Research Opportunity Announcement (ROA): OTA-25-001
Post-Crash EMS Data Science Initiative (PC-EMS-DSI)

Section 1: Overview Information

Participating Organization(s)	National Institutes of Health (NIH) National Highway Traffic Safety Administration (NHTSA)
Components of Participating Organizations	*Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) NHSTA Office of Emergency Medical Services (OEMS) NIH Office of Emergency Care Research (OECR)
ROA Title	Post-Crash EMS Data Science Initiative (PC-EMS-DSI)
Activity Code	**OT2: Application for an Other Transaction Agreement**
Research Opportunity Number	OTA-25-001
Related Notices	None available
Application Due Date	December 6, 2024
Earliest Possible Start Date	February 1, 2025
Funding Instrument	Other Transaction: An assistance mechanism that is not a grant, contract, or cooperative agreement. Other Transaction awards are subject to the requirements of the NIH Other Transactions Policy Guide (PDF 922 KB)
Funds Available and Anticipated Number of Awards	NICHD intends to fund one award, up to $800,000 (Total Cost), for the PC-EMS-DSI
Award Budget and Project Period	24 months

Section 2: Objectives of this Opportunity

The purpose of this Research Opportunity Announcement (ROA) is to invite applications from eligible organizations to support the Post-Crash Emergency Medical Services Data Science Initiative (PC-EMS-DSI). This initiative aims to: 1) develop and explore a novel dataset/s to evaluate post-crash EMS care in United States; 2) identify the most effective EMS care, which can save patient lives and decrease morbidity; and 3) validate and/or strengthen the National Highway Traffic Safety Administration's (NHTSA) National EMS Information System (NEMSIS) data case definitions for improved understanding of associations between post-crash EMS care and health outcomes.

Background

Motor vehicle (traffic)-related injuries (MVI) are a leading cause of death in the United States.[1] From 2020 to 2021, there was a 10% increase in MVI fatalities with more than 47,000 people dying due to MVI in 2021.[2] MVI is the leading cause of death among individuals ages 5-14 years.[2]

Post-crash care of a person who suffers a MVI is a critical strategy that often begins at the scene and regularly involves EMS providers. Approximately 14,000 EMS agency provider groups exist across the nation who respond to nearly 1.5 million annual motor vehicle crashes.[3] These EMS agencies operate under differing care delivery models and practices; utilize variable interventions and treatments protocols; and may have variability in resultant outcomes of injured persons.

Given the significant MVI burden on U.S. populations, enhanced, cutting edge research on post-crash care and associated outcomes of individuals who experience MVIs is urgently needed. Progressive data science methodologies to address the multifaceted aspects of post-crash EMS care delivery across the United States is necessary to address this leading public health threat.

NHTSA NEMSIS

The NHTSA Office of EMS administers the publicly available NEMSIS, a standardized data framework for documenting and exchanging EMS operations and patient care data.[3] This data ecosystem compiles, in near-real time, EMS data across EMS agencies in all 50 states, the District of Columbia, and three U.S. territories. The NEMSIS supports surveillance

efforts, facilitates research, and allows for comparative analysis. The NEMSIS also enables measurement and benchmarking of EMS agency performance. Part of this work is led by the NEMSIS Technical Assistance Center that provides case definitions for EMS scenarios. Together, these efforts inform the development of best practices, protocols, and evidence-based guidelines ultimately leading to more effective patient care. Although the NEMSIS data collected at the national level holds significant value, it lacks comprehensive detail that local EMS data provides. Further, it does not encompass all data points from other sources (i.e., crash reports, health system standards/levels, electronic health records, claims, death or medical examiner reports).

Scope and Program Components

This proposed PC-EMS-DSI aims to systematically and rigorously study the complex and multifaceted aspects of post-crash EMS care. The PC-EMS-DSI will achieve these tasks via two interrelated phases. Phases will occur over a collective approximately 24 months, with each phase providing bi-directional feedback to strengthen iterations and achieve and scientific fidelity.

Phase I – Dataset/s Development will result in the creation of a de-identified dataset/s of linked local EMS, crash report, health system, and/or electronic health record data (and may include other unanticipated data sources including but not limited to claims, death, or medical examiner reports). Dataset/s development from the multiple data sources will be an iterative process, ensuring that all governance and technical considerations are met per the NICHD Office of Data Science and Sharing (ODSS) Record Linkage Implementation Checklist (PDF 238 KB).

Phase II – Data Exploration will entail rich exploration and rigorous evaluation utilizing advanced data science methodologies, such as artificial intelligence (AI), machine learning (ML), and/or others, to:

- Analyze and test the newly developed dataset/s for associations between patient mortality, morbidity, and other outcomes with differing post-crash EMS service delivery models, response types, assessment practices, interventions and treatments, transport decisions, dispositions, and others.
- Assess, test, validate, and/or strengthen national-level NEMSIS case definitions within this dataset/s for improved accuracy and better understanding of

associations between post-crash EMS care and health outcomes. Such case definitions include but are not limited to the NEMSIS “Motor Vehicle Crash (MVC)” and “Serious Injury” case definitions.

