain direct patient identifiers within each institution and will not share this information with the Coordinating Center except in defined study contexts. Patients will be assigned a site-level Patient Identifier that has no internal meaning. Institutions will retain the mapping between the site-level Patient Identifier and local identifiers (such as a medical record number) to enable reidentification at the local institution. 6.7.2 Reidentification All studies requiring reidentification will have Institutional Review Board oversight. Patient reidentifiers of interest, and the institutions will perform the reidentification. 6.7.3 Network-wide Identifiers The Coordinating Center will maintain a unique network-wide PEDSnet Patient Identifier, which will not be disclosed to sites outside defined study context, in order to maintain a honest broker role. [1] 		[1] <u>http</u> (Access

Source

esponses to PEDSnet Questions HOP/PEDSnet Interview (as part of predecessor ort)

ttps://pedsnet.org/resources/governance/ essed: 4/18/23)

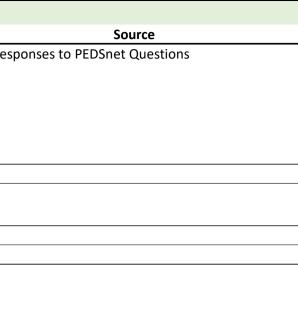
Jalasel J -	PEDSnet Limited Data Sets (LDS		• • • • •	
		Raw Language	Interpretation	
6.3	, , , , , , , , , , , , , , , , , , , ,		PEDSnet CDM is based on OMOP and	[1] <u>htt</u>
	data collection	PEDSnet chose from the onset of the network to establish a pediatric-	includes all PCORnet CDMs in addition to	(Access
		specific Common Data Model (PEDSnet CDM) for the storage of PEDSnet	important data elements not yet addressed	
		· · · ·	in PCORnet.	(Access
		domains or data elements needed by pediatric investigators. Two		
		examples are age-normalized anthropomorphic measurements (height,		
		weight, BMI percentiles based on CDC routines) and census block		
		geocoding for location-based data queries linked to geocoded		
		environmental data sets. The PEDSnet CDM is based on the Observational		
		Health Data Sciences and Informatics collaborative's OMOP common data		
		model. This CDM focuses strongly on terminology standardization,		
		resulting in use of common standard terminologies such as SNOMED-CT,		
		RxNorm, CPT, and LOINC for both clinical and demographic facts. The		
		OMOP model was expanded to include the PCORnet and pediatric specific		
		data standards, as developed by PEDSnet. The PEDSnet CDM subsumes all		
		PCORnet elements, but addresses important data elements not yet		
		addressed in the PCORnet-wide CDM.		
		PCORnet Common Data Model		
		PCORnet created the PCORnet Common Data Model, summarized below		
		for networks in the PCORnet initiative, to facilitate the sharing of		
		information across the wider PCORnet network. The PCORnet Common		
		Data Model is based on the Mini-Sentinel Common Data Model, and is		
		used for PCORnet sponsored studies and data queries. As a PCORnet		
		network, PEDSnet participates in these queries when approved by PEDSnet		
		governing bodies.		
		The PEDSnet DCC has developed automated transformations from the		
		PEDSnet CDM to the PCORnet CDM, demonstrating the feasibility of		
		interconversion between CDM representations of similar content, and		
		supporting participation in many collaborative research communities. [1]		
		The PEDSnet Coordinating Center will support research done using the		
		PCORnet Common Data Model, and will maintain a translation between		
		the PEDSnet and the PCORnet Common Data Models. As per PCORnet		
		policy, the PCORnet Common Data Model will be modified on an annual		
		basis. [2]		
7	Prior Data Linkages			
7.1	Dataset linked with other datasets			
7.1.1	Name of other dataset linked to this dataset	Information not available/found	Information not available/found	
7.1.2	Other dataset type (clinical, EHR,	PEDSnet has used PPRL for linkage to large claims and pharmacy benefits	1. Claims	[1] Res
	survey, claims, SDOH, etc.)	datasets, and is currently employing linkage to mortality data as part of the	2. Mortality	
		RECOVER EHR ini[ti]ative. We have also pursued clear text linkage in		
		smaller study and registry contexts where participant consent was		
		available. Finally, clear text linkage at sites is routinely used for purposes		
		such as identifying charts to review. [1]		

Source

ttps://pedsnet.org/data/common-data-model/ essed: 4/18/23) ttps://pedsnet.org/resources/governance/ essed: 4/18/23)

esponses to PEDSnet Questions

		Raw Language	Interpretation	
7.1.4	Linking methodology (PPRL or non- PPRL); linkage technology	PEDSnet has used PPRL for linkage to large claims and pharmacy benefits datasets, and is currently employing linkage to mortality data as part of the	1. PPRL 2. PPRL	[1] Res
		RECOVER EHR iniative. We have also pursued clear text linkage in smaller study and registry contexts where participant consent was available. Finally, clear text linkage at sites is routinely used for purposes such as identifying charts to review. [1]	3. Non-PPRL (clear text linkage)	
7.1.5	PII elements used for the linkage	Information not available/found	Information not available/found	
7.1.6	Entity resolver (data originator or data linker or third party)	Information not available/found	Information not available/found	
7.1.7	Party performing the linkages	Information not available/found	Information not available/found	
7.1.8	Linkage quality assessment	Information not available/found	Information not available/found	
7.1.9	Linked data sharing method (linkage maps or pre-linked dataset)	Information not available/found	Information not available/found	



	GOVERNANCE INFORMATION	
Use Case 3: SA	ARS-CoV-2 Vaccination and Asthma-Relate	ed School Absence - Does SARS-CoV-2 vaccination result in reduced asthma-related school absences at 3/6/12
Dataset 10 -	- RADx-UP Return to School Hawaii S	Study (Empowering schools as community assets to mitigate the adverse impacts of COVID-19
	Dataset Source	RADx Data Hub
	Dataset Source Agency	NIH
	Dataset Type (Clinical, EHR, Survey, SDOH,	Survey, socioeconomic
	etc.)	
	Information Sources	Website, Interview Meeting Summary/Recording, RADx Data Hub documentation provided by ODSS, RADx consent doc
Dataset 10 -		
Dataset 10		Development
•		Raw Language
1	Data Collection	
1.1	Authorizations and Applicable	
1.1.1	Regulations/Policies Authorizations	
1.1.1.1	Assent	 First Visit: If you agree to participate, we will give you an appointment time and ask you to complete the following: 1. Survey: Before you come, we will ask that you take a survey either online or through video teleconferencing. a. We will ask you for basic information such as your name, date of birth, address, contact information, race, ethnicity, gender, language, health insurance status. Your name and contact information will enable us to provide results to you. They are also required by the Hawaii Department of Health for all those taking a COVID-19 test. b. We will ask you for information about COVID-19, including information about any symptoms, such as fever or headache, and test results. We will ask about your medical history and if you have or have not had vaccines and why. c. We will ask you for information about your health, education, knowledge, and attitude about Covid-19 infection, prevention, testing, vaccination, employment status, income, alcohol consumption, tobacco use. 2. SARS-CoV-2 Antigen Test. This test will tell us if you are currently infected with the virus that causes Covid-19. Either trained professional will swab their nose with a special cotton swab or we will train you to do your own nasal sampling. Once the sample is done, we will place it on the antigen test card. Results will be available in about an hour, sometimes sooner. [1]

12+ n	nonths post-vaccination?	
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ocume	entation sent by RADx UP researcher, Respon	se to RADx Data Hub Questions
	Interpretation	Source
	P	
	1. Assent from children	
	2. Consent from parents	
	3. AHARO Health Centers/Comprehensive Health Center IRB	
	4. Hawaii DOE Data Governance and	
	Analytics Branch	
	Assent from children authorizes data	[1] Assent Form
	collection.	
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Dataset 10 -			• • • • • • •	
4.4.4.2		Raw Language	Interpretation	Source
1.1.1.2	Consent	The Hawaii consent form was modified after reviewing with community members. [1]	Consent from parents authorizes data collection.	[1] RADx UP Meeting 1[2] Parental Consent Form for Students
		First Visit: If you agree for your child to participate, we will give them an appointment and ask to complete the following		
		information. We estimate that it will take your child about 30 minutes to complete all the steps.		
		1. Survey: Before your child comes, we will ask that they take a survey either online or in person. a. We will ask for your child's name, date of birth, address, contact information, race, ethnicity, gender, language. Their		
		name and preferred contact method will enable us to provide results to you. These are also required by the Hawaii		
		Department of Health for anyone taking a COVID-19 test. b. We will ask questions about COVID-19, including any symptoms, such as fever or headache. We will ask about their		
		medical history and if your child has or not had the COVID vaccines. c. We will ask questions about your child's overall health, school grade, and a few questions about their thoughts about		
		Covid-19 infection, prevention, testing, and vaccination.		
		2. SARS-CoV-2 Antigen Test: This test will tell us if your child is currently infected with the virus that causes Covid-19. Either a trained professional will swab their nose with a special cotton swab or we will train your child to do their own		
		nasal sampling. We will provide instructions on how to take the sample and will be present to answer questions. Once the sample is done, we will place it on the antigen test card. Results will be available in about 30 minutes, often sooner.		
		Retesting: Sometimes we will need to retest a person on the same day to make sure the results are accurate.		
		a. All positive tests will be confirmed with a PCR nasal swab test to make sure the results are correct. This is a very good method to detect infection but it usually takes 1-2 days to process.		
		b. If your child's first test is NEGATIVE but have had serious exposure to Covid-19, or have developed symptoms, we may also ask for a second test.		
		c. To make sure everyone is safe during this waiting period, we will ask that your child leaves school and quarantine at		
		home. We will call you as soon as the results are available. [2]		
1.1.1.3	IRB/equivalent Privacy Board	The Hawaii study is under the IRB of the main community health center [AHARO Health Centers] that has oversight over	AHARO Health Centers/Comprehensive	[1] RADx UP Meeting 1
	determination		Health Center IRB authorizes data collection.	[2] RADx UP Meeting 2
1.1.1.4	Local/state/federal laws	The Hawaii Department of Education (DOE) Data Governance and Analytics Branch department had to approve since the	Hawaii DOE Data Governance and Analytics	[1] RADx UP Meeting 1
		study was based at schools. The only data we gathered directly was testing data for the students, teachers, staff who underwent school-based testing. [1, 2]	Branch authorizes data collection.	[2] RADx UP Meeting 2
1.1.1.5	Institutional Certification	Information not available/found	Information not available/found	
1.1.1.6	Data originator agreement	Information not available/found	Information not available/found	
1.1.1.7	Repository agreements/policies	Information not available/found	Information not available/found	
1.1.1.8	Other (specify)	Information not available/found	Information not available/found	
1.1.2	Applicable Regulations/Policies	Information not available/found	Information not available /found	
1.1.2.1	Local regulations/policies	Information not available/found Information not available/found	Information not available/found Information not available/found	
	Tribal regulations/policies			
1.1.2.3	State regulations/policies Federal regulations/policies	Information not available/found Information not available/found	Information not available/found Information not available/found	
1.1.2.4	International regulations/policies	Information not available/found	Information not available/found	
1.1.2.5	Contractual obligations	Information not available/found	Information not available/found	
1.1.2.7	Repository policies	Information not available/found	Information not available/found	
1.2		access, and use based on data collection authorization or applicable regulations/policies (i.e., the origin of the g		

