DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

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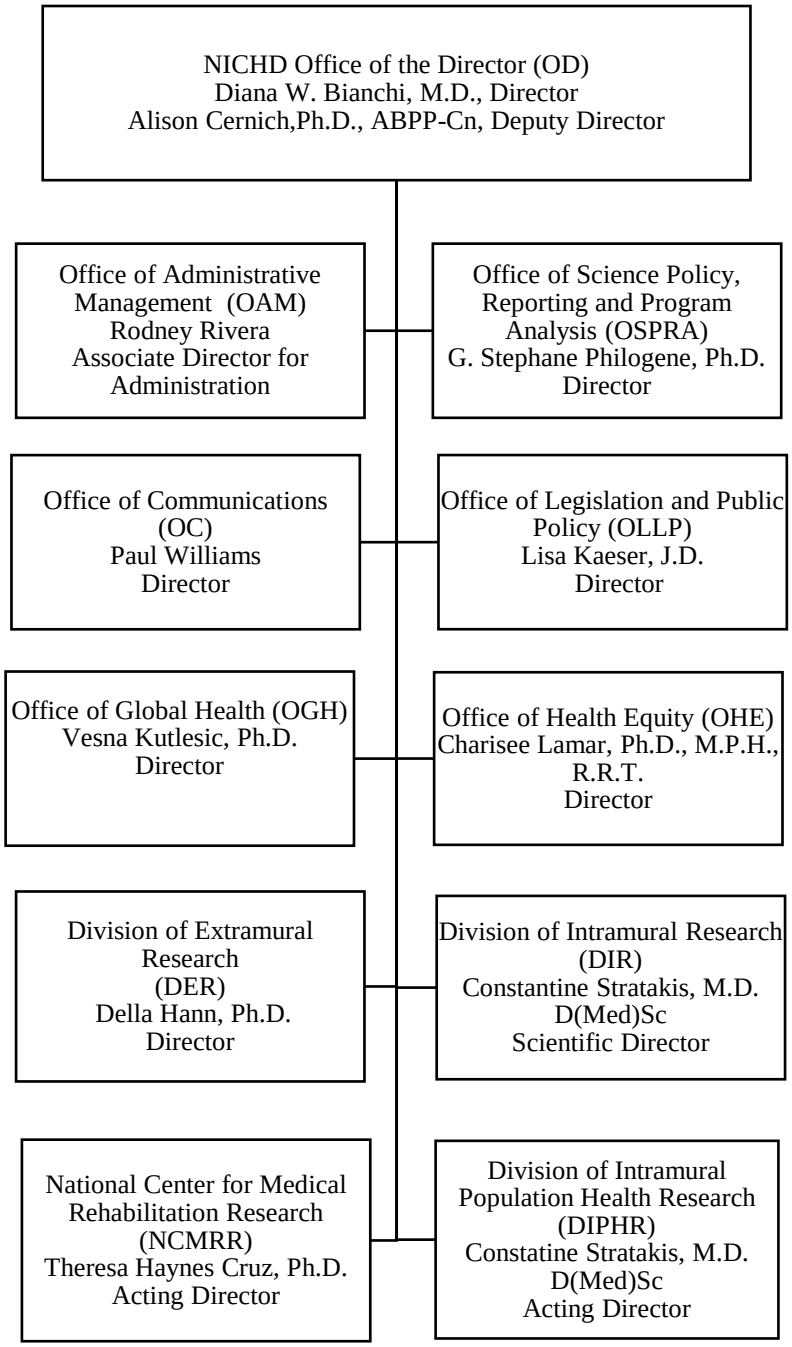
National Institute of Child Health and Human Development



NATIONAL INSTITUTES OF HEALTH

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

For carrying out section 301 and title IV of the PHS Act with respect to child health and human development, [$1,556,879,000]*$1,416,366,000*.

NATIONAL INSTITUTES OF HEALTH
National Institute of Child Health and Human Development

Amounts Available for Obligation[1]
(Dollars in Thousands)

Source of Funding	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
Appropriation	$1,506,458	$1,556,879	$1,416,366
Mandatory Appropriation: (non-add)			
Type 1 Diabetes	*(0)*	*(0)*	*(0)*
Other Mandatory financing	*(0)*	*(0)*	*(0)*
Rescission	0	0	0
Sequestration	0	0	0
Secretary's Transfer	-5,175	0	0
Subtotal, adjusted appropriation	$1,501,283	$1,556,879	$1,416,366
OAR HIV/AIDS Transfers	-32	30	0
HEAL Transfer from NINDS	0	0	0
Subtotal, adjusted budget authority	$1,501,251	$1,556,909	$1,416,366
Unobligated balance, start of year[2]	7,501	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	$1,508,752	$1,556,909	$1,416,366
Unobligated balance lapsing	-149	0	0
Total obligations	$1,508,603	$1,556,909	$1,416,366

[1] Excludes the following amounts (in thousands) for reimbursable activities carried out by this account:
FY 2019 - $29,958 FY 2020 - $33,000 FY 2021 - $30,100

[2] Reflects HEAL Initiative funding not obligated in FY 2018 and carried over into FY 2019.

NATIONAL INSTITUTES OF HEALTH
National Institute of Child Health and Human Development

Budget Mechanism - Total[1]
(Dollars in Thousands)

MECHANISM	FY 2019 Final		FY 2020 Enacted		FY 2021 President's Budget		FY 2021 +/- FY 2020 Enacted	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	1,240	$608,662	1,325	$651,669	1,336	$596,525	11	-$55,144
Administrative Supplements	*(41)*	5,258	*(50)*	8,970	*(40)*	5,000	*(-10)*	-3,970
Competing:								
Renewal	41	22,997	41	22,766	36	18,438	-5	-4,328
New	492	181,974	487	180,145	423	145,898	-64	-34,247
Supplements	3	1,221	3	1,209	3	979	0	-230
Subtotal, Competing	536	$206,192	531	$204,119	462	$165,315	-69	-$38,804
Subtotal, RPGs	1,776	$820,112	1,856	$864,758	1,798	$766,840	-58	-$97,918
SBIR/STTR	95	43,943	98	45,324	88	40,744	-10	-4,580
Research Project Grants	1,871	$864,054	1,954	$910,082	1,886	$807,584	-68	-$102,498
Research Centers:								
Specialized/Comprehensive	50	$68,280	52	$68,198	50	$62,427	-2	-$5,771
Clinical Research	0	0	0	0	0	0	0	0
Biotechnology	4	4,977	4	4,933	4	4,728	0	-205
Comparative Medicine	0	513	0	313	0	291	0	-22
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Research Centers	54	$73,770	56	$73,444	54	$67,446	-2	-$5,998
Other Research:								
Research Careers	226	$40,065	238	$42,582	213	$41,923	-25	-$659
Cancer Education	0	0	0	0	0	0	0	0
Cooperative Clinical Research	56	29,187	56	28,461	33	13,736	-23	-14,725
Biomedical Research Support	0	0	0	0	0	0	0	0
Minority Biomedical Research Support	0	0	0	0	0	0	0	0
Other	133	42,609	135	40,483	162	41,073	27	590
Other Research	415	$111,861	429	$111,526	408	$96,732	-21	-$14,794
Total Research Grants	2,340	$1,049,685	2,439	$1,095,052	2,348	$971,762	-91	-$123,290
Ruth L Kirchstein Training Awards:	FTTPs		FTTPs		FTTPs		FTTPs	
Individual Awards	217	$10,579	256	$12,693	246	$12,172	-10	-$521
Institutional Awards	416	23,332	415	23,755	404	23,108	-11	-647
Total Research Training	633	$33,911	671	$36,448	650	$35,280	-21	-$1,168
Research & Develop. Contracts	116	$135,608	107	$136,000	109	$136,000	2	$0
(SBIR/STTR) (non-add)	*(3)*	*(476)*	*(3)*	*(490)*	*(3)*	*(465)*	*(0)*	*(-25)*
Intramural Research	307	207,756	321	212,914	321	197,154	0	-15,760
Res. Management & Support	218	74,291	240	76,495	240	76,170	0	-325
Res. Management & Support (SBIR Admin) (non-add)	*(0)*	*(305)*	*(0)*	*(350)*	*(0)*	*(333)*	*(0)*	*(-17)*
Construction		0		0		0		0
Buildings and Facilities		0		0		0		0
Total, NICHD	525	$1,501,251	561	$1,556,909	561	$1,416,366	0	-$140,543

[1] All items in italics and brackets are non-add entries.