Section 3: Potential Award Information

NIH funds to conduct this initiative will be awarded only after successful completion of both stages of application and review.

Statutory Justification for the Use of the Other Transaction Authority (OTA)

Section 402(n) of the Public Health Service (PHS) Act (42 U.S.C. 282(n)), as amended by the SUPPORT for Patients and Communities Act in 2018, authorizes the Director of NIH to approve requests by NIH institutes, centers, and offices to engage in transactions other than a contract, grant, or cooperative agreement with respect to projects that carry out certain objectives. The proposed PC-EMS-DSI meets the statutory requirements of the PHS Act for “high-impact, cutting-edge research that fosters scientific creativity and increases fundamental biological understanding leading to the prevention, diagnosis, or treatment of diseases and disorders,” specifically pertaining to understanding of our nation’s post-motor vehicle crash (post-crash) EMS care, and that the research is “urgently required to respond to a public health threat” ((42 U.S.C. 282 (n)(1)(c))) of MVI, which is a leading cause of death in the United States.[1]

Section 4: Eligibility

This ROA will establish the PC-EMS-DSI. Applications from senior/key personnel and groups with the following characteristics are encouraged.

Required

- A strong track record of successfully building and/or linking datasets from disparate data sources with adherence to data source governance, technical policies, and considerations
- Demonstrated success exploring and analyzing novel or newly linked datasets using advanced data science methodologies, such as but not limited to AI, ML, and others

- Expertise in using electronic health information data and data from other administrative or real-world data sources such as police crash reports, insurance claims, death or medical examiner reports, or others, for scientific research

Desired

- Expertise or demonstrated experience in policy, governance, and/or compliance related to data linkage
- Expertise in data science pertaining to EMS care
- Demonstrated experience working with and analyzing NEMSIS data, including NEMSIS case definitions
- A team with a demonstrable history of working together, to rapidly and rigorously achieve the goals of a project
- Successful track record of working with community, state, local, and/or federal partners to complete complicated tasks, demonstrating mutual respect for all engaged

Proposals nonresponsive to the terms of this ROA will not be considered.

Organizations

Non-domestic (non-U.S.) entities (foreign applicants) are not eligible to apply. Non-domestic (non-U.S.) components of U.S. organizations are not eligible to apply. Foreign components are not allowed.

The following entities are eligible to apply under this ROA:

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-Serving Institutions
- Historically Black Colleges and Universities

- Tribally Controlled Colleges and Universities
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Faith-Based or Community-Based Organizations
- Regional Organizations

For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- Eligible Agencies of the Federal Government
- U.S. Territory or Possession Other
- Independent School Districts
- Native American Tribal Organizations (other than federally recognized tribal governments)

Section 5: Application Information and Submission

Application Overview

Application Format and Requirements: Applications should clearly and fully demonstrate the applicant/s capabilities, knowledge, and experience. Applications shall also include a separate budget.

Plans must be submitted by the due date, in text-recognizable PDF (Adobe) format, use Arial 10-point font with 1" margins, and be single-spaced. The application may not exceed 12 pages (excluding biosketches, budget, letters of support, and bibliography).

Cover Page (no more than 1 page):

- Number and title of this ROA
- Project title
- Principal Investigator(s) first and last name, title, institution, mailing address, email address, and phone number. If multiple Principal Investigators are named, then the contact Principal Investigator is clearly identified.
- Other involved personnel names, roles, and organizations (multiple Principal Investigators, co-Investigators, collaborators, contractors, authors of letters of support, etc.)
- Name and address of the submitting organization and department, if any, with the organizational DUNS number and employment identification number provided
- Authorized organizational representative first and last name, title, institution, mailing address, email address, and phone number
- Proposed project period dates
- Confirmation that the work involves data from human subjects
- Proposed budget per year (direct and total)

Abstract (no more than 1 page): The project abstract is a succinct and accurate description of the proposed work and should be able to stand on its own (separate from the application). It should be informative to other persons working in the same or related fields

and understandable to a scientifically literate reader. If the application is funded, the project abstract will be entered into an NIH database and made available on the NIH Research Portfolio Online Reporting Tool Expenditures and Results (RePORTER) and will become public information.

Specific Aims (no more than 1 page): State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the research will have on the research field. List succinctly the specific objectives of the proposed work.