	RADx-UP	Raw Language	Interpretation	Source
1.2.1	Whether the data can be linked	1. The project is funded by the National Institutes of Health (NIH). It is part of the NIH RADx-UP, a health research	1. Parental informed consent and assent do	
	Whether the data can be inked	program to learn more about Covid-19 disease. If you join RADx-UP, we will gather some data (information) about your child. We will combine the data from all who join, to understand how to help more people at risk for or with COVID-19. [1]	not specify linkage. Raw language referring to "other research studies" is interpreted by the study PI as leaving the option open for data linkage.	
		2. The Hawaii study consent form contains language that the data will be used to participate in the overall cohort for RADx-UP but does not explicitly mention linking to other datasets. "Your data can be used for other research studies"	2. AHARO Health Centers/Comprehensive Health Center IRB specifies that data can be	
		language leaves the option for the data to be used for linkage. [2]	linked at an individual level only if the IRB approves the linkage.	
		 3. Linkage is possible but any linkage at an individual level must be approved by the Comprehensive Health Center IRB. Anything beyond [general research purposes] (such as linking data and working with identifiers) must be approved by the community IRB. [2] 		
1.2.2	With what other data can it be linked or can it not be linked (scope of linkage)	Linkage is possible but any linkage at an individual level must be approved by the Comprehensive Health Center IRB. Anything beyond [general research purposes] (such as linking data and working with identifiers) must be approved by the community IRB. [1]	· ·	[1] RADx UP Meeting 2
1.2.3	Whether data can be shared	The project is funded by the National Institutes of Health (NIH). It is part of the NIH RADx-UP, a health research program to learn more about Covid-19 disease. If you join RADx-UP, we will gather some data (information) about your child. We will combine the data from all who join, to understand how to help more people at risk for or with COVID-19. [1]	Parental informed consent specifies that data will be shared with other researchers.	[1] Parental Consent Form for Students
		When the data is shared with other researchers, they will not have information that can identify your child. [1]		
1.2.4	How data can be shared (de- identification status, disclosure review)	Does not authorize/specify	Does not authorize/specify	
1.2.5	How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.)	Does not authorize/specify	Does not authorize/specify	
1.2.6	How data can be used (data use limitations)	Does not authorize/specify	Does not authorize/specify	
1.2.7	Other (specify)	Does not authorize/specify	Does not authorize/specify	
2	Data Linkage			
2.1	Authorizations and Applicable Regulations/Policies			
2.1.1	Authorizations		1. AHARO Health Centers/Comprehensive Health Center IRB	
2.1.1.1	Assent	Does not authorize/specify	Does not authorize/ specify	[1] Assent Form[2] RADx UP Meeting 2
		The project is funded by the National Institutes of Health (NIH). It is part of the NIH RADx-UP, a health research program to learn more about Covid-19 disease. If you join RADx-UP, we will gather some data (information) about your child. We will combine the data from all who join, to understand how to help more people at risk for or with COVID-19. [1]		
		The Hawaii study consent form contains language that the data will be used to participate in the overall cohort for RADx- UP but does not explicitly mention linking to other datasets. "Your data can be used for other research studies" language leaves the option for the data to be used for linkage. [2]		

		Raw Language
2.1.1.2	Consent	Does not authorize/specify
		The project is funded by the National Institutes of Health (NIH). It is part of the NIH RADx-UP, a health research program to learn more about Covid-19 disease. If you join RADx-UP, we will gather some data (information) about your child. W will combine the data from all who join, to understand how to help more people at risk for or with COVID-19. [1]
		The Hawaii study consent form contains language that the data will be used to participate in the overall cohort for RAD UP but does not explicitly mention linking to other datasets. "Your data can be used for other research studies" language leaves the option for the data to be used for linkage. [2]
2.1.1.3	IRB/equivalent Privacy Board determination	Linkage is possible but any linkage at an individual level must be approved by the Comprehensive Health Center IRB [AHARO Health Center]. Anything beyond [general research purposes] (such as linking data and working with identifier must be approved by the community IRB. [1]
2.1.1.4	Local/state/federal laws	Information not available/found
2.1.1.5	Institutional Certification	Information not available/found
2.1.1.6	Data originator agreement	Information not available/found
2.1.1.7	Repository agreements/policies	Information not available/found
2.1.1.8	Other (specify)	Information not available/found
2.1.2	Applicable Regulations/Policies	
2.1.2.1	Local regulations/policies	Information not available/found
2.1.2.2	Tribal regulations/policies	Information not available/found
2.1.2.3	State regulations/policies	Information not available/found
2.1.2.4	Federal regulations/policies	Information not available/found
2.1.2.5	International regulations/policies	Information not available/found
2.1.2.6	Contractual obligations	Information not available/found
2.1.2.7	Repository policies	Information not available/found
2.2		ccess, and use based on data linkage authorization or applicable regulations/policies (i.e., the origin of the g
2.2.1	Whether the data can be linked	 The project is funded by the National Institutes of Health (NIH). It is part of the NIH RADx-UP, a health research program to learn more about Covid-19 disease. If you join RADx-UP, we will gather some data (information) about your child. We will combine the data from all who join, to understand how to help more people at risk for or with COVID-19. [1]
		 The Hawaii study consent form contains language that the data will be used to participate in the overall cohort for RADx-UP but does not explicitly mention linking to other datasets. "Your data can be used for other research studies" language leaves the option for the data to be used for linkage. [2]
		3. Linkage is possible but any linkage at an individual level must be approved by the Comprehensive Health Center IRB. Anything beyond [general research purposes] (such as linking data and working with identifiers) must be approved by community IRB. [2]
2.2.2	With what other data can it be linked or can it not be linked (scope of linkage)	Linkage is possible but any linkage at an individual level must be approved by the Comprehensive Health Center IRB. Anything beyond [general research purposes] (such as linking data and working with identifiers) must be approved by t community IRB. [1]
2.2.3	Whether data can be shared	The project is funded by the National Institutes of Health (NIH). It is part of the NIH RADx-UP, a health research program to learn more about Covid-19 disease. If you join RADx-UP, we will gather some data (information) about your child. We will combine the data from all who join, to understand how to help more people at risk for or with COVID-19. [1]
		When the data is shared with other researchers, they will not have information that can identify your child. [1]

	Interpretation	Source
	Does not authorize/ specify	[1] Parental Consent Form for Students
		[2] RADx UP Meeting 2
am		
Ne		
Dx-		
age		
	AHARO Health Centers/Comprehensive	[1] RADx UP Meeting 2
ers)	Health Center IRB authorizes data linkage.	
	Information not available/found	
	Information not available/found	
gove	rnance)	
-	1. Parental informed consent and assent do	[1] Parental Consent Form for Students
ur	not specify linkage. Raw language refering	[2] RADx UP Meeting 2
9.	to "other research studies" is interpreted by	
	the study PI as leaving the option open for	
	data linkage.	
	2. AHARO Health Centers/Comprehensive	
	Health Center IRB specifices that data can	
	be linked at an individual level only if the	
	IRB approves the linkage.	
3.		
y the		
-		
	AHARO Health Centers/Comprehensive	[1] RADx UP Meeting 2
y the	Health Center IRB specifies that any data	
	linkages at an individual level or outside of	
	general research purposes must be	
	approved by the AHARO Health Centers IRB.	
am	Parental informed consent specifies that	[1] Parental Consent Form for Students
Ne	data will be shared with other researchers.	

Dataset 10	- RADx-UP	
		Raw Language
2.2.4	How data can be shared (de- identification status, disclosure review)	Does not authorize/specify
2.2.5	How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.)	Does not authorize/specify
2.2.6	How data can be used (data use limitations)	Does not authorize/specify
2.2.7	Other (specify)	Does not authorize/specify
3	Data Sharing	
3.1	Authorizations and Applicable Regulations/Policies	
3.1.1	Authorizations	
3.1.1.1	Assent	It is part of the NIH RADx-UP, a health research program to learn more about Covid-19 disease. If you join RADx-UP, will gather some data (information) about you. We will combine these with data from other people who join RADx-U We will study the data from all who join to understand how to help more people at risk for or with COVID-19. [1] When the data is shared with other researchers, they will not have information that can identify you. [1]
3.1.1.2	Consent	The project is funded by the National Institutes of Health (NIH). It is part of the NIH RADx-UP, a health research progr to learn more about Covid-19 disease. If you join RADx-UP, we will gather some data (information) about your child. will combine the data from all who join, to understand how to help more people at risk for or with COVID-19. [1] When the data is shared with other researchers, they will not have information that can identify your child. [1]
3.1.1.3	IRB/equivalent Privacy Board determination	Information not available/found
3.1.1.4	Local/state/federal laws	The data was collected indirectly from schools, so FERPA applies to the data collected. [1]

	Interpretation	Source
	Does not authorize/specify	
	 Assent from children Consent from parents FERPA Data originator agreement (Agreement For Disclosure And Transfer Of Confidential Information And Protected Health Information) Registration of studies in dbGaP RADx Institutional Certification 	
we JP.	Assent from children authorizes data sharing.	[1] Assent Form
ram We	Consent from parents authorizes data sharing.	[1] Parental Consent Form for Students
	Information not available/found	
	FERPA authorizes data sharing.	[1] RADx UP Meeting 2