Major Changes in the Fiscal Year 2021 President's Budget Request

Major changes by budget mechanism and/or budget activity detail are briefly described below. Note that there may be overlap between budget mechanisms and activity detail and these highlights will not sum to the total change for the FY 2021 President's Budget for NICHD, which is a reduction of 9.0 percent below the FY 2020 Enacted level, for a total of $1,416.4 million. The FY 2021 President's Budget reflects the Administration's fiscal policy goals for the Federal Government. Within that framework, NICHD will pursue its highest research priorities through strategic investments and careful stewardship of appropriated funds.

Research Project Grants (RPGs) (-$102.5 million, total $807.6 million):
NICHD will support a total of 1,798 Research Project Grant (RPG) awards in FY 2021, excluding SBIR/STTR awards. Non-competing RPGs will increase by 11 awards to an estimated level of 1,336 awards, while the amount to support the costs associated with the commitments of these prior year competing awards will decrease by $55.1 million compared to the FY 2020 Enacted level. Competing RPGs will decrease by 58 grants compared to the FY 2020 Enacted level of 531 awards, and the amount to support the costs associated with new competing awards will decrease by $38.8 million compared to the FY 2020 Enacted level. In addition, awards under the Small Business Research programs will decrease by 10 awards and $4.6 million compared to the FY 2020 Enacted level.

Research Centers (-$6.0 million, total $67.4 million):
NICHD will support a total of 54 Research Centers awards in FY 2021, two less than the FY 2020 Enacted level.

Other Research (-$14.8 million, total $96.7 million):
NICHD will support a total of 408 awards in the Other Research areas in FY 2021, a decrease of 21 awards compared with the FY 2020 Enacted level of 429 awards. NICHD will continue to support Career awards within these funding amounts.

Intramural Research (-$15.8 million, total $197.2 million):
NICHD will reduce support for the Intramural Research program by $15.8 million compared to the FY 2020 Enacted level, while still maintaining support for research and innovation at the Clinical Center.

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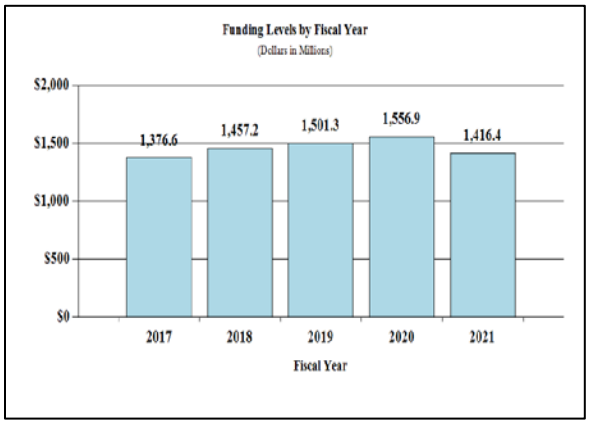
Summary of Changes
(Dollars in Thousands)

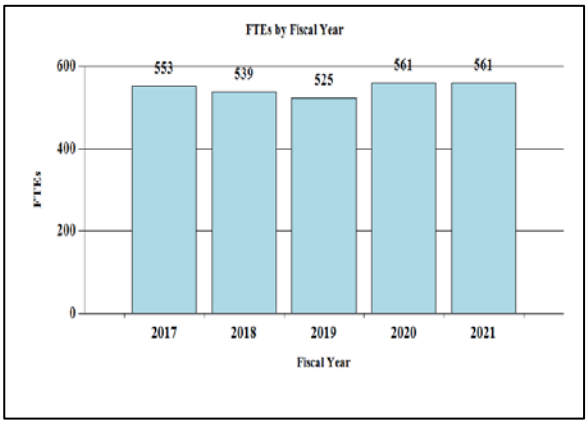
FY 2020 Enacted	$1,556,909
FY 2021 President's Budget	$1,416,366
Net change	-$140,543

CHANGES	FY 2021 President's Budget		Change from FY 2020 Enacted	
	FTEs	Budget Authority	FTEs	Budget Authority
A. Built-in:				
1. Intramural Research:				
a. Annualization of January 2020 pay increase & benefits		$73,375		$471
b. January FY 2021 pay increase & benefits		73,375		1,071
c. Paid days adjustment		73,375		-270
d. Differences attributable to change in FTE		73,375		0
e. Payment for centrally furnished services		35,221		0
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		88,559		95
Subtotal				$1,367
2. Research Management and Support:				
a. Annualization of January 2020 pay increase & benefits		$40,693		$254
b. January FY 2021 pay increase & benefits		40,693		605
c. Paid days adjustment		40,693		-148
d. Differences attributable to change in FTE		40,693		0
e. Payment for centrally furnished services		963		-51
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		34,514		-273
Subtotal				$388
Subtotal, Built-in				$1,755

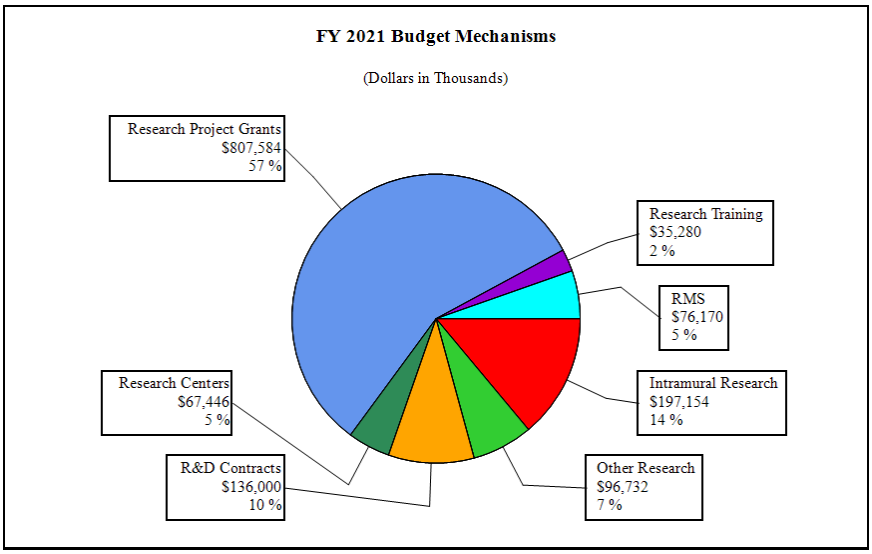
CHANGES	FY 2021 President's Budget		Change from FY 2020 Enacted	
	No.	Amount	No.	Amount
B. Program:				
1. Research Project Grants:				
a. Noncompeting	1,336	$601,525	11	-$59,114
b. Competing	462	165,315	-69	-38,804
c. SBIR/STTR	88	40,744	-10	-4,580
Subtotal, RPGs	1,886	$807,584	-68	-$102,498
2. Research Centers	54	$67,446	-2	-$5,998
3. Other Research	408	96,732	-21	-14,794
4. Research Training	650	35,280	-21	-1,168
5. Research and development contracts	109	136,000	2	0
Subtotal, Extramural		$1,143,042		-$124,458
	FTEs		FTEs	
6. Intramural Research	321	$197,154	0	-$17,127
7. Research Management and Support	240	76,170	0	-713
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, Program	561	$1,416,366	0	-$142,298
Total changes				-$140,543

History of Budget Authority and FTEs:

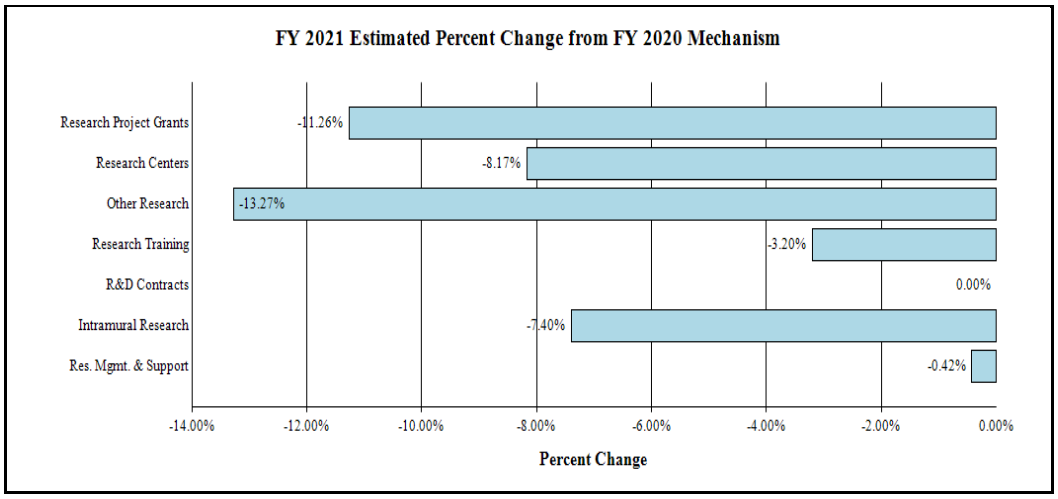




Distribution by Mechanism:



Change by Selected Mechanisms:



NATIONAL INSTITUTES OF HEALTH
National Institute of Child Health and Human Development

Budget Authority by Activity[1]
(Dollars in Thousands)

	FY 2019 Final		FY 2020 Enacted		FY 2021 President's Budget		FY 2021 +/- FY2020	
Extramural Research	**FTE**	**Amount**	**FTE**	**Amount**	**FTE**	**Amount**	**FTE**	**Amount**
Detail	-	-	-	-	-	-	-	-
	-	-	-	-	-	-	-	-
Reproductive Health, Pregnancy, and Perinatology	-	$370,513	-	$385,200	-	$347,377	-	-$37,823
Child Health	-	369,201	-	383,836	-	346,147	-	-37,690
Intellectual and Developmental Disabilities	-	134,722	-	140,063	-	126,310	-	-13,753
Demography and Behavior	-	258,236	-	268,472	-	242,110	-	-26,362
Rehabilitation	-	86,531	-	89,928	-	81,098	-	-8,830
Subtotal, Extramural	-	**$1,219,204**	-	**$1,267,500**	-	**$1,143,042**	-	**-$124,458**
Intramural Research	**307**	**$207,756**	**321**	**$212,914**	**321**	**$197,154**	**0**	**-$15,760**
Research Management & Support	**218**	**$74,291**	**240**	**$76,495**	**240**	**$76,170**	**0**	**-$325**
TOTAL	**525**	**$1,501,251**	**561**	**$1,556,909**	**561**	**$1,416,366**	**0**	**-$140,543**

[1].Includes FTEs whose payroll obligations are supported by the NIH Common Fund.

NATIONAL INSTITUTES OF HEALTH
National Institute of Child Health and Human Development

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2020 Amount Authorized	FY 2020 Enacted	2021 Amount Authorized	FY 2021 President's Budget
Research and Investigation	Section 301	42§241	Indefinite	$1,556,909,000	Indefinite	$1,416,366,000
National Institute of Child Health and Human Development	Section 401(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority				$1,556,909,000		$1,416,366,000

NATIONAL INSTITUTES OF HEALTH
National Institute of Child Health and Human Development

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2012	$1,352,189,000	$1,352,189,000	$1,303,016,000	$1,323,900,000
Rescission				$2,502,171
2013	$1,320,600,000		$1,324,603,000	$1,321,397,829
Rescission				$2,642,796
Sequestration				($66,325,085)
2014	$1,339,360,000		$1,330,459,000	$1,282,595,000
Rescission				$0
2015	$1,283,487,000			$1,286,571,000
Rescission				$0
2016	$1,318,061,000	$1,305,586,000	$1,345,355,000	$1,339,802,000
Rescission				$0
2017[1]	$1,338,348,000	$1,373,408,000	$1,395,811,000	$1,380,295,000
Rescission				$0
2018	$1,032,029,000	$1,401,727,000	$1,426,092,000	$1,452,006,000
Rescission				$0
2019	$1,339,592,000	$1,469,346,000	$1,507,251,000	$1,506,458,000
Rescission				$0
2020	$1,296,732,000	$1,580,084,000	$1,587,278,000	$1,556,879,000
Rescission				$0
2021	$1,416,366,000			

[1] Budget Estimate to Congress includes mandatory financing.

Justification of Budget Request

Eunice Kennedy Shriver National Institute of Child Health and Human Development

Authorizing Legislation: Section 301 and Title IV of the Public Health Service Act, as amended.

Budget Authority (BA):

	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 + / - FY 2020
BA	$1,501,251,000	$1,556,909,000	$1,416,366,000	-$140,543,000
FTE	525	561	561	0

Program funds are allocated as follows: Competitive Grants/Cooperative Agreements; Contracts; Direct Federal/Intramural and Other.

Director's Overview

For over five decades, the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) has been a global leader in biomedical and behavioral health research for women, children, and people with disabilities. The NICHD mission is to "*lead research and training to understand human development, improve reproductive health, enhance the lives of children and adolescents, and optimize abilities for all*." Through these efforts, the institute hopes to fulfill its vision of "*Healthy pregnancies. Healthy children. Healthy and optimal lives*."

In 2019, NICHD, in partnership with its many stakeholders, developed a new Strategic Plan to guide the institute's activities over the next five years. The strategic plan outlines key scientific and public health priorities to advance research, enhance scientific stewardship, and support innovation in management and accountability. The strategic plan presents the institute's scientific research goals and objectives under five broad research themes:

1. Understanding the Molecular, Cellular, and Structural Basis of Development
2. Promoting Gynecologic, Andrologic, and Reproductive Health
3. Setting the Foundation for Healthy Pregnancies and Lifelong Wellness
4. Improving Child and Adolescent Health and the Transition to Adulthood
5. Advancing Safe and Effective Therapeutics and Devices for Pregnant and Lactating Women, Children, and People with Disabilities

To support the institute's success, the plan integrates and emphasizes cross cutting priorities including health disparities, prevention, infectious diseases, nutrition, and global health.

Human development is a complex process. Although understanding of that process has dramatically improved over the last few decades, a great deal remains to be learned about the cellular and structural basis of development and about how to apply that knowledge to clinical practice. In the not-too-distant past, human embryonic development was commonly referred to as a "black box." Today, 'omics and other technologies create unprecedented opportunities for progress in the science of normative and atypical human development. Scientists are now poised to map gene regulatory networks that govern development; better profile single cell types as they

differentiate and mature; and describe epigenetic processes. NICHD has prioritized efforts to identify new and optimally timed interventions to prevent and treat structural birth defects and neurodevelopmental disorders, and to optimize health and function for individuals with intellectual and developmental disabilities.

Gynecologic conditions cause considerable pain and suffering for millions of American women. Capitalizing on investments in integrated genetic, genomic, and phenotypic data, scientists are now poised to uncover the mechanisms of common conditions that affect gynecologic and andrologic health. Many couples experience infertility without ever identifying a specific cause, and undergo intensive, costly interventions without success. Large-scale data at the individual, community, and population levels are available to help identify biologic, social, and environmental factors that can lead to female and male infertility and/or early pregnancy loss. Additionally, advances in developmental sciences will improve our understanding of the timing of puberty and its effects on reproductive health.

Two women die each day (total=700/year) in the US as a result of pregnancy-related complications. Many of these deaths are preventable. Sizeable racial disparities exist, with black women almost four times more likely to die from pregnancy-related complications than white women. American Indian and Alaska native women also have increased rates of mortality due to pregnancy and childbirth.[1] Moreover, the preterm birth rate remains unacceptably high. Over the next five years, NICHD will accelerate research to improve pregnancy outcomes to maximize the lifelong health of women and their children. To reduce maternal morbidity and mortality, the institute is hastening the development of targeted strategies to prevent placental complications, preeclampsia, thromboembolism, postpartum hemorrhage, and other serious conditions. Considerable efforts are also on the way to characterize the mechanisms of the human gestational clock and the potential causes of preterm birth, and to improve the survival and long-term health of infants born preterm or with low birthweight.

Childhood and adolescence involve rapid and transformative changes in physical, emotional, and behavioral health. Current understanding of child and adolescent health has been based largely on data collected many years ago from non-diverse samples of children. Research on adolescent health has often focused on a limited number of high-risk behaviors. The impact of exposure to digital media and the effects of physical and psychological trauma demand further study. Risk-reduction strategies to improve child health in the United States and globally are now available for rigorous testing. Large-scale data and artificial intelligence offer opportunities to improve assessment of the impact of social and environmental factors and to improve prevention strategies. For children and adolescents with critical illness or disabilities, technologies such as 3-D printing of individualized devices can open up opportunities for personalized treatment and rehabilitation. Both typically-developing adolescents and those with disabilities will benefit from research focused on the transition from adolescence to adult medical care.