Dataset 10 -	RADx-UP	Douglanguage	Intorprototion	Course
3.1.1.5	Institutional Certification	Raw Language The		Source [1] Rapid Acceleration for Diagnostics Program (RADx) Institutional Certification: https://radx-up.org/wp- content/uploads/2022/05/RADx- INSTITUTIONAL-CERTIFICATION-FINAL- 02022021-1.pdf (Accessed 4/17/23)
3.1.1.6	Data originator agreement	Discloser wishes to share with Duke, or Duke will be given access to (i) research subjects' information that constitutes Protected Health Information ("PHI"), as defined in the Health Insurance Portability and Accountability Act of 1996, as amended ("HIPAA"), including, but not limited to, research subjects' contact information and (ii) other information that Discloser considers to be confidential ("Discloser Confidential Information") to enable Duke to: (a) obtain research subjects' written informed consent/HIPAA authorization ("Subject Authorization"), RADx-UP Common Data Elements, related questionnaires, surveys and forms for performing data analyses and for collecting follow up data from research subjects; (b) better understand COVID-19 testing patterns among underserved and vulnerable populations; (c) strengthen the understanding of the impact of relevant data on disparities in infection rates, disease progression, and outcomes; (d) develop strategies to reduce disparities in COVID-19 testing; and (e) fulfill Duke's obligation as the CDCC under the Project to provide de-identified Project data and the results of its analyses to the Awarding Agency (collectively, "Duke Purpose") [1]	Agreement For Disclosure And Transfer Of Confidential Information And Protected Health Information authorizes data sharing.	 [1] Agreement For Disclosure And Transfer Of Confidential Information And Protected Health Information: <u>https://radx-up.org/research/cdes/</u> (Accessed 4/17/23)
3.1.1.7	Repository agreements/policies	Information not available/found	Information not available/found	
3.1.1.8	Other	Information not available/found	Information not available/found	
3.1.2	Applicable Regulations/Policies			
3.1.2.1	Local regulations/policies	Information not available/found	Information not available/found	
3.1.2.2	Tribal regulations/policies	Information not available/found	Information not available/found	
3.1.2.3	State regulations/policies	Information not available/found	Information not available/found	
3.1.2.4	Federal regulations/policies	Information not available/found	Information not available/found	
3.1.2.5	International regulations/policies	Information not available/found	Information not available/found	
3.1.2.6	Contractual obligations	Information not available/found	Information not available/found	
3.1.2.7	Repository policies	Every study loaded into the Data Hub must be registered in the dbGaP system first. The study registration process starts when the Principal Investigator (PI) emails the dbGaP Registration Form to the Genomic Program Administrator (GPA) [1] approver and the appropriate C(DCC) Administrator. Using the information from the form, the GPA enters the study registration information into dbGaP. Once the study has been successfully registered in dbGaP, the GPA will send the dbGaP Registration Form (PDF file) to the Super User. [2]	RADx Data Hub policy	 [1] RADx Data Hub Email Communication [2] <u>https://radx-</u> <u>hub.nih.gov/docs/dcc/create-study-</u> <u>page.html</u> (Accessed 4/17/23)
3.2	Governance for data linkage, sharing, a	ccess, and use based on data sharing authorization or applicable regulations/policies (i.e., the origin of the gov	ernance)	
3.2.1	Whether the data can be linked	1. The project is funded by the National Institutes of Health (NIH). It is part of the NIH RADx-UP, a health research program to learn more about Covid-19 disease. If you join RADx-UP, we will gather some data (information) about your child. We will combine the data from all who join, to understand how to help more people at risk for or with COVID-19. [1]	Parental informed consent and assent do not specify linkage. Raw language refering to "other research studies" is interpreted by the study PI as leaving the option open for data linkage.	[1] Parental Consent Form for Students[2] RADx UP Meeting 2
		2. The Hawaii study consent form contains language that the data will be used to participate in the overall cohort for RADx-UP but does not explicitly mention linking to other datasets. "Your data can be used for other research studies" language leaves the option for the data to be used for linkage. [2]		

Dataset 10 - R	Pataset 10 - RADx-UP				
		Raw Language	Interpretation	Source	
3.2.2	With what other data can it be linked or can it not be linked (scope of linkage)	Does not authorize/specify	Does not authorize/specify		
3.2.3	Whether data can be shared	When the data is shared with other researchers, they will not have information that can identify your child. [1] The data was collected indirectly from schools, so FERPA applies to the data collected. [2]	 The following specify that data can be shared: 1. Parental informed consent language 2. FERPA 3. Agreement For Disclosure And Transfer Of Confidential Information And Protected 	 [1] Parental Consent Form for Students [2] RADx UP Meeting 2 [3] Agreement For Disclosure And Transfer Of Confidential Information And Protected Health Information: https://radx-up.org/research/cdes/ 	
		Fulfill Duke's obligation as the CDCC under the Project to provide de-identified Project data and the results of its analyses to the Awarding Agency (collectively, "Duke Purpose") [3]	Health Information (study data, including PHI, to be sent to Duke (CDCC) and for Duke to provide de-identified project data for the awarding agency.)	(Accessed 4/17/23) [4] <u>https://radx-</u>	
		Every study loaded into the Data Hub must be registered in the dbGaP system first. [4] The hereby assures that submission of data from the study entitled	4. Study registration in dbGaP5. RADx Institutional Certification (in the RADx Data Hub by the CDCC/Duke)	[5] Institutional Certification: <u>https://radx-up.org/wp-</u> <u>content/uploads/2022/05/RADx-</u> INSTITUTIONAL-CERTIFICATION-FINAL-	
		to an NIH-designated data repository meets the following expectations: The data submission is consistent, as appropriate, with applicable national, tribal, and state laws and regulations as well as relevant institutional policies. Any limitations on the research use of the data, as expressed in the informed consent documents, are delineated in the table on page 3. The identities of research participants will not be disclosed to NIH-designated data repositories. 		02022021-1.pdf (Accessed 4/17/23)	
		• An Institutional Review Board (IRB), and/or Privacy Board, and/or equivalent body, and a relevant senior-level institutional staff (e.g., Dean, Vice President/Provost for Research, Chief Science Officer) as applicable, has reviewed the investigator's proposal for data submission and assures that: o The protocol for the collection of genomic and phenotypic data is consistent with 45 CFR Part 46;2 o Data submission and subsequent data sharing for research purposes are consistent with the informed consent of study participants from whom the data were obtained;			
		 o Consideration was given to risks to individual participants and their families associated with data submitted to NIH-designated data repositories and subsequent sharing, including unrestricted access to genomic summary results; o To the extent relevant and possible, consideration was given to risks to groups or populations associated with submitting data to NIH-designated data repositories and subsequent sharing, including unrestricted access to genomic summary results; a To the extent relevant and possible, consideration was given to risks to groups or populations associated with submitting data to NIH-designated data repositories and subsequent sharing, including unrestricted access to genomic summary results; and b The investigator's plan for de-identifying datasets is consistent with the HHS Regulations for the Protection of Human Subjects** [5] 	5		

Dataset 10 - R	ADx-UP			
		Raw Language	Interpretation	Source
3.2.4	How data can be shared (de- identification status, disclosure review)	Please confirm our understanding that all data shared in RADx Data Hub are de-identified. "Correct" [1] Every study loaded into the Data Hub must be registered in the dbGaP system first [2]	 RADx policy specifies that the study be registered in dbGaP prior to sharing through RADx Data Hub. The RADx Institutional Certification specifies that all data shared in an NIH 	hub.nih.gov/docs/dcc/create-study- page.html (Accessed 4/17/23) [3] Rapid Acceleration for Diagnostics Program (RADx) Institutional Certification: <u>https://radx-up.org/wp-</u> content/uploads/2022/05/RADx-
		The identities of research participants will not be disclosed to NIH-designated data repositories. [3]	designated repository must be de- identified. 3. The RADx DCC works with study teams to de-identify zip codes, shift dates, and adjust	
		Zip codes. The RADxSM DCC will send awardees software to de-identify zip code data consistent with Section 164.514(a) of the Health Information Portability and Accountability Act (HIPAA) Privacy Rule to ensure the coordination centers receive HIPAA de-identified zip code data.	ages into categories for specific ages.	<u>02022021-1.pdf</u> (Accessed 4/17/23) [4] Proposal for RADxSM (C)DCC Data Sharing with the RADx Data Hub
		All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geocodes, except for the initial three digits of the ZIP code if, according to the current publicly available data from the Bureau of the Census:		
		 (1) The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000 		
		Date shifting. The RADxSM DCC will send the awardees software to de-identify dates by using a randomly selected, constant # of days (e.g., add 4 days to all dates) to ensure that date data submitted to the coordination centers are de-identified; awardees will keep a record of these data interval constants for each participant used for all data submissions.		
		The process for randomly choosing the number of offset days will be discussed among the RADx coordination centers to ensure consistency across RADxSM programs. Preliminary discussions suggested the time interval should be 10 days (e.g., if the interval is -5 to 5 days from day 0, the original date, one research participant may have all their dates shifted 3 days forward while another research participant may have their dates shifted 5 days back).		
		Age. For age, if a research participant is less than one year old, the submitted data will be listed as "0"; if a participant is 21 years old or above, the submitted age will be listed within +/- 2 years of the chronological age. In cases where the research participant is 90 years old or above, the submitted age element will be aggregated into a single number "90". The RADxSM Data Hub will alert Awardees about these two age groups.		
		Note: For projects that are generating data with no HIPAA-de-identifiers, awardees' projects may require modifications to their IRB protocols (including consent form modifications), and require modifications to , Data Use and/or Data Transfer agreements, depending on the identifiers contained in the data. Additionally, a system for research participant notification of data breaches may be required depending on the identifier. [4]		
3.2.5	How data can be accessed (access type, data use agreement, data access	All data in the RADx Data Hub are considered controlled access. [1]	RADx Institutional Certification specifies that all individual-level data are controlled	[1] Responses to RADx Data Hub Questions
	committee/group approval, IRB LOD, etc.)	The individual-level data are to be made available through (check one) -controlled-access -unrestricted access [2]	access.	 [2] Rapid Acceleration for Diagnostics Program (RADx) Institutional Certification: <u>https://radx-up.org/wp-</u> <u>content/uploads/2022/05/RADx-</u> <u>INSTITUTIONAL-CERTIFICATION-FINAL-</u> <u>02022021-1.pdf</u> (Accessed 4/17/23)

Dataset 10	- RADx-UP	
		Raw Language
3.2.6	How data can be used (data use limitations)	 NIH expects the submitting institution(s) to select one of the three standard Data Use Limitations (DULs) for appropriate secondary use, or, if necessary, create a customized DUL. DULs are developed based on the original informed consent of the participant(s). -General Research Use (GRU): Use of the data is s limited only by the terms of the Data Use Certification: these data will be added to the dbGaP Collection. -Health/Medical/Biomedical (HMB): Use of the data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry -Disease-specific [list disease] (DS): Use of the data must be related to the specified disease -Other
		Additional modifiers to the standard DULs (e.g., Not-for-profit Use Only) can be indicated, if appropriate. Use of the modifiers should have a basis in the informed consent from the participants or in special knowledge of the preferences the original study population. -IRB Approval Required (IRB): Requestor must provide documentation of local IRB approval -Publication Required (PUB): Requestor agrees to make results of studies using the data available to the larger scientific community. -Collaboration Required (COL): Requestor must provide a letter of collaboration with the primary study investigator(s). -Not-for-profit Use Only (NPU): Use of the data is limited to not-for-profit organizations -Methods (MDS): Use of the data includes methods development research (e.g., development and testing of software or algorithms) -Genetic Studies Only (GSO): Use of the data is limited to genetic studies only. [1] The data that was shared with Duke can be used for general research purposes. [2]
3.2.7	Other (specify)	Does not authorize/specify
4	Other (specify) Data Access	Does not authorize/specify
4.1	Authorizations and Applicable Regulations/Policies	
4.1.1	Authorizations	
4.1.1.1	Assent	Does not authorize/specify
4.1.1.2	Consent	Does not authorize/specify
4.1.1.3	IRB/equivalent Privacy Board determination	Information not available/found not all RADx-UP studies require IRB to access. Since the Return to School Hawaii stud has not been submitted to the RADx Data Hub, information is not available on whether and IRB/equivalen Privacy Board determination is required for data access.
		Additional modifiers to the standard DULs (e.g., Not-for-profit Use Only) can be indicated, if appropriate. Use of the modifiers should have a basis in the informed consent from the participants or in special knowledge of the preferences the original study population. Data Use Limitation Modifiers (Optional) -IRB Approval Required (IRB): Requestor must provide documentation of local IRB approval [1]
4.1.1.4	Local/state/federal laws	Information not available/found
4.1.1.5	Institutional Certification	Information not available/found

	Interpretation	Source
ate	RADx Institutional Certification specifies	[1] Rapid Acceleration for Diagnostics
of	that the data can be used for general	Program (RADx) Institutional
	research purposes.	Certification: <u>https://radx-up.org/wp-</u>
/ill		content/uploads/2022/05/RADx-
		INSTITUTIONAL-CERTIFICATION-FINAL-
de		<u>02022021-1.pdf</u> (Accessed 4/17/23)
		[2] RADx UP Meeting 2
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or		
U.		
	Does not authorize/specify	
	Information not available/found	
	Does not authorize/specify	
	Does not authorize/specify	
udy	Information not available/found	[1] Rapid Acceleration for Diagnostics
ard		Program (RADx) Institutional
		Certification: <u>https://radx-up.org/wp-</u>
		<pre>content/uploads/2022/05/RADx-</pre>
		INSTITUTIONAL-CERTIFICATION-FINAL-
es of		02022021-1.pdf (Accessed 4/17/23)
	Information not available/found	
	Information not available/found	
	Information not available/found	

		Raw Language	Interpretation	Source
4.1.1.7	Repository agreements/policies	Investigators and their institutions are responsible for safeguarding the accessed datasets. They must also adhere to the terms of access described in the Data Use Certification (DUC) Agreement and the Genomic Data User Code of Conduct that were signed as part of the data access request. [1]	 Three repository agreements authorize data access: 1. RADx Data Use Certification (DUC) Agreement 2. Genomic Data Use Coder of Conduct 	 [1] <u>https://sharing.nih.gov/accessing-data/accessing-genomic-data/how-to-request-and-access-datasets-from-dbga</u> (Accessed 4/17/23) [2] RADx Data Use Certification
		RADxSM Data User Code of Conduct: Key principles and practices agreed to by all research investigators requesting access to RADxSM data. The elements within RADxSM Data User Code of Conduct reflect the terms of access in the Data Use Certification Agreement. Failure to abide by the RADxSM Data User Code of Conduct may result in revocation of an investigator's access to any and all approved datasets. [2]	3. RADxSM Data User Code of Conduct	Agreement [3] Responses to RADx Data Hub Questions
		Must researchers sign the Code of Conduct to access RADx-UP data in the RADx Data Hub and if so, when is it signed? [A]t the time of the Data Access Request in submitted into the dbGaP system and attested to by the institutional signing official. [3]		
4.1.1.8	Other (specify)	Information not available/found	Information not available/found	
4.1.2	Applicable Regulations/Policies			
4.1.2.1	Local regulations/policies	Information not available/found	Information not available/found	
4.1.2.2	Tribal regulations/policies	Information not available/found	Information not available/found	
4.1.2.3	State regulations/policies	Information not available/found	Information not available/found	
4.1.2.4	Federal regulations/policies	Information not available/found	Information not available/found	
4.1.2.5	International regulations/policies	Information not available/found	Information not available/found	
4.1.2.6	Contractual obligations	Information not available/found	Information not available/found	
4.1.2.7	Repository policies	Investigators and their institutions are responsible for safeguarding the accessed datasets. They must also adhere to the terms of access described in the Data Use Certification (DUC) Agreement and the Genomic Data User Code of Conduct that were signed as part of the data access request. [1] RADxSM Data User Code of Conduct: Key principles and practices agreed to by all research investigators requesting access to RADxSM data. The elements within RADxSM Data User Code of Conduct reflect the terms of access in the Data Use Certification Agreement. Failure to abide by the RADxSM Data User Code of Conduct may result in revocation of an investigator's access to any and all approved datasets. [2]	RADx Data Hub policy	 [1] <u>https://sharing.nih.gov/accessing-data/accessing-genomic-data/how-to-request-and-access-datasets-from-dbga</u> (Accessed 4/17/23) [2] RADx Data Use Certification Agreement [3] Responses to RADx Data Hub Questions
		Must researchers sign the Code of Conduct to access RADx-UP data in the RADx Data Hub and if so, when is it signed? [A]t the time of the Data Access Request in submitted into the dbGaP system and attested to by the institutional signing official. [3]		
4.2		ccess, and use based on data access authorization or applicable regulations/policies (i.e., the origin of the gove		
4.2.1	Whether the data can be linked	Does not authorize/specify	Does not authorize/specify	
4.2.2	With what other data can it be linked or can it not be linked (scope of linkage)	Does not authorize/specify	Does not authorize/specify	
4.2.3	Whether data can be shared	Does not authorize/specify	Does not authorize/specify	
4.2.4	How data can be shared (de- identification status, disclosure review)	Does not authorize/specify	Does not authorize/specify	

Dataset 10	RADx-UP			
		Raw Language	Interpretation	Source
4.2.5	How data can be accessed (access type,	1) To create a RADx Data Hub account users must have an eRA commons or Login.gov account. Any email may be used to		[1] <u>https://www.radxdatahub.info/faqs</u>
	data use agreement, data access committee/group approval, IRB LOD,	create a Login.gov account. All users can view and use tutorial data, but study data access is controlled on a study-by- study basis. To view or use a particular study's data, you must have dbGaP access to that study and log in with your eRA	specifies RADx Data Hub data access. The requirements/steps specify that the	(Accessed: 4/17/23) [2] <u>https://sharing.nih.gov/accessing-</u>
	etc.)	commons account.	user/eligible investigator:	data/accessing-genomic-data/using-
		[1]	1) Must have an eRA commons or Login.gov	
			account	4/17/23)
		2) Invesitgator Submits Data Access Request in dbGaP (Those eligible to apply for data access must be a permanent	2) Must submit a Data Access Request	[3] Responses to RADx Data Hub
		employee of their institution and either: At a level equivalent to a tenure-track professor, or Senior scientist with	(DAR). Data Use Certification (DUC)	Questions
		responsibilities that may include laboratory or research program administration and oversight.)	Agreement, the Genomic Data User Code of	
		3) Signing Official Reviews, Approves, and Co-signs Request	Conduct, and the RADx SM Data User Code of Conduct are signed as part of the DAR	
		Once a data access request is submitted in dbGaP, it is automatically routed to the investigator's institutional Signing	process	
		Official (SO) for review, approval, and co-signature.	3) Must ensure that the Signing Official	
			from investigator's institution reviews,	
		4) Data Access Committee Reviews Request approves, and co-signs the request	approves, and co-signs the request	
		Once the SO approves and signs the data access request, the system forwards the data access request to the appropriate	4) Must receive approval from Data Access	
		NIH Data Access Committee(s) (DAC) for review.	Committee	
			5) Must access the controlled access data	
		The DACs review all access requests for human genomic datasets distributed through dbGaP to ensure the data access request complies with the NIH GDS policy, any IC or program-specific requirements, and any limitations or restrictions on	through RADx Data Hub Jupyter Notebooks	
		data use. Each dataset has an associated DAC.		
		Based on their review, DACs approve or reject data access requests, or return data access requests for revision.		
		The DAC may ask for more information from the investigator requesting data if the proposed research is inconsistent with	1	
		any applicable data use limitations, if the research intent is unclear, or if there is concern about potential harm (e.g.,		
		stigmatization) to groups or populations.		
		5) Access Data		
		Investigators and their institutions are responsible for safeguarding the accessed datasets. They must also adhere to the		
		terms of access described in the Data Use Certification (DUC) Agreement and the Genomic Data User Code of Conduct		
		that were signed as part of the data access request.		
		Once approved, investigators will be able to access the data for one year. Prior to the expiration of the one-year access		
		period, investigators must submit a project renewal or close-out report, describing the progress made on the approved		
		research project.		
		[2]		
		All data in the RADx Data Hub are considered controlled access. [3]		
4.2.6	How data can be used (data use	Does not authorize/specify	Does not authorize/specify	
	limitations)			
4.2.7 5	Other (specify) Data Use	Does not authorize/specify	Does not authorize/specify	
5.1	Authorizations and Applicable			
	Regulations/Policies			
5.1.1	Authorizations		1. Institutional Certification	
5.1.1.1	Assent	Does not authorize/specify	Does not authorize/specify	
5.1.1.2	Consent	Does not authorize/specify	Does not authorize/specify	
5.1.1.3	IRB/equivalent Privacy Board determination	Does not authorize/specify	Does not authorize/specify	
5.1.1.4	Local/state/federal laws	Does not authorize/specify	Does not authorize/specify	