Every day, pregnant women and lactating women and their clinicians are forced to make decisions about whether to treat their own medical conditions such as epilepsy, hypertension, asthma, mastitis, and hyperemesis without adequate scientific knowledge of the safety and efficacy of medications in the developing fetus or newborn. Historically, highly publicized cases

[1] https://www.cdc.gov/reproductivehealth/maternal-mortality/index.html.

of prescription drug use by pregnant women that ended with tragic results, such as thalidomide and diethylstilbestrol, have led to the exclusion of pregnant women from most pharmacological research. However, the dynamic physiologic changes that occur during pregnancy and lactation affect drug levels and action in the body, and both medication and disease that is left untreated can negatively affect a fetus. Today, clinicians, researchers and policymakers recognize that inclusion of pregnant women and lactating women in clinical research is essential. Pregnant women can be protected *through* research instead of *from* research. Opportunities to accelerate progress are available, as advances in pharmacogenomics and bioinformatics now make it possible to improve understanding of how pharmaceuticals may act differently in different individuals. Over the next five years, NICHD will support foundational research in pharmacokinetics, pharmacodynamics, pharmacogenomics, dosing, and formulation. Large-scale datasets will be used to help scientists measure response to therapy, and NICHD will lead efforts to develop and evaluate new and existing therapeutics and devices specifically to meet the unique needs of pregnant and lactating women, children, and people with intellectual and physical disabilities.

Overall Budget Policy: The FY 2021 President's Budget request for NICHD is $1,416.4 million, a decrease of $140.5 million or 9.0 percent below the FY 2020 Enacted level.

Program Descriptions and Accomplishments

Reproductive Health, Pregnancy, and Perinatology: The program in reproductive health, pregnancy, and perinatology supports basic, clinical, and translational research on gynecologic and andrologic disorders; contraception; fertility and infertility; pregnancy; and newborn care. NICHD manages a broad research portfolio to understand, treat, and prevent common, painful, and costly gynecologic health conditions, including uterine fibroids, chronic pelvic pain, pelvic floor disorders, and endometriosis. For example, researchers looking at the potential role of the microbiome in endometriosis tested a broad-spectrum antibiotic (metronidazole) in a mouse model. The scientists found that this medication greatly limited the early growth and progression of endometrial lesions.[2] Their discovery could lead to better treatment of this common, but often misdiagnosed gynecological disorder.

Millions of couples across the United States have difficulty conceiving and establishing a healthy pregnancy, yet only limited information is available to understand the causes of infertility, minimize risk factors, and improve treatment options. Current infertility treatments are often expensive and invasive, and new methods are needed to preserve or restore fertility. A recent "proof of concept" experiment demonstrated a novel technique with potential for restoring fertility in male childhood cancer survivors. Using rhesus macaques, the researchers froze immature testicular tissue from animals too young to produce sperm. Then, as the animals approached puberty, the researchers defrosted and implanted tissue samples in them. Sperm

[2] Chadchan SB, Cheng M, Parnell LA, Yin Y, Schriefer A, Mysorekar IU, Kommagani R. Antibiotic therapy with metronidazole reduces endometriosis disease progression in mice: a potential role for gut microbiota. Human Reproduction 2019 Jun 4;34(6):1106-1116.

from the treated animals was then used to establish a successful IVF pregnancy in a female macaque, which resulted in a live birth.[3]

NICHD-supported pregnancy-related research spans preconception care, pregnancy, fetal growth, labor and delivery, and maternal and neonatal health. New discoveries can now help women and their clinicians make more informed choices. A recent study of low-dose aspirin, already recommended on the basis of scientific evidence to reduce the risk of preeclampsia, has found that pregnant women who are obese may need adjustments in the standard aspirin dosing for the medication to be effective.[4] Another study of pregnant women with multiple sclerosis (MS) found that risks of poor birth outcomes and pregnancy complications were similar whether women continued their MS medication in early pregnancy or went without it.[5]

Perinatal research supported by NICHD continues to yield important advances, including early detection of and protection against disorders that threaten the survival and development of newborns. About 15 percent of deaths among newborns admitted to intensive care are attributed to genetic disorders. Many of these conditions progress rapidly, although timely diagnosis is critical for informed treatment decisions. Seeking a better option than the time-consuming, standard procedures for genome sequencing, researchers deployed an artificial intelligence (AI) program to match results of automated genome sequencing with patient record data. The accuracy and rapidity of the AI-assisted approach means that diagnosis and management of rare genetic disorders can be accomplished within a day.[6] In another promising advance, researchers were able to reduce fetal death rates and prevent the birth defects caused by Zika infection during pregnancy, by injecting an inflammation-reducing drug into the placenta of infected pregnant experimental mice. Fewer mice died in the treatment group compared with untreated animals, and surviving offspring of the treated mice were free of the birth defects seen in the untreated mice.[7]

Budget Policy: The budget request for this program is $347.4 million, a decrease of $37.8 million or 9.8 percent compared with the FY 2020 Enacted level. Addressing maternal morbidity and mortality will remain a very high priority for this program. The program also aims to prioritize pharmacological studies to improve the evidence base for treatment of pregnant women, research on the effects of opioids on pregnant women and newborns, and support for endometriosis research.

[3] Fayomi AP, Peters K, Sukhwani M, Valli-Pulaski H, Shetty G, Meistrich ML, Houser L, Robertson N, Roberts V, Ramsey C, Hanna C, Hennebold JD, Dobrinski I, Orwig KE. Autologous grafting of cryopreserved prepubertal rhesus testis produces sperm and offspring. Science. 2019 Mar 22;363(6433):1314-1319.
[4] Finneran MM, Gonzalez-Brown V, Smith DD et al. Obesity and laboratory aspirin resistance in high-risk pregnant women treated with low-dose aspirin. American Journal of Obstetrics and Gynecology 2019 Apr;220(4):385.e1-385.e6.
[5] MacDonald SC, McElrath TF, Hernández-Díaz S. Use and Safety of Disease-Modifying Therapy in Pregnant Women with Multiple Sclerosis. Pharmacoepidemiology and Drug Safety, 2019, 28(4), 556–560.
[6] Clark, MM et al. Diagnosis of genetic diseases in seriously ill children by rapid whole-genome sequencing and automated phenotyping and interpretation. Science Translational Medicine, 2019 11(489).
[7] Lei, J, et al. IL-1 receptor antagonist therapy mitigates placental dysfunction and perinatal injury following Zika virus infection. Journal of Clinical Investigation Insight, 2019 4(7) pii: 122678.

Program Portrait: Endometriosis

Endometriosis is a leading cause of chronic pelvic pain and infertility in reproductive-aged women. In women with endometriosis, some of the endometrial tissue abnormally grows outside of the uterus, causing inflammation, painful menstruation, and infertility. Endometriosis affects about 10 percent of reproductive-aged women, yet many cases go undetected for years, and its genetic, molecular, or environmental causes are not well understood. Current treatments include pain medications, surgery, or hormone treatment, but these remedies are complex, can have long-term side effects, and have limited effectiveness for many women. Limited progress has been made towards early, non-invasive detection or personalized treatment.

NICHD is expanding basic, clinical, and translational research to understand the mechanisms of endometriosis, identify early diagnostic markers, and develop new treatment methods. Scientists are studying genetic and non-genetic DNA modifications and remodeling, inflammation and immune responses, hormone signaling, environmental influences, and cell signaling components that can cause endometriosis. Other research efforts look to identify and validate factors that can be used as biomarkers for detection in blood, or modified as targets for treatment. One research group has identified 10 miRNAs (which are small RNA molecules that help control gene expression) that are significantly changed in endometriosis. A multi-center study is underway to determine which miRNAs are ideal biomarkers for non-invasively diagnosing mild, moderate, or severe endometriosis. Another longitudinal study will examine pain characteristics and changes in inflammation, oxidative stress, and central pain sensitization to be used together as biomarkers to distinguish endometriosis cases among over 1,500 women and adolescents that have been followed up to 6 years. To address infertility, clinical trials in four universities across the United States are using a promising hormone blocking pretreatment prior to in vitro fertilization to improve live birth rates in women with endometriosis, also using miRNA biomarkers as a screening tool.