Dataset 10 - F	RADx-UP			
		Raw Language	Interpretation	Source
5.1.1.5	Institutional Certification	 NIH expects the submitting institution(s) to select one of the three standard Data Use Limitations (DULs) for appropriate secondary use, or, if necessary, create a customized DUL. DULs are developed based on the original informed consent of the participant(s). -General Research Use (GRU): Use of the data is limited only by the terms of the Data Use Certification: these data will be added to the dbGaP Collection. -Health/Medical/Biomedical (HMB): Use of the data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry -Disease-specific [list disease] (DS): Use of the data must be related to the specified disease -Other Additional modifiers to the standard DULs (e.g., Not-for-profit Use Only) can be indicated, if appropriate. Use of the modifiers should have a basis in the informed consent from the participants or in special knowledge of the preferences of the original study population. -IRB Approval Required (IRB): Requestor must provide documentation of local IRB approval -Publication Required (PUB): Requestor agrees to make results of studies using the data available to the larger scientific community. -Collaboration Required (COL): Requestor must provide a letter of collaboration with the primary study investigator(s). -Not-for-profit Use Only (NPU): Use of the data is limited to genetic studies only. -Genetic Studies Only (GSO): Use of the data is limited to genetic studies only. [1] The data that was shared with Duke can be used for general research purposes. 	The RADx Institutional Certification authorizes data use.	 [1] Rapid Acceleration for Diagnostics Program (RADx) Institutional Certification: <u>https://radx-up.org/wp-content/uploads/2022/05/RADx-INSTITUTIONAL-CERTIFICATION-FINAL-02022021-1.pdf</u> (Accessed 4/17/23) [2] RADx UP Meeting 2
		[2]		
5.1.1.6	Data originator agreement	Does not authorize/specify	Does not authorize/specify	
5.1.1.7	Repository agreements/policies	This Data Use Certification Agreement outlines the terms of use for requested RADx datasets maintained in the RADx Data Hub. [1]	RADx Data Use Certification Agreement authorizes data use.	[1] RADx Data Use Certification Agreement
5.1.1.8	Other (specify)	Information not available/found	Information not available/found	
5.1.2	Applicable Regulations/Policies			
5.1.2.1	Local regulations/policies	Information not available/found	Information not available/found	
5.1.2.2	Tribal regulations/policies	Information not available/found	Information not available/found	
5.1.2.3	State regulations/policies	Information not available/found	Information not available/found	
5.1.2.4	Federal regulations/policies	Information not available/found	Information not available/found	
5.1.2.5	International regulations/policies	Information not available/found	Information not available/found	
5.1.2.6	Contractual obligations	Information not available/found	Information not available/found	
5.1.2.7	Repository policies	Investigators and their institutions are responsible for safeguarding the accessed datasets. They must also adhere to the terms of access described in the Data Use Certification (DUC) Agreement and the Genomic Data User Code of Conduct that were signed as part of the data access request. [1] RADxSM Data User Code of Conduct: Key principles and practices agreed to by all research investigators requesting access to RADxSM data. The elements within RADxSM Data User Code of Conduct reflect the terms of access in the Data Use Certification Agreement. Failure to abide by the RADxSM Data User Code of Conduct may result in revocation of an investigator's access to any and all approved datasets. [2] Must researchers sign the Code of Conduct to access RADx-UP data in the RADx Data Hub and if so, when is it signed? [A]t the time of the Data Access Request in submitted into the dbGaP system and attested to by the institutional signing official. [3]		 [1] <u>https://sharing.nih.gov/accessing-data/accessing-genomic-data/how-to-request-and-access-datasets-from-dbgap</u> (Accessed 4/17/23) [2] RADx Data Use Certification Agreement [3] Responses to RADx Data Hub Questions
5.2	Governance for data linkage, sharing, ac	ccess, and use based on data access authorization or applicable regulations/policies (i.e., the origin of the gove	rnance)	
5.2.1		Does not authorize/specify	Does not authorize/specify	
5.2.2	With what other data can it be linked or can it not be linked (scope of linkage)	Does not authorize/specify	Does not authorize/specify	

		Raw Language	Interpretation	Source
2.3	Whether data can be shared	The hereby assures that submission of data from the study entitled to an NIH-designated data repository meets the following expectations:	RADx Institutional Certification specifies that the CDCC (Duke in the case of RADx UP)	[1] Rapid Acceleration for Diagnostic
				Certification: <u>https://radx-up.org/w</u> content/uploads/2022/05/RADx-
		• Any limitations on the research use of the data, as expressed in the informed consent documents, are delineated in the		INSTITUTIONAL-CERTIFICATION-FIN 02022021-1.pdf (Accessed 4/17/23
		 table on page 3. The identities of research participants will not be disclosed to NIH-designated data repositories. 		02022021-1.put (Accessed 4/17/25
		• An Institutional Review Board (IRB), and/or Privacy Board, and/or equivalent body, and a relevant senior-level institutional staff (e.g., Dean, Vice President/Provost for Research, Chief Science Officer) as applicable, has reviewed the investigator's proposal for data submission and assures that:		
		o The protocol for the collection of genomic and phenotypic data is consistent with 45 CFR Part 46;2		
		o Data submission and subsequent data sharing for research purposes are consistent with the informed consent of study participants from whom the data were obtained;		
		o Consideration was given to risks to individual participants and their families associated with data submitted to NIH- designated data repositories and subsequent sharing, including unrestricted access to genomic summary results;		
		o To the extent relevant and possible, consideration was given to risks to groups or populations associated with submitting	,	
		data to NIH-designated data repositories and subsequent sharing, including unrestricted access to genomic summary results; and		
		o The investigator's plan for de-identifying datasets is consistent with the HHS Regulations for the Protection of Human Subjects** [1]		
.2.4	How data can be shared (de- identification status, disclosure review)	Please confirm our understanding that all data shared in RADx Data Hub are de-identified. "Correct" [1]	1. RADx Institutional Certification specifies that all data shared in the RADx Data Hub	[1] Responses to RADx Data Hub Questions
		The hereby assures that submission of data from the study entitled	must be-identified. 2. RADx Institutional Certification specifies	[2] Rapid Acceleration for Diagnost Program (RADx) Institutional
		to an NIH-designated data repository meets the following expectations:	that all data be shared to an NIH-designated	Certification: <u>https://radx-up.org/v</u>
		• The data submission is consistent, as appropriate, with applicable national, tribal, and state laws and regulations as well as relevant institutional policies.	repository [RADx Data Hub].	content/uploads/2022/05/RADx- INSTITUTIONAL-CERTIFICATION-FIN
		• Any limitations on the research use of the data, as expressed in the informed consent documents, are delineated in the table on page 3.		02022021-1.pdf (Accessed 4/17/23
		• The identities of research participants will not be disclosed to NIH-designated data repositories.		
		• An Institutional Review Board (IRB), and/or Privacy Board, and/or equivalent body, and a relevant senior-level institutional staff (e.g., Dean, Vice President/Provost for Research, Chief Science Officer) as applicable, has reviewed the		
		investigator's proposal for data submission and assures that:		
		o The protocol for the collection of genomic and phenotypic data is consistent with 45 CFR Part 46;2 o Data submission and subsequent data sharing for research purposes are consistent with the informed consent of study		
		participants from whom the data were obtained; o Consideration was given to risks to individual participants and their families associated with data submitted to NIH-		
		designated data repositories and subsequent sharing, including unrestricted access to genomic summary results;		
		o To the extent relevant and possible, consideration was given to risks to groups or populations associated with submitting data to NIH-designated data repositories and subsequent sharing, including unrestricted access to genomic summary		
		results; and o The investigator's plan for de-identifying datasets is consistent with the HHS Regulations for the Protection of Human Subjects**[2]		
2.5	How data can be accessed (access type,	All data in the RADx Data Hub are considered controlled access.	RADx Institutional Certification specifies	[1] Responses to RADx Data Hub
.2.J	data use agreement, data access	[1]	that all individual-level data are controlled	Questions
	committee/group approval, IRB LOD, etc.)	The individual-level data are to be made available through (check one)	access.	[2] Rapid Acceleration for Diagnos Program (RADx) Institutional
		-controlled-access -unrestricted access		Certification: <u>https://radx-up.org/</u> content/uploads/2022/05/RADx-
		[2]		INSTITUTIONAL-CERTIFICATION-FII 02022021-1.pdf (Accessed 4/17/2

Dataset 10 - R	ADx-UP			
		Raw Language	Interpretation	Source
5.2.6	limitations)	NH expects the submitting institution(s) to select one of the three standard Data Use Limitations (DULs) for appropriate secondary use, or, if necessary, create a customized DUL. DULs are developed based on the original informed consent of the participant(s). -General Research Use (GRU): Use of the data is limited only by the terms of the Data Use Certification: these data will be added to the dbGaP Collection. -Health/Medical/Biomedical (HMB): Use of the data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry -Disease-specific [list disease] (DS): Use of the data must be related to the specified disease -Other Additional modifiers to the standard DULs (e.g., Not-for-profit Use Only) can be indicated, if appropriate. Use of the modifiers should have a basis in the informed consent from the participants or in special knowledge of the preferences of the original study population. -IRB Approval Required (IRB): Requestor must provide documentation of local IRB approval -Publication Required (PUB): Requestor must provide documentation of local IRB approval -Publication Required (COL): Requestor must provide a letter of collaboration with the primary study investigator(s). -Not-for-profit Use Only (NPU): Use of the data is limited to not-for-profit organizations -Methods (MDS): Use of the data includes methods development research (e.g., development and testing of software or algorithms) -Genetic Studies Only (GSO): Use of the data is limited to genetic studies only. [1] "The RADxSM Data Hub- Addendum to this Agreement outlines additional terms and information which are specific to each requested dataset such as: • Data Use Limitation(s) • Sponsoring NIH Institute or Center • Responsible Data Access Committee • Study Description • Suggested Acknowledgement Statement" [2] The data that was shared with Duke can be used for general research purposes. [3]	RADx Institutional Certification specifies that the use of data is for general research purposes.	[1] Rapid Acceleration for Diagnostics Program (RADx) Institutional Certification: https://radx-up.org/wp- content/uploads/2022/05/RADx- INSTITUTIONAL-CERTIFICATION-FINAL- 02022021-1.pdf (Accessed 4/17/23) [2] RADx Data Use Certification Agreement [3] RADx UP Meeting 2
5.2.7	Other (specify)	Does not authorize/specify	Does not authorize/specify	
6	PII Elements			
6.1		Data privacy is super important in communities that we're working in. With large numbers of native Hawaiian pacific islanders, the study has been careful about identifiers. The Hawaii study does not collect SSN but does collect DOB and names. [1] The Hawaii study also collects the email address of both the parent and the child. Duke does not have identifiers, only zip codes and sex. The study sites have the rest of the data elements such as name, DOB, etc. [2]	The study collects date of birth, names, parent email address, child email address, zip code, and sez.	[1] RADx UP Meeting 1[2] RADx UP Meeting 2
	PII)	Duke does not have identifiers, only zip codes and sex. The study sites have the rest of the data elements such as name, DOB, etc. There are indigenous (Native Hawaiian/Pacific Islander) considerations and the IRB only approved for using de- identified data. [1]	Duke holds zip code and sex. The study sites hold the rest of the PII (name, date of birth, and email addresses).	[1] RADx UP Meeting 2
	collection	In order to ensure consistency in how RADx-UP projects collect data for the RADx Data Hub and simplify the analysis of that data, the NIH defined a set of Common Data Elements (CDEs). The NIH RADx-UP CDEs provide a standard set of study questions that RADx-UP projects are required to use in their COVID-19 testing studies. [1]	RADx-UP studies use common data elements as defined by RADx-UP	 [1] <u>https://radx-up.org/research/cdes/</u> (Accessed 4/17/23) [2] RADx UP Meeting 2
		The Hawaii study uses the format/common data elements that RADx-UP set up. [2]		
7				

ataset 10 -	RADx-UP			
		Raw Language	Interpretation	Source
7.1.1	Name of other dataset linked to this dataset	PI has worked on individual level location-based secondary analyses such as neighborhood socioeconomic status using Census blocks with geocodes and public datasets from the CDC. [1]	Neighborhood socioeconomic status from Census blocks, public datasets from the CDC	[1] RADx UP Meeting 2
7.1.2	Other dataset type (clinical, EHR, survey, claims, SDOH, etc.)	PI has worked on individual level location-based secondary analyses such as neighborhood socioeconomic status using Census blocks with geocodes and public datasets from the CDC. [1]	Social determinants of health, COVID data	[1] RADx UP Meeting 2
7.1.3	Other dataset source(s)	PI has worked on individual level location-based secondary analyses such as neighborhood socioeconomic status using Census blocks with geocodes and public datasets from the CDC. [1]	CDC	[1] RADx UP Meeting 2
7.1.4	Linking methodology (PPRL or non-PPRL); linkage technology	PI has worked on individual level location-based secondary analyses such as neighborhood socioeconomic status using Census blocks with geocodes and public datasets from the CDC. [1]	Non-PPRL; linked with geocodes	[1] RADx UP Meeting 2
7.1.5	PII elements used for the linkage	PI has worked on individual level location-based secondary analyses such as neighborhood socioeconomic status using Census blocks with geocodes and public datasets from the CDC. [1]	Zip code	[1] RADx UP Meeting 2
7.1.6	Entity resolver (data originator or data linker or third party)	PI has worked on individual level location-based secondary analyses such as neighborhood socioeconomic status using Census blocks with geocodes and public datasets from the CDC. [1]	Data originator	[1] RADx UP Meeting 2
7.1.7	Party performing the linkages	PI has worked on individual level location-based secondary analyses such as neighborhood socioeconomic status using Census blocks with geocodes and public datasets from the CDC. [1]	Study team	[1] RADx UP Meeting 2
7.1.8	Linkage quality assessment	Information not available/found	Information not available/found	
7.1.9	Linked data sharing method (linkage maps or pre-linked dataset)	Information not available/found	Information not available/found	

	GOVERNANCE INFORMATION	\sim Absence Deco CADS CoV 2 receivation receivation receivation advect estimation related estimates at $2/C/12$ receivation	he next version tion?	
	· EPA Daily Air Quality Data	ool Absence - Does SARS-CoV-2 vaccination result in reduced asthma-related school absences at 3/6/12+ mont	ns post-vaccination?	
Dataset II -		Air Quality System		
	Dataset Source	Air Quality System		
	Dataset Source Agency	Environmental Protection Agency (EPA)		
	Dataset Type (Clinical, EHR, Survey, SDOH, etc.)	Air quality data		
	Information Sources	Website		
Dataset 11 -	EPA Daily Air Quality Data			
		Raw Language	Interpretation	Source
1	Data Collection			
1.1	Authorizations and Applicable			
	Regulations/Policies			
1.1.1	Authorizations		1. Clean Air Act	
1.1.1.1	Assent	N/A	N/A	
1.1.1.2	Consent	N/A	N/A	
1.1.1.3	IRB/equivalent Privacy Board determination	N/A The Clean Air Act requires that state, legal, and tribal air pollution control agonsies monitor the air for ambient levels of	N/A	[1]
1.1.1.4	Local/state/federal laws	The Clean Air Act requires that state, local, and tribal air pollution control agencies monitor the air for ambient levels of certain pollutants. This data is useful for health and policy research relating to air pollution and its control (Fann et al.	Clean Air Act authorizes data collection by state/local/tribal air pollution control	[1] https://aqs.epa.gov/aqsweb/documents/a
		2015). The requirements for the monitoring program are codified in 40 CFR Part 58. In addition to the required	agencies for reporting to the EPA.	bout_aqs_data.html (Accessed: 4/18/23)
		monitoring, many agencies perform additional and/or voluntary monitoring of substances and meteorological		
		parameters. The monitoring program is designed to meet three objectives (40 CFR Part 58 Appendix D.1):		
		Provide air pollution data to the public in a timely manner;		
		Support compliance with ambient air quality standards and emissions strategy development; and		
		Support for air pollution research studies.		
		This data is reported to the United State Environmental Protection Agency (EPA). The monitoring agencies are required		
		to report the measured data, along with metadata about the site and monitoring equipment and associated quality		
		assurance data to the US EPA's Air Quality System (AQS). AQS and its predecessors have been accepting and storing this		
		data for more than 50 years and currently contains more than 3 billion measurements. This document describes (1) the		
		methods by which the data can be obtained, (2) the general nature of of the AQS data set, and (3) some background material about the monitoring program that may help users select and interpret data.		
		[1]		
1.1.1.5	Institutional Certification	N/A Information not available/found	N/A Information not available/found	
1.1.1.6	Data originator agreement Repository agreements/policies	N/A	N/A	
1.1.1.7	Other (specify)	Information not available/found	Information not available/found	
1.1.2	Applicable Regulations/Policies			
1.1.2.1	Local regulations/policies	Information not available/found	Information not available/found	
1.1.2.2	Tribal regulations/policies	Information not available/found	Information not available/found	
1.1.2.3	State regulations/policies	Information not available/found	Information not available/found	
1.1.2.4	Federal regulations/policies	Information not available/found	Information not available/found	
1.1.2.5	International regulations/policies	Information not available/found	Information not available/found	
1.1.2.6	Contractual obligations	Information not available/found	Information not available/found	
1.1.2.7	Repository policies		N/A	
1.2		, and use based on data collection authorization or applicable regulations/policies (i.e., the origin of the govern		
1.2.1	Whether the data can be linked	Does not authorize/specify	Does not authorize/specify	
1.2.2	With what other data can it be linked or can it not be linked (scope of linkage)	Does not authorize/specify	Does not authorize/specify	
1.2.3	Whether data can be shared	Does not authorize/specify	Does not authorize/specify	
2.2.0				1

Dataset 11 -	EPA Daily Air Quality Data			
		Raw Language	Interpretation	Source
1.2.4	How data can be shared (de-identification status, disclosure review)	The Clean Air Act requires that state, local, and tribal air pollution control agencies monitor the air for ambient levels of certain pollutants. This data is useful for health and policy research relating to air pollution and its control (Fann et al. 2015). The requirements for the monitoring program are codified in 40 CFR Part 58. In addition to the required monitoring, many agencies perform additional and/or voluntary monitoring of substances and meteorological parameters. The monitoring program is designed to meet three objectives (40 CFR Part 58 Appendix D.1): Provide air pollution data to the public in a timely manner;	Clean Air Act specifies that ambient air data be shared through EPA's Air Quality System (AQS).	[1] https://aqs.epa.gov/aqsweb/documents/a bout aqs data.html (Accessed: 4/18/23)
		Support compliance with ambient air quality standards and emissions strategy development; and Support for air pollution research studies.		
		This data is reported to the United State Environmental Protection Agency (EPA). The monitoring agencies are required to report the measured data, along with metadata about the site and monitoring equipment and associated quality assurance data to the US EPA's Air Quality System (AQS). AQS and its predecessors have been accepting and storing this data for more than 50 years and currently contains more than 3 billion measurements. This document describes (1) the methods by which the data can be obtained, (2) the general nature of of the AQS data set, and (3) some background material about the monitoring program that may help users select and interpret data.		
1.2.5	How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.)	Does not authorize/specify	Does not authorize/specify	
1.2.6	How data can be used (data use limitations)	Does not authorize/specify	Does not authorize/specify	
1.2.7	Other (specify)	Does not authorize/specify	Does not authorize/specify	
2	Data Linkage			
2.1	Authorizations and Applicable Regulations/Policies			
2.1.1	Authorizations		None found	
2.1.1.1	Assent	N/A	N/A	
2.1.1.2	Consent	N/A	N/A	
2.1.1.3	IRB/equivalent Privacy Board determination	N/A	N/A	
2.1.1.4	Local/state/federal laws	Information not available/found	Information not available/found	
2.1.1.5	Institutional Certification	N/A	N/A	
2.1.1.6 2.1.1.7	Data originator agreement Repository agreements/policies	Information not available/found The ambient monitoring data in EPA's Air Quality System (AQS) are public domain. You are welcome to download the data and use freely, without submitting a request.	Information not available/found AQS being in the public domain authorizes data linkage.	[1] <u>https://www.epa.gov/outdoor-air-</u> quality-data/do-i-need-request-permission- use-monitoring-data-and-graphics-airdata
2.1.1.8	Other (specify)	Information not available/found	Information not available/found	
2.1.2	Applicable Regulations/Policies			
2.1.2.1	Local regulations/policies	Information not available/found	Information not available/found	
2.1.2.2	Tribal regulations/policies	Information not available/found	Information not available/found	
2.1.2.3	State regulations/policies	Information not available/found	Information not available/found	
2.1.2.4	Federal regulations/policies	Information not available/found	Information not available/found	
2.1.2.5	International regulations/policies	Information not available/found	Information not available/found	
2.1.2.6 2.1.2.7	Contractual obligations Repository policies	Information not available/found The ambient monitoring data in EPA's Air Quality System (AQS) are public domain. You are welcome to download the data and use freely, without submitting a request.	Information not available/found AQS policy	[1] <u>https://www.epa.gov/outdoor-air-</u> quality-data/do-i-need-request-permission- use-monitoring-data-and-graphics-airdata
2.2	Governance for data linkage, sharing, access	and use based on data linkage authorization or applicable regulations/policies (i.e., the origin of the governan		
2.2.1	Whether the data can be linked	N/A		
2.2.1	With what other data can it be linked or can it not be linked (scope of linkage)	N/A N/A	N/A N/A	
2.2.3	Whether data can be shared	N/A	N/A	
2.2.4	How data can be shared (de-identification status, disclosure review)	N/A	N/A	
2.2.5	How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.)	N/A	N/A	