Program Portrait: HHS Task Force on Medications for Pregnant Women and Lactating Women

Pregnant women and lactating women have long been known to be "drug orphans," because they and their clinicians must decide about medicating maternal illnesses -- from hypertensive or seizure disorders to diabetes, asthma, or severe vomiting in pregnancy -- with little or no solid scientific evidence to support such decisions. Some studies have found that among the approximately 6 million women in the United States who are pregnant each year, over 90 percent use at least one medication during pregnancy and a sizeable minority take multiple medications, without evidence-based data to assess the medicines' safety, efficacy, dosing, or outcomes for women or their offspring. For the estimated 80 percent of new mothers in the United States who breastfeed, scientific evidence on their use or effects of medication is almost wholly lacking.[8]

Recognizing this urgent public health need, Congress directed the Secretary of the Department of Health and Human Services to establish a "Task Force on Research Specific to Pregnant Women and Lactating Women" (PRGLAC) as part of the 21st Century Cures Act (P.L. 114-255). The Task Force, led by NICHD on behalf of NIH, includes members from other NIH Institutes and Centers, the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the HHS Office of Women's Health, representatives of professional and patient organizations, the industry, and other stakeholders. The Task Force reported its findings on the extensive shortfalls in research, with 15 recommendations, to the Secretary and Congress in September 2018. Recommendations addressed inclusion of pregnant women and lactating women in the clinical research agenda, increases in research both for therapeutic products already in use by pregnant women and lactating women, and for discovery

[8] https://www.nichd.nih.gov/sites/default/files/2018-09/PRGLAC_Report.pdf.

and development of new therapeutic products for these populations. Other recommendations included expanding the work force of clinicians and investigators with expertise in obstetric and lactation pharmacology and therapeutics, removing regulatory barriers to research with pregnant women, and improving public awareness and clinician information regarding research with pregnant women and lactating women.[9] As authorized by the Secretary, an extension or "Phase II" of the Task Force began in March 2019, with a new charge to a develop a plan to implement the PRGLAC recommendations. NICHD Director Diana W. Bianchi chairs this phase of PRGLAC. Four Task Force work groups (Research/Training, Regulatory, Communication, Discovery) are working to develop a full implementation plan to bring the Task Force recommendations to fruition.

Child Health: Child health research spans health promotion and prevention of disease; behavioral and social science research; normative physical, cognitive, and socio-emotional development; translational research from bench to bedside; and clinical research in pediatric and adolescent medicine. Behavioral pediatric studies are essential to inform health policy. Almost one-third of children and adolescents nationwide are overweight or obese.[10] Researchers have been testing strategies to help children maintain a healthy weight into adulthood. A computer modeling study suggested that common recommendations from hospitals and infant formula manufacturers for introducing solid foods to infants could raise the risk of overfeeding or underfeeding.[11] In another study, using data from over 4,500 children ages 8 to 11 years old, researchers determined that children who slept the recommended 9 to 11 hours, viewed less than 2 hours of screen time, and completed 1 hour of physical activity each day had higher cognitive scores than children who met none of these recommendations.[12]

Researchers continue to use and expand the transformational genomic sequencing data developed under the NIH Common Fund's Gabriella Miller Kids First Pediatric Research Program,[13] which has a major focus on structural birth defects. The program has launched a centralized database of clinical and genetic sequence data from patients with childhood cancer or structural birth defects, as well as their families. Data sets from children with some cancers, adolescent idiopathic scoliosis, congenital heart disease, orofacial clefts, disorders of sex development, and congenital diaphragmatic hernia are now available to researchers worldwide. The resource will enable researchers to perform data mining across diverse disorders, and to understand shared developmental pathways.

Determining safe and effective drug dosing for sick children requires specialized research to ensure that medications are safe and effective specifically for children's growing bodies and changing metabolism. However, this type of research presents complex challenges because multiple factors -- including a child's condition, weight, and physiological maturity -- affect how the body processes the drug. Milrinone is a powerful drug that treats the sudden worsening of cardiac failure in adults, but the drug has not been formally approved by the FDA for patients

[9] https://www.nichd.nih.gov/sites/default/files/2018-09/PRGLAC_Report.pdf.
[10] https://www.cdc.gov/obesity/childhood/index.html.
[11] Ferguson, M. The impact of following solid food feeding guides on GBMI among infants: A simulation study. American Journal of Preventative Medicine. July 2019. 57(3):355-364.
[12] Walsh JJ, Barnes JD, Cameron JD, Goldfield GS, Chaput JP, Gunnell KE, Ledoux AA, Zemek RL, Tremblay MS. Associations between 24 hour movement behaviours and global cognition in US children: a cross-sectional observational study. Lancet Child and Adolescent Health. 2018 Nov;2(11):783-791.
[13] https://commonfund.nih.gov/kidsfirst/overview.

under 18 years of age. Researchers developed a statistically-based model for pediatric dosing of milrinone that can be used in patients from newborns to age 18, allowing physicians to recommend a tailored dosing regimen for infants and small children.[14] Accounting for variations in how the drug affects children at different developmental stages, researchers have produced data on appropriate intravenous and oral dosing for drugs that are commonly used to treat a range of conditions in children. For example, based on an NICHD-supported study on the safety and efficacy of the drug acyclovir, the FDA changed the label on acyclovir to include dosing instructions for neonates and infants.[15]

For children affected by trauma or critical illness, evidence-based emergency and critical care can be lifesaving. For example, in cases of appendicitis, the appendix can swell and cause serious complications if not treated quickly. Diagnosing appendicitis requires imaging tests that use radiation, but too much radiation exposure can harm the body. NICHD's Collaborative Pediatric Critical Care Research Network aims to improve care for infants, children, and adolescents with life-threatening, often complex conditions that typically require technology-intensive interventions. Researchers supported by NICHD developed and validated a new tool to gauge children's risk of appendicitis, which was found to be more effective than the current most widely used risk assessment method.[16]

Budget Policy: The budget request for this program is $346.12 million, a decrease of $37.7 million or 9.8 percent compared with the FY 2020 Enacted level. As described in NICHD's strategic plan, high priority areas for this program include studies on the transition from adolescence to adulthood, rigorous research to explore the impact of electronic media use in childhood, pediatric pharmacology research, and basic science research in development from the earliest stages through childhood.

Intellectual and Developmental Disabilities: Intellectual and developmental disabilities (IDDs) were once thought to be permanent and untreatable, but new basic science discoveries have challenged this belief, inspiring renewed efforts to improve the lives of individuals with IDDs. NICHD's program on IDDs supports research and research training aimed at preventing and ameliorating common and rare neurodevelopmental and neuromuscular disorders, such as Down syndrome, Fragile X syndrome (FXS), Rett syndrome, and muscular dystrophy; inborn errors of metabolism; autism spectrum disorders; congenital conditions currently or potentially detectable through newborn screening; and IDDs that have no identified cause or are not associated with a specific syndrome.

The *Eunice Kennedy Shriver* Intellectual and Developmental Disabilities Research Centers (IDDRCs) employ advanced technologies to support a broad range of research projects. For example, one IDDRC project focuses on Rett syndrome, a severely disabling brain disorder that

[14] Hornik CP, Yogev R, Mourani PM et al. for BPCA-PTN Steering Committee. Population pharmacokinetics of milrinone in infants, children, and adolescents. Journal of Clinical Pharmacology 2019 Jul 17. doi: 10.1002/jcph.1499.
[15] https://www.nichd.nih.gov/newsroom/news/020819-acyclovir.
[16] Kharbanda AB, Vazquez-Benitez G, Ballard DW, Vinson DR, Chettipally UK, Kene MV, et al. "Development and Validation of a Novel Pediatric Appendicitis Risk Calculator (pARC)." Pediatrics, 2018, 141(4), pii: e20172699.

occurs more commonly in girls. Children with Rett syndrome often experience typical early growth and development until about 6 to 18 months of age, but then they regress and lose their ability to move, with reduced expressions and language. Therefore, standard tests that assess cognitive abilities in typically developing children are not useful for children with Rett syndrome. Researchers have developed a method that tracks eye movements to help assess how difficulties in focusing affect the development of children with Rett syndrome.[17]

Similarly, the Centers for Collaborative Research in Fragile X support research to improve the diagnosis and treatment of FXS by stimulating multidisciplinary research. FXS is a genetic condition that causes a range of issues, including learning disabilities, cognitive impairment, delayed speech and language, and sensory processing deficits. Researchers used a mouse model to measure electrical activity in the brain with electroencephalography (EEG), showing differences in mice with and without FXS and suggesting how early differences in brain activity may contribute to deficits in sensory processing.[18] In 2019, NICHD led the efforts to update the NIH's national research plan on Fragile X syndrome and associated disorders.[19]

Up to half of people with Fragile X syndrome also meet the criteria for autism spectrum disorder (ASD). NICHD supports a broad portfolio of research on ASD. NICHD's research includes studies on genetic and environmental risk factors. NICHD research also emphasizes comorbid conditions (such as gastrointestinal dysfunction and mental illness) and developing effective interventions. Individuals with ASD typically have difficulties in socializing because they struggle to recognize facial expressions and maintain eye contact, among other challenges. In a collaboration with the National Institute of Biomedical Imaging and Bioengineering (NIBIB) and private organizations, NICHD supported a study of an app that uses applied behavioral analysis and Google Glass technology to help encourage facial engagement and provide feedback to a child during social interactions.[20] Another key component of NICHD's portfolio is the NIH Autism Centers of Excellence (ACE) Program, supported by NICHD along with four other NIH Institutes.[21] One ACE center developed a video app that could potentially screen for ASDs at home, using automated methods to analyze children's behaviors and movements.[22]