	EPA Daily Air Quality Data	Paul anguaga	Internetation	Course
2.2.6	How data can be used (data use limitations)	Raw Language	Interpretation N/A	Source
2.2.0		N/A	N/A	
	Other (specify)	N/A	N/A	
3	Data Sharing			
3.1	Authorizations and Applicable			
	Regulations/Policies			
3.1.1	Authorizations		1. Clean Air Act	
3.1.1.1	Assent	N/A	N/A	
3.1.1.2	Consent	N/A	N/A	
3.1.1.3	IRB/equivalent Privacy Board determination	N/A	N/A	
3.1.1.4	Local/state/federal laws	The Clean Air Act requires that state, local, and tribal air pollution control agencies monitor the air for ambient levels of	Clean Air Act authorizes data sharing.	[1]
		certain pollutants. This data is useful for health and policy research relating to air pollution and its control (Fann et al.		https://aqs.epa.gov/aqsweb/documents/
		2015). The requirements for the monitoring program are codified in 40 CFR Part 58. In addition to the required		bout_aqs_data.html (Accessed: 4/18/23)
		monitoring, many agencies perform additional and/or voluntary monitoring of substances and meteorological		
		parameters. The monitoring program is designed to meet three objectives (40 CFR Part 58 Appendix D.1):		
		Provide air pollution data to the public in a timely manner;		
		Support compliance with ambient air quality standards and emissions strategy development; and		
		Support for air pollution research studies.		
		This data is reported to the United State Environmental Protection Agency (EPA). The monitoring agencies are required		
		to report the measured data, along with metadata about the site and monitoring equipment and associated quality		
		assurance data to the US EPA's Air Quality System (AQS). AQS and its predecessors have been accepting and storing this		
		data for more than 50 years and currently contains more than 3 billion measurements. This document describes (1) the		
		methods by which the data can be obtained, (2) the general nature of of the AQS data set, and (3) some background		
		material about the monitoring program that may help users select and interpret data.		
3.1.1.5	Institutional Certification	N/A	N/A	
3.1.1.6	Data originator agreement	Information not available/found	Information not available/found	
3.1.1.7	Repository agreements/policies	Information not available/found	Information not available/found	
3.1.1.8	Other	Information not available/found	Information not available/found	
3.1.2	Applicable Regulations/Policies			
3.1.2.1	Local regulations/policies	Information not available/found	Information not available/found	
3.1.2.2	Tribal regulations/policies	Information not available/found	Information not available/found	
3.1.2.3	State regulations/policies	Information not available/found	Information not available/found	
3.1.2.4	Federal regulations/policies	Information not available/found	Information not available/found	
3.1.2.5	International regulations/policies	Information not available/found	Information not available/found	
3.1.2.6	Contractual obligations	Information not available/found	Information not available/found	
3.1.2.7	Repository policies	Information not available/found	Information not available/found	
3.2		, and use based on data sharing authorization or applicable regulations/policies (i.e., the origin of the governan		•
3.2.1	Whether the data can be linked	Does not authorize/specify	Does not authorize/specify	
3.2.2	With what other data can it be linked or can it		Does not authorize/specify	
	not be linked (scope of linkage)			

Dataset 11 - I	EPA Daily Air Quality Data			
		Raw Language	Interpretation	Source
3.2.3	Whether data can be shared	The Clean Air Act requires that state, local, and tribal air pollution control agencies monitor the air for ambient levels of certain pollutants. This data is useful for health and policy research relating to air pollution and its control (Fann et al. 2015). The requirements for the monitoring program are codified in 40 CFR Part 58. In addition to the required monitoring, many agencies perform additional and/or voluntary monitoring of substances and meteorological parameters. The monitoring program is designed to meet three objectives (40 CFR Part 58 Appendix D.1):	Clean Air Act specifies that ambient air data can be shared.	[1] https://aqs.epa.gov/aqsweb/documents/a bout aqs data.html (Accessed: 4/18/23)
		Provide air pollution data to the public in a timely manner;		
		Support compliance with ambient air quality standards and emissions strategy development; and		
		Support for air pollution research studies.		
		This data is reported to the United State Environmental Protection Agency (EPA). The monitoring agencies are required to report the measured data, along with metadata about the site and monitoring equipment and associated quality assurance data to the US EPA's Air Quality System (AQS). AQS and its predecessors have been accepting and storing this data for more than 50 years and currently contains more than 3 billion measurements. This document describes (1) the methods by which the data can be obtained, (2) the general nature of of the AQS data set, and (3) some background material about the monitoring program that may help users select and interpret data. [1]		
3.2.4	How data can be shared (de-identification status, disclosure review)	The Clean Air Act requires that state, local, and tribal air pollution control agencies monitor the air for ambient levels of certain pollutants. This data is useful for health and policy research relating to air pollution and its control [1].	Clean Air Act specifies that full geographic identifiers including site address, zip code, CBSA, county, and state are shared.	[1] https://aqs.epa.gov/aqsweb/documents/a bout_aqs_data.html (Accessed: 4/18/23)
		Site Address The street address giving an approximate location of the site.		[2] https://aqs.epa.gov/aqsweb/documents/A
				<u>QS_Data_Dictionary.html</u> (Accessed:
		Zip Code		8/22/23)
		The postal zip code in which the monitoring site resides.		
		CBSA The name of the core based statistical area (metropolitan area) where the monitoring site is located.		
		CBSA Code The code of the core based statistical area (metropolitan area) where the monitoring site is located.		
		County The name of the county where the monitoring site is located.		
		County Code The FIPS County Code where the monitor resides.		
		State Code The FIPS code of the state in which the monitor resides. [2]		
3.2.5	How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.)	Does not authorize/specify	Does not authorize/specify	
3.2.6	How data can be used (data use limitations)	Does not authorize/specify	Does not authorize/specify	
3.2.7	Other (specify)	Does not authorize/specify	Does not authorize/specify	
4	Data Access			
4.1	Authorizations and Applicable Regulations/Policies			
4.1.1	Authorizations		1. AQS in public domain	
4.1.1.1	Assent	N/A	N/A	
4.1.1.2	Consent	N/A	N/A	
4.1.1.3	IRB/equivalent Privacy Board determination Local/state/federal laws	N/A Information not available/found	N/A Information not available/found	
4.1.1.4	Institutional Certification	N/A	N/A	
4.1.1.6	Data originator agreement	Information not available/found	Information not available/found	

Dataset 11 -	EPA Daily Air Quality Data			
		Raw Language	Interpretation	Source
4.1.1.7	Repository agreements/policies	The ambient monitoring data in EPA's Air Quality System (AQS) are public domain. You are welcome to download the	AQS being in the public domain authorizes	[1] <u>https://www.epa.gov/outdoor-air-</u>
		data and use freely, without submitting a request. [1]	data access.	quality-data/do-i-need-request-permission
				use-monitoring-data-and-graphics-airdata
4.1.1.8	Other (specify)	Information not available/found	Information not available/found	
4.1.2	Applicable Regulations/Policies			
4.1.2.1	Local regulations/policies	Information not available/found	Information not available/found	
4.1.2.2	Tribal regulations/policies	Information not available/found	Information not available/found	
4.1.2.3	State regulations/policies	Information not available/found	Information not available/found	
4.1.2.4	Federal regulations/policies	Information not available/found	Information not available/found	
4.1.2.5	International regulations/policies	Information not available/found	Information not available/found	
4.1.2.6	Contractual obligations	Information not available/found	Information not available/found	
4.1.2.7	Repository policies	The ambient monitoring data in EPA's Air Quality System (AQS) are public domain. You are welcome to download the	AQS policy	[1] https://www.epa.gov/outdoor-air-
		data and use freely, without submitting a request. [1]		guality-data/do-i-need-request-permission
		uata and use neery, without submitting a request. [1]		use-monitoring-data-and-graphics-airdata
4.2	Covernance for data linkage shering access	 and use based on data assess sutherization or explicable regulations/nolicies/i.e. the origin of the sourcement	a)	
4.2		and use based on data access authorization or applicable regulations/policies (i.e., the origin of the governanc		
4.2.1	Whether the data can be linked	Does not authorize/specify	Information not available/found	
4.2.2	With what other data can it be linked or can it	Does not authorize/specify	Does not authorize/specify	
	not be linked (scope of linkage)			
4.2.3	Whether data can be shared	Does not authorize/specify	Does not authorize/specify	
4.2.4	How data can be shared (de-identification	The Clean Air Act requires that state, local, and tribal air pollution control agencies monitor the air for ambient levels of	AQS policy specifies that full geographic	[1]
	status, disclosure review)	certain pollutants. This data is useful for health and policy research relating to air pollution and its control [1].	identifiers including site address, zip code,	https://aqs.epa.gov/aqsweb/documents/a
			CBSA, county, and state are shared.	bout_aqs_data.html (Accessed: 4/18/23)
		Site Address		[2]
		The street address giving an approximate location of the site.		https://aqs.epa.gov/aqsweb/documents//
				QS Data Dictionary.html (Accessed:
		Zip Code		8/22/23)
		The postal zip code in which the monitoring site resides.		
		CBSA		
		The name of the core based statistical area (metropolitan area) where the monitoring site is located.		
		The name of the core based statistical area (metropolitan area) where the monitoring site is located.		
		CBSA Code		
		The code of the core based statistical area (metropolitan area) where the monitoring site is located.		
		County		
		The name of the county where the monitoring site is located.		
		County Code		
		The FIPS County Code where the monitor resides.		
		State Code		
		The FIPS code of the state in which the monitor resides.		
		[2]		
		The ambient monitoring data in EPA's Air Quality System (AQS) are public domain. You are welcome to download the	AQS being in the public domain specifies	[1] https://www.epa.gov/outdoor-air-
4.2.5	How data can be accessed (access type, data			
4.2.5	How data can be accessed (access type, data use agreement, data access committee/group		that the data is open access.	quality-data/do-i-need-request-permission
4.2.5	use agreement, data access committee/group	data and use freely, without submitting a request.	that the data is open access.	
4.2.5			that the data is open access.	
	use agreement, data access committee/group approval, IRB LOD, etc.)	data and use freely, without submitting a request.		
4.2.6	use agreement, data access committee/group approval, IRB LOD, etc.) How data can be used (data use limitations)	data and use freely, without submitting a request. Does not authorize/specify	Does not authorize/specify	
4.2.6 4.2.7	use agreement, data access committee/group approval, IRB LOD, etc.) How data can be used (data use limitations) Other (specify)	data and use freely, without submitting a request.		
4.2.6 4.2.7	use agreement, data access committee/group approval, IRB LOD, etc.) How data can be used (data use limitations) Other (specify) Data Use	data and use freely, without submitting a request. Does not authorize/specify	Does not authorize/specify	
4.2.6 4.2.7	use agreement, data access committee/group approval, IRB LOD, etc.) How data can be used (data use limitations) Other (specify)	data and use freely, without submitting a request. Does not authorize/specify	Does not authorize/specify	
4.2.6 4.2.7	use agreement, data access committee/group approval, IRB LOD, etc.) How data can be used (data use limitations) Other (specify) Data Use	data and use freely, without submitting a request. Does not authorize/specify	Does not authorize/specify	
4.2.6 4.2.7 5.1	use agreement, data access committee/group approval, IRB LOD, etc.) How data can be used (data use limitations) Other (specify) Data Use Authorizations and Applicable	data and use freely, without submitting a request. Does not authorize/specify	Does not authorize/specify	
4.2.6 4.2.7 5.1	use agreement, data access committee/group approval, IRB LOD, etc.) How data can be used (data use limitations) Other (specify) Data Use Authorizations and Applicable Regulations/Policies	data and use freely, without submitting a request. Does not authorize/specify	Does not authorize/specify Does not authorize/specify	<u>quality-data/do-i-need-request-permissior</u> <u>use-monitoring-data-and-graphics-airdata</u>
4.2.6 4.2.7 5.1 5.1.1 5.1.1.1	use agreement, data access committee/group approval, IRB LOD, etc.) How data can be used (data use limitations) Other (specify) Data Use Authorizations and Applicable Regulations/Policies Authorizations Assent	data and use freely, without submitting a request. Does not authorize/specify Does not authorize/specify N/A	Does not authorize/specify Does not authorize/specify 1. AQS in public domain N/A	
4.2.6 4.2.7 5.1 5.1.1 5.1.1.1 5.1.1.2	use agreement, data access committee/group approval, IRB LOD, etc.) How data can be used (data use limitations) Other (specify) Data Use Authorizations and Applicable Regulations/Policies Authorizations Assent Consent	data and use freely, without submitting a request. Does not authorize/specify Does not authorize/specify N/A N/A	Does not authorize/specify Does not authorize/specify 1. AQS in public domain N/A N/A	
4.2.6 4.2.7 5.1 5.1.1 5.1.1.1	use agreement, data access committee/group approval, IRB LOD, etc.) How data can be used (data use limitations) Other (specify) Data Use Authorizations and Applicable Regulations/Policies Authorizations Assent	data and use freely, without submitting a request. Does not authorize/specify Does not authorize/specify N/A	Does not authorize/specify Does not authorize/specify 1. AQS in public domain N/A	<u>quality-data/do-i-need-request-permission</u> <u>use-monitoring-data-and-graphics-airdata</u>

Dataset 11 -	ataset 11 - EPA Daily Air Quality Data						
		Raw Language	Interpretation	Source			
<u>5.1.1.6</u> 5.1.1.7	Data originator agreement Repository agreements/policies	N/A The ambient monitoring data in EPA's Air Quality System (AQS) are public domain. You are welcome to download the data and use freely, without submitting a request. [1]	N/A AQS being in the public domain authorizes data use.	[1] <u>https://www.epa.gov/outdoor-air-</u> <u>quality-data/do-i-need-request-permission-</u> <u>use-monitoring-data-and-graphics-airdata</u>			
5.1.1.8	Other (specify)	Information not available/found	Information not available/found				
5.1.2	Applicable Regulations/Policies						
5.1.2.1	Local regulations/policies	The ambient monitoring data in EPA's Air Quality System (AQS) are public domain. You are welcome to download the data and use freely, without submitting a request. [1]	No data use limitations since the data is open access	[1] <u>https://www.epa.gov/outdoor-air-</u> <u>quality-data/do-i-need-request-permission-</u> <u>use-monitoring-data-and-graphics-airdata</u>			
5.1.2.2	Tribal regulations/policies	Information not available/found	Information not available/found				
5.1.2.3	State regulations/policies	Information not available/found	Information not available/found				
5.1.2.4	Federal regulations/policies	Information not available/found	Information not available/found				
5.1.2.5	International regulations/policies	Information not available/found	Information not available/found				
5.1.2.6	Contractual obligations	Information not available/found	Information not available/found				
5.1.2.7	Repository policies	The ambient monitoring data in EPA's Air Quality System (AQS) are public domain. You are welcome to download the data and use freely, without submitting a request. [1]	AQS policy	[1] <u>https://www.epa.gov/outdoor-air-</u> <u>quality-data/do-i-need-request-permission-</u> <u>use-monitoring-data-and-graphics-airdata</u>			
5.2	Governance for data linkage, sharing, access,	and use based on data access authorization or applicable regulations/policies (i.e., the origin of the governanc	e)				
5.2.1	Whether the data can be linked	Does not authorize/specify	Does not authorize/specify				
5.2.2	With what other data can it be linked or can it not be linked (scope of linkage)	Does not authorize/specify	Does not authorize/specify				
5.2.3	Whether data can be shared	Does not authorize/specify	Does not authorize/specify				
5.2.4	How data can be shared (de-identification status, disclosure review)	Does not authorize/specify	Does not authorize/specify				
5.2.5	How data can be accessed (access type, data use agreement, data access committee/group approval, IRB LOD, etc.)	Does not authorize/specify	Does not authorize/specify				
5.2.6	How data can be used (data use limitations)	N/A - no data use limitations The ambient monitoring data in EPA's Air Quality System (AQS) are public domain. You are welcome to download the data and use freely, without submitting a request. [1]	N/A	[1] <u>https://www.epa.gov/outdoor-air-</u> <u>quality-data/do-i-need-request-permission-</u> <u>use-monitoring-data-and-graphics-airdata</u>			
5.2.7	Other (specify)	Does not authorize/specify	Does not authorize/specify				
6	PII Elements						
6.1	PII elements collected	Address Address where the monitoring site is located. City Name of the city, town, village or other municipality in which the site is located. Blank if the site is not located within	Address, city, county, state, and EPA Region are available for each monitor.	[1] <u>https://www.epa.gov/outdoor-air-quality-data/about-air-data-</u> reports#aqidaily			
		such a jurisdiction, or if no value was provided. County Name of the county (or equivalent jurisdiction) in which a site is located. State Postal abbreviation for the state or territory in which a site is located. EPA Region					
		EPA Region number in which the site is located. There are ten EPA regions. [1]					

Dataset 11 -	EPA Daily Air Quality Data			
		Raw Language	Interpretation	Source
6.2	PII elements holder (i.e., party that holds the PII)	Address Address where the monitoring site is located.	AQS holds the location data.	[1] https://www.epa.gov/outdoor-air- quality-data/about-air-data- reports#aqidaily
		City Name of the city, town, village or other municipality in which the site is located. Blank if the site is not located within such a jurisdiction, or if no value was provided.		
		County Name of the county (or equivalent jurisdiction) in which a site is located.		
		State Postal abbreviation for the state or territory in which a site is located.		
		EPA Region EPA Region number in which the site is located. There are ten EPA regions. [1]		
6.3	Use of common data model, if any, for data collection	Information not available/found	Information not available/found	Information not available/found
7	Prior Data Linkages			
7.1	Dataset linked with other datasets			
7.1.1	Name of other dataset linked to this dataset	Information not available/found	Information not available/found	
7.1.2	Other dataset type (clinical, EHR, survey, claims, SDOH, etc.)	Information not available/found	Information not available/found	
7.1.3	Other dataset source(s)	Information not available/found	Information not available/found	
7.1.4	Linking methodology (PPRL or non-PPRL); linkage technology	Information not available/found	Information not available/found	
7.1.5	PII elements used for the linkage	Information not available/found	Information not available/found	
7.1.6	Entity resolver (data originator or data linker or third party)	r Information not available/found	Information not available/found	
7.1.7	Party performing the linkages	Information not available/found	Information not available/found	
7.1.8	Linkage quality assessment	Information not available/found	Information not available/found	
7.1.9	Linked data sharing method (linkage maps or pre-linked dataset)	Information not available/found	Information not available/found	