One of the most common, yet least studied, symptoms of ASD is gastrointestinal distress. Researchers supported by NICHD have created a zebrafish model of ASD, and this model showed that a mutation of a particular gene associated with autism is also implicated in digestive issues.[23]

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[17] Rose SA, Wass S, Jankowski JJ. Impaired visual search in children with Rett Syndrome. Pediatric Neurology 2019 Mar;92:26-31.
[18] Wen TH, Lovelace JW, Ethel IM et al. Developmental changes in EEG phenotypes in a mouse model of Fragile X Syndrome. Neuroscience 2019;398:126-143.
[19] https://www.nichd.nih.gov/sites/default/files/2019-11/NIH_ResearchPlan_FMR1_2019.pdf.
[20] Voss C, Schwartz J, Daniels J et al. Effect of Wearable Digital Intervention for Improving Socialization in Children with Autism Spectrum Disorder. A Randomized Clinical Trial JAMA Pediatrics, 173(5):446-454.
[21] https://www.nichd.nih.gov/research/supported/ace.
[22] Egger HOL. Dawson G, Hashemi J et al. Automatic emotion and attention analysis of young children at home: a Research Kit autism feasibility study. Autism. 2019 Apr;23(3):619-628.
[23] James DM, Kozol RA, Kajiwara Y, Wahl AL, Storrs EC, Buxbaum JD, Klein M, Moshiree B, Dallman JE. Intestinal dysmotility in a zebrafish (Danio rerio) shank3a;shank3b mutant model of autism. Molecular Autism. 2019 Jan 31;10:3.

Budget Policy: The budget request for this program is $126.3 million, a decrease of $13.8 million or 9.8 percent compared with the FY 2020 Enacted level. Within the IDD program, NICHD plans to prioritize efforts to include individuals with disabilities in clinical research studies, as well as translational research to help develop therapies and treatments for IDDs and comorbid conditions.

Program Portrait: Down syndrome

Down syndrome is the most common genetic cause of mild to moderate intellectual disability and occurs in 1 out of every 700 babies born in the United States. This condition results from having an extra copy of chromosome 21 or an extra piece of that chromosome. Since its establishment, NICHD has led NIH's research on the causes, progression, treatment, and management of Down syndrome and associated conditions. NICHD's extensive Down syndrome portfolio includes basic and translational sciences research to understand how the underlying genetic changes lead to intellectual disability, ultimately providing an evidence base for prevention and treatment efforts. For example, NICHD-supported researchers are using brain imaging to study a group of infants with Down syndrome over a two-year period. The scientists will use these data to develop biomarkers that can be used to evaluate future therapies, based on characterization of early neurodevelopmental patterns.

Both children and adults with Down syndrome tend to be at elevated risk for comorbid conditions, including obesity, cardiovascular disease, and early-onset Alzheimer's disease. Advances in medicine have increased Down syndrome life expectancy over recent decades; however, mortality from diabetes and cardiovascular disease in people with Down syndrome remains high. In a recent study supported by NICHD, scientists measured body composition—body fat percentage, whole-body lean mass, whole-body fat mass, and visceral fat—along with glucose, insulin, lipoprotein particles, lipids, and inflammatory factors in adolescents with and without Down syndrome to understand how body composition in Down syndrome individuals relates to adiposity and cardiometabolic risk. Research on Alzheimer's disease in Down syndrome populations has increased scientists' understanding of both conditions. In a recent NICHD-supported study, researchers studied brain tissue from deceased individuals with Down syndrome, Alzheimer's disease, or both. They found that individuals with Down syndrome – whether they also had Alzheimer's or not -- were often affected by plaque buildup in the brain's arteries and by small bleeding episodes ("microbleeding") in the brain. These issues may cause dementia in people with Down syndrome, regardless of Alzheimer's disease, or they may worsen Alzheimer's-related dementia.

Demography and Behavior: The program in demography and behavior incorporates NICHD's strong portfolio on behavioral and social influences on health. A comparison of physician antibiotic prescribing practices showed that clinical guidelines for antibiotic prescribing – to prevent overuse of the medications – were the least likely to be followed in telemedicine care. A possible explanation, suggested by the researchers, was that without seeing a young patient in person, physicians may be less able to distinguish between bacterial infections, for which antibiotics may be appropriate, and viral illnesses.[24] Addressing another current public health issue, NICHD-supported researchers recently found that in teens, sleep characteristics such as insomnia mediated associations between depressive symptoms and various screen activities (such as web surfing, TV/movies, and gaming). The research suggested that developing

[24] KN Ray et al. Antibiotic Prescribing During Pediatric Direct-to-Consumer Telemedicine Visits. Pediatrics. 2019;143(5):e20182491.

interventions focused on improving adolescent sleep, together with regulation of screen activities, could help with depression.[25]

Understanding the effects of interventions to improve health of specific populations is a central component of NICHD's demographic and behavioral research. For example, one NICHD-funded study used economic modeling to calculate the impacts of California residents' prenatal participation in the Federal Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). They found that WIC benefits had prevented 7,575 preterm births in the state and produced cost-savings of about $349 million.[26] Another study found that school-based nutrition interventions, whether or not paired with exercise interventions, had lowered eight-graders' body mass indices (BMI – a standard measure of healthy or unhealthy weight) over a period of three years. No such change was found among students in schools with an exercise-only intervention.[27]

NICHD also supports behavioral research related to reproductive health. For example, NICHD-funded researchers assessed the impact of a change in one state's Medicaid policy, to include in a hospital delivery fee the cost of long-acting contraceptives (LARC) provided to women after they give birth but before hospital discharge. An expected benefit was that lengthening the interval between pregnancies, with LARC, would reduce the known adverse effects for newborns of short intervals between pregnancies. The evaluation also found increasing uptake of LARC among Medicaid beneficiaries over time, as well as reversal of a prior, upward trend in short-interval births among adolescents.[28]

Budget Policy: The budget request for this program is $242.1 million, a decrease of $26.4 million or 9.8 percent compared with the FY 2020 Enacted level. Within this program, priorities include efforts to take advantage of population-level data from electronic health records and other sources, improving data sharing, and supporting research designed to help address health disparities and improve health equity.

Rehabilitation: The NICHD's National Center for Medical Rehabilitation Research (NCMRR) fosters research and research training to enhance the health, independence, and quality of life of people with physical disabilities. With its leadership role in trans-NIH and broader medical rehabilitation research collaborations, NCMRR takes a collaborative approach to advance a broad range of research and research training, including efforts to understand the underlying biology of injury and disability and the body's own mechanisms of recovery and adaptation. Developed in 2016 with stakeholders across the NIH and other Federal agencies, as well as researchers, practitioners, and representatives of individuals with disabilities, the comprehensive

[25] X Li et al. Sleep mediates the association between adolescent screen time and depressive symptoms. Sleep Medicine 2019, 57, 51-60.
[26] Nianogo RA, Wang MC, Basurto-Davila R et al. Economic evaluation of California prenatal participation in the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) to prevent preterm birth. Preventive Medicine 2019 Jul;124:42-49.
[27] Ickovics JR, Duffany K O'C, Shebi FM et al. Implementing school-based policies to prevent obesity: Cluster randomized trial. American Journal of Preventive Medicine 2019 Jan;56(1):e1-e11.
[28] Steenland MW, Pace LE, Sinaiko AD, Cohen JL. Association between South Carolina Medicaid's change in payment for immediate postpartum long-acting reversible contraception and birth intervals. JAMA. 2019 Jun 3. doi: 10.1001/jama.2019.6854.

NIH Research Plan on Rehabilitation identifies six priority areas: rehabilitation across the lifespan; family and community; technology use and development; research design and methodology; translational science; and building research capacity and infrastructure.[29]

NCMRR places a special emphasis on translational research to create and refine real-world interventions that can help individuals with disabilities where they live and work. NCMRR has supported several small businesses that develop technologies to improve the lives of amputees. For example, scientists used the electrical signals generated by an amputee's remaining muscle to control prosthetic devices. Researchers have partially restored limb function to rats with spinal cord injury; the researchers used a rapid 3D printing technology to create scaffolds that precisely fit the injury site, which helped to reconnect regenerating nerve fibers.[30] The Medical Rehabilitation Research Resource (MR3) Network, supported by NICHD, NIBIB and the National Institute of Neurological Disorders and Stroke, builds research infrastructure in medical rehabilitation by providing researchers with access to expertise, technologies, and collaborative opportunities from other disciplines, such as neuroscience, engineering, applied behavior, and the social sciences.

NCMRR is also leading a multi-institute initiative to stimulate pediatric rehabilitation research. Examples of priority areas include children with spinal cord injury, spina bifida, cerebral palsy/stroke, and limb loss. This initiative complements existing NCMRR investments including a large, international study to evaluate the impacts of interventions on outcomes in children with severe traumatic brain injury (TBI), and large trials of "constraint-induced movement therapy" (CIMT) for children with cerebral palsy. In CIMT, a device restricts a patient's ability to use their unaffected limb, thereby forcing patients to use an impaired limb.

TBI and concussion are associated with various cognitive, emotional, physical, interpersonal, and psychological problems. NICHD-supported researchers determined that women and girls with a concussion are more likely than males to also have a neck injury, according to an analysis of emergency department visits. These results suggest that physicians evaluating females for concussion should also consider evaluating them for neck injury so that they can benefit from treatment as soon as possible.[31]

Budget Policy: The budget request for this program is $81.1 million, a decrease of $8.8 million or 9.8 percent compared with the FY 2020 Enacted level. In FY 2021, NCMRR will be working with NIH colleagues and external stakeholders to update the NIH Research Plan on Rehabilitation. NCMRR priorities will be guided by this plan, which will lay out priorities in medical rehabilitation research; guide NIH support for rehabilitation medicine; and benefit individuals with temporary or chronic limitations in physical, cognitive, or sensory function that require rehabilitation.

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[29] https://www.nichd.nih.gov/sites/default/files/publications/pubs/Documents/NIH_ResearchPlan_Rehabilitation.pdf#search=NIH_ResearchPlan_Rehabilitation.

[30] Koffler, J, et al. Biomimetic 3D-printed scaffolds for spinal cord injury repair. Nature Medicine 2019 25(2):263-269.

[31] Sutton, M, et al. Neck injury comorbidity in concussion-related emergency department visits: a population-based study of sex differences across the life span. Journal of Women's Health 2018, 28(4):473-482.

Intramural Research: NICHD's Division of Intramural Research (DIR) has created a multidisciplinary environment for scientists to develop new insights into the physics, chemistry, and biology of cells; the processes that govern cellular function; and the impact on the body when these processes fail. DIR researchers discover answers to fundamental biomedical research questions and use this knowledge to solve difficult clinical problems. For example, DIR researchers recently revealed how a protein essential to the bacterium that causes Legionnaires' disease works by stealing iron from the host cells it infects. In a series of experiments, the researchers determined the shape of the protein as it weaves through a membrane inside the cell. Their findings may provide useful information for designing new drug treatments.[32]

Congenital heart disease (CHD) is the most common birth defect and a leading cause of infant death. Detecting CHD early improves an infant's response to surgery, chance of survival, and long-term brain function, but diagnosing the condition before birth is difficult. Currently, healthcare providers use an advanced imaging technique to detect CHD in fetuses but making a diagnosis from the resulting images can be time-consuming and inconsistent. DIR scientists used a new method, called fetal intelligent navigation echocardiography (FINE), to automatically display standard views of the heart. The researchers applied FINE to identify cases of CHD in second- and third-trimester fetuses.[33]

DIR has recently expanded its endocrinology, reproduction, and gynecological health research by establishing a new program on pediatric and adolescent gynecology. DIR investigators study a wide array of diseases, from Cushing syndrome to acromegaly, various reproductive defects, familial endocrinopathies and tumor predisposition syndromes, abnormal growth and development, hypertension, inborn errors of metabolism and other conditions. The new program on pediatric and adolescent gynecology will also study polycystic ovarian syndrome, disorders of sexual differentiation, and issues related to transgender medicine, while expanding coverage of women's health research across ages. DIR medical staff also train early-career scientists through fellowship programs in endocrinology, maternal-fetal medicine, genetics, pediatric gynecology, and reproduction and infertility.

DIR's wide-ranging expertise in endocrinology, clinical studies, and behavioral research has allowed researchers to uncover new interventions to address the obesity epidemic that has affected over 93 million adults and nearly 14 million children in the United States. For example, DIR researchers conducted a small pilot clinical trial of the drug colchicine, normally used to treat gout, to see if it could be helpful for individuals with obesity-related type 2 diabetes. Colchicine suppresses a multi-protein complex that can trigger the inflammation seen in obesity.[34] DIR's neuroscientists recently uncovered a new receptor for diazepam, a medication that has been used for decades with largely unknown effects on the brain. Diazepam is a benzodiazepine that is widely used for the treatment of anxiety, alcohol withdrawal and seizures, among other applications. The newly identified receptor modulates diazepam and other

[32] Christenson, ET, et al. The iron-regulated vacuolar Legionella pneumophila MavN protein is a transition-metal transporter. Proceedings of the National Academy of Sciences 2019 Sep 3;116(36):17775-17785.
[33] Yeo L, Luewan S, Romero R. Fetal Intelligent Navigation Echocardiography (FINE) Detects 98% of Congenital Heart Disease. Journal of Ultrasound in Medicine, 2018, 37(11), 2577–2593.
[34] Demidowich, AP et al. Effects of colchicine in adults with metabolic syndrome: a pilot randomized controlled trial. Diabetes, Endocrinology, and Metabolism, 2019, 21(7):1642-1651.

benzodiazepines' actions in the brain and may improve understanding of the effects of these medications on the nervous system and possibly the design of better drugs for a host of conditions in the future.[35]

NICHD's Division of Intramural Population Health Research (DIPHR) studies health and disease outcomes at the population level. A series of DIPHR studies have recently demonstrated how air pollution negatively affects the health of pregnant women, infants, and children. DIPHR scientists recently uncovered associations between exposure to volatile organic compounds and both gestational diabetes and preeclampsia in pregnant women.[36] Exposure to high levels of certain common air pollutants in early pregnancy was also associated with an increased risk of pregnancy-induced high blood pressure.[37] These negative effects of pollution exposure also extended to infants and young children. Infants born to women exposed to high levels of air pollution in the week before delivery were more likely to be admitted to a newborn intensive care unit.[38] DIPHR researchers also determined that young children who live close to a major roadway were twice as likely to score lower on tests of communications skills, compared to those who live farther away from a major roadway. Moreover, children born to women exposed during pregnancy to higher-than-normal levels of traffic-related pollutants – ultra-fine airborne particles and ozone – had a small but significantly higher likelihood of developmental delays during infancy and early childhood. [39]

Budget Policy: The budget request for this program is $197.2 million, a decrease of $15.8 million or 7.4 percent compared with the FY 2020 Enacted level. DIR's priorities will emphasize support for implementation of NICHD's strategic plan, such as the program in pediatric and adolescent gynecology, as well as support for the Clinical Center.

Research and Management Support (RMS): RMS activities include administrative and technical functions that support and enhance the effectiveness of NICHD's research investments. Included among these functions are public communications; budget, contracts, and grants management; peer review; reporting; program evaluation; public policy; and information technology. The RMS budget also supports NICHD's health-related outreach activities. For example, the NICHD-led Safe to Sleep® campaign, formerly the Back to Sleep® campaign, provides information to educate parents and caregivers about a safe sleep environment, including the importance of placing healthy babies on their backs to sleep, for naps and at night to reduce the risk of Sudden Infant Death Syndrome. NICHD anticipates increased investment in information technology development to support sophisticated data analysis for research, to take advantage of advanced technologies to support administration and reporting, and to modernize

[35] Han W, Li J, Pelkey KA, Pandey S, Chen X, Wang YX, Wu K, Ge L, Li T, Castellano D, Liu C, Wu LG, Petralia RS, Lynch JW, McBain CJ, Lu W. Shisa7 is a GABAA receptor auxiliary subunit controlling benzodiazepine actions. Science. 2019 Oct 11;366(6462):246-250.
[36] AD Williams et al. Ambient Volatile Organic Compounds and Racial/Ethnic Disparities in Gestational Diabetes Mellitus: Are Asian/Pacific Islander Women at Greater Risk?, American Journal of Epidemiology, 2019, 188(20, 389-397.
[37] Nobles, CJ, et al. Differential effect of ambient air pollution exposure on risk of gestational hypertension and preeclampsia. Hypertension, 2019 74(2):384-390.
[38] Seeni, I, et al. Acute air pollution exposure and NICU admission: a case-crossover analysis. Annals of Epidemiology. 2019 Sep;37:64-70.
[39] Ha, S, et al. Prenatal and early life exposure to ambient air pollution and development. Environmental Research. 2019, S0013-9351(19)30198-7.

program monitoring systems. To support responsible stewardship of valuable resources, NICHD will continue to support systematic evaluations of NICHD's scientific and administrative programs, helping to identify ways to ensure program effectiveness.

Budget Policy: The budget request for this program is $76.2 million, a decrease of $0.3 million or 0.4 percent compared with the FY 2020 Enacted level. Priorities for RMS will emphasize information technology development and efforts to maintain excellent stewardship of federal resources, as determined through the development of the NICHD Strategic Plan. NICHD will also support a renovation of its on-campus administrative facility in FY 2021.

NATIONAL INSTITUTES OF HEALTH
National Institute of Child Health and Human Development

Budget Authority by Object Class[1]
(Dollars in Thousands)

		FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Total compensable workyears:				
	Full-time equivalent	561	561	0
	Full-time equivalent of overtime and holiday hours	0	0	0
	Average ES salary	$181	$182	$1
	Average GM/GS grade	12.5	12.5	0.0
	Average GM/GS salary	$116	$117	$1
	Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	$141	$143	$2
	Average salary of ungraded positions	$132	$133	$1
OBJECT CLASSES		**FY 2020 Enacted**	**FY 2021 President's Budget**	**FY 2021 +/- FY 2020**
	Personnel Compensation	-	-	-
11.1	Full-Time Permanent	40,417	42,282	1,865
11.3	Other Than Full-Time Permanent	26,425	26,729	304
11.5	Other Personnel Compensation	1,827	1,848	21
11.7	Military Personnel	902	926	24
11.8	Special Personnel Services Payments	14,572	15,004	433
11.9	**Subtotal Personnel Compensation**	**$84,143**	**$86,789**	**$2,646**
12.1	Civilian Personnel Benefits	25,163	26,506	1,343
12.2	Military Personnel Benefits	753	773	20
13.0	Benefits to Former Personnel	0	0	0
	Subtotal Pay Costs	**$110,059**	**$114,067**	**$4,008**
21.0	Travel & Transportation of Persons	2,202	1,278	-924
22.0	Transportation of Things	108	52	-56
23.1	Rental Payments to GSA	1	1	0
23.2	Rental Payments to Others	15	11	-3
23.3	Communications, Utilities & Misc. Charges	921	474	-446
24.0	Printing & Reproduction	0	0	0
25.1	Consulting Services	1,473	572	-901
25.2	Other Services	22,398	16,169	-6,228
25.3	Purchase of goods and services from government accounts	154,769	152,393	-2,376
25.4	Operation & Maintenance of Facilities	1,207	1,108	-99
25.5	R&D Contracts	125,869	124,598	-1,272
25.6	Medical Care	1,149	1,193	45
25.7	Operation & Maintenance of Equipment	3,900	2,297	-1,603
25.8	Subsistence & Support of Persons	0	0	0
25.0	**Subtotal Other Contractual Services**	**$310,765**	**$298,330**	**-$12,435**
26.0	Supplies & Materials	12,325	9,958	-2,368
31.0	Equipment	5,560	2,613	-2,946
32.0	Land and Structures	0	0	0
33.0	Investments & Loans	0	0	0
41.0	Grants, Subsidies & Contributions	1,114,951	989,578	-125,373
42.0	Insurance Claims & Indemnities	0	0	0
43.0	Interest & Dividends	4	3	-1
44.0	Refunds	0	0	0
	Subtotal Non-Pay Costs	**$1,446,850**	**$1,302,299**	**-$144,551**
	Total Budget Authority by Object Class	**$1,556,909**	**$1,416,366**	**-$140,543**

[1] Includes FTEs whose payroll obligations are supported by the NIH Common Fund.

NATIONAL INSTITUTES OF HEALTH
National Institute of Child Health and Human Development

Salaries and Expenses
(Dollars in Thousands)

OBJECT CLASSES	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Personnel Compensation			
Full-Time Permanent (11.1)	$40,417	$42,282	$1,865
Other Than Full-Time Permanent (11.3)	26,425	26,729	304
Other Personnel Compensation (11.5)	1,827	1,848	21
Military Personnel (11.7)	902	926	24
Special Personnel Services Payments (11.8)	14,572	15,004	433
Subtotal Personnel Compensation (11.9)	**$84,143**	**$86,789**	**$2,646**
Civilian Personnel Benefits (12.1)	$25,163	$26,506	$1,343
Military Personnel Benefits (12.2)	753	773	20
Benefits to Former Personnel (13.0)	0	0	0
Subtotal Pay Costs	**$110,059**	**$114,067**	**$4,008**
Travel & Transportation of Persons (21.0)	$2,202	$1,278	-$924
Transportation of Things (22.0)	108	52	-56
Rental Payments to Others (23.2)	15	11	-3
Communications, Utilities & Misc. Charges (23.3)	921	474	-446
Printing & Reproduction (24.0)	0	0	0
Other Contractual Services:			
Consultant Services (25.1)	1,473	572	-901
Other Services (25.2)	22,398	16,169	-6,228
Purchases from government accounts (25.3)	113,751	109,247	-4,504
Operation & Maintenance of Facilities (25.4)	1,207	1,108	-99
Operation & Maintenance of Equipment (25.7)	3,900	2,297	-1,603
Subsistence & Support of Persons (25.8)	0	0	0
Subtotal Other Contractual Services	**$142,729**	**$129,393**	**-$13,336**
Supplies & Materials (26.0)	$12,325	$9,958	-$2,368
Subtotal Non-Pay Costs	**$158,299**	**$141,166**	**-$17,133**
Total Administrative Costs	**$268,358**	**$255,233**	**-$13,124**

NATIONAL INSTITUTES OF HEALTH
National Institute of Child Health and Human Development

Detail of Full-Time Equivalent Employment (FTE)

OFFICE/DIVISION	FY 2019 Final			FY 2020 Enacted			FY 2021 President's Budget		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
DIPHR	-	-	-	-	-	-	-	-	-
Direct:	29	-	29	30	-	30	30	-	30
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	29	-	29	30	-	30	30	-	30
Division of Extramural Research	-	-	-	-	-	-	-	-	-
Direct:	115	-	115	131	-	131	131	-	131
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	115	-	115	131	-	131	131	-	131
Division of Intramural Programs	-	-	-	-	-	-	-	-	-
Direct:	271	6	277	282	6	288	282	6	288
Reimbursable:	3	-	3	3	-	3	3	-	3
Total:	274	6	280	285	6	291	285	6	291
National Center for Medical Rehabilitation Research	-	-	-	-	-	-	-	-	-
Direct:	8	-	8	8	-	8	8	-	8
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	8	-	8	8	-	8	8	-	8
Office of the Director	-	-	-	-	-	-	-	-	-
Direct:	85	-	85	92	-	92	92	-	92
Reimbursable:	8	-	8	9	-	9	9	-	9
Total:	93	-	93	101	-	101	101	-	101
	-	-	-	-	-	-	-	-	-
Total	519	6	525	555	6	561	555	6	561
Includes FTEs whose payroll obligations are supported by the NIH Common Fund.									
FTEs supported by funds from Cooperative Research and Development Agreements.	0	0	0	0	0	0	0	0	0

FISCAL YEAR	Average GS Grade
2017	12.3
2018	12.3
2019	12.5
2020	12.5
2021	12.5

NATIONAL INSTITUTES OF HEALTH
National Institute of Child Health and Human Development

Detail of Positions[1]

GRADE	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
Total, ES Positions	1	1	1
Total, ES Salary	176,490	181,079	182,256
GM/GS-15	56	59	59
GM/GS-14	72	77	77
GM/GS-13	81	86	86
GS-12	57	64	64
GS-11	22	30	30
GS-10	2	2	2
GS-9	10	13	13
GS-8	16	16	16
GS-7	13	16	16
GS-6	3	3	3
GS-5	4	4	4
GS-4	1	1	1
GS-3	1	1	1
GS-2	0	0	0
GS-1	0	0	0
Subtotal	338	372	372
Grades established by Act of July 1, 1944 (42 U.S.C. 207)	-	-	-
Assistant Surgeon General	0	0	0
Director Grade	5	5	5
Senior Grade	1	1	1
Full Grade	0	0	0
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	6	6	6
Ungraded	185	192	192
Total permanent positions	338	372	372
Total positions, end of year	530	571	571
Total full-time equivalent (FTE) employment, end of year	525	561	561
Average ES salary	176,490	181,079	182,256
Average GM/GS grade	12.5	12.5	12.5
Average GM/GS salary	112,525	115,676	116,578

[1] Includes FTEs whose payroll obligations are supported by the NIH Common Fund.