Biosketches of Senior/Key Personnel and Other Significant Contributors (no more than 5 pages per individual): At a minimum, the information in the biosketch should include the name and position title, education/training (including institution, degree, date (or expected date), and field; list of positions and employment in chronological order (including dates); and a personal statement that briefly describes the individual's role in the project and why they are well-suited for this role. The format, downloadable as a Microsoft Word file from https://grants.nih.gov/grants/forms/biosketch-blankformat.docx (DOCX 31 KB), used for an NIH grant application is acceptable.

Research Strategy (no more than 6 pages; organized into the following sections to facilitate review):

Section 1: The potential impact of the work to be done if it were successfully implemented

At a minimum:

- Describe the scientific question(s) (i.e., user stories that articulate the desired outcomes for a given analysis or analyses) and resultant impact of the proposed work.
- Describe each of the considered/identified data source/s and data type/s that are being proposed to be linked and their related applicability to achieving the aims described in the ROA.

Section 2: Plans for dataset/s development and linking data sources, describing how relevant governance and technical considerations will be met per the NICHD ODSS Record Linkage Implementation Checklist (PDF 238 KB)

At a minimum:

- Describe the strategy for convening all relevant parties, including researchers, data stewards, and other involved parties to make decisions about and design the record linkage strategy that addresses all pertinent elements of the checklist.
- Describe the proposed technical plans for linking each data source/s to create the novel dataset/s and the scope of the datasets anticipated to be part of the linkage. Include the expected method and/or software that would be used to link the dataset/s and the platform environment(s) where the linkages will be performed, and the novel dataset/s will be created.
- Describe the planned approach for performing a governance analysis to identify governance factors relevant to each data source, including all rules and controls that define and enforce appropriate data collection (or acquisition), sharing, linking, access, and use. Describe the strategy for systematically reviewing, extracting, and interpreting rules from governance documentation such as participant consents, institutional review board determinations, laws, agreements, and policy documents, and how this information will be synthesized to determine whether the data can be linked, and if so, how the respective rules and controls impact the strategy for linking, using, and sharing the linked dataset for this project. Describe how the team will address these governance considerations in their successful work.
- Propose potential processes and controls for mitigating re-identifiability of the data that may be introduced by any/all linkages.
- Describe the process and potential security requirements needed to protect personally identifiable information elements, if relevant.
- Describe contingency plans for alternate data sources/types, software and platforms if alternate sources and models are necessary.

Section 3: Plans for data science application

- Describe the types of data science methodology (AI, ML, or other) that are anticipated to be used for exploring the novel dataset/s and NEMSIS data.
- Demonstrate how each data science methodology proposed will ensure fidelity of the analysis and achieve the overarching aims described in the ROA.

- Prove evidence to demonstrate successful use of these methodologies in similar endeavors.
- Describe the skillset, capacity, and capability to conduct these data science endeavors.
- Describe the platform environment(s) where the linked data will be hosted during analysis and the environment's capacity to support the expected scale and complexity of the analysis (e.g., cloud-based systems for large-scale compute).

Section 4: Openness to sharing and coordination; nimbleness to course correct

- Describe the openness of the team to share processes, algorithms, newly created tools or software, and other resources with all PC-EMS-DSI partners, including vested federal parties and potential other applicants throughout the endeavor. For projects that propose AI/ML applications, describe how model transparency will be achieved.
- Describe the nimbleness of the team to correct course, as needed, if alternate strategies and/or variation in scope is presented.

Section 5: Past performance and expertise of the team members and complementarity with other groups

At a minimum:

- Identify key personnel, project leads, and other personnel.
- Specify effort levels and specific roles for each person.
- If applicable, detail community partners and specific roles for each partner.
- Describe how key personnel and partners will accomplish the objective(s).
- Describe how the project will leverage the expertise of the federal and other relevant partners who are part of the PC-EMS-DSI team.
- Include applicable past performance for the team and any prior experience working together.
- Detail a leadership plan for plans that involve multiple Principal Investigators.

Section 6: The adequacy and appropriateness of the project management plan

- Include a project management plan with defined timeline and milestones.
- Include risks and dependencies for 2 and 5 months post award at a minimum.

Include any graphs, pictures, or data tables in the body of the text.

Resource Sharing Plan (no more than 1 page): All applications should include a Resource Sharing Plan addressing how tools, workflows, and/or pipelines created or used with support from this funding will be shared with the wider scientific community in a timely manner that would enable other researchers to replicate and build on for future research efforts. Plans should align to open-source practices and other NIH Best Practices for Sharing Research Software Frequently Asked Questions as much as possible. Data sharing plans **should not** be included in this section. Data sharing information must be described in the Data Management and Sharing (DMS) Plan. The Resource Sharing Plan will be considered during peer review and by program staff as award decisions are being made as appropriate and consistent with achieving the goals of the program.

DMS Plan (no more than 2 pages): The Final NIH Policy for Data Management and Sharing (NOT-OD-21-013) expects researchers to maximize the sharing of scientific data and data to be accessible as soon as possible and no later than the time of an associated publication or the end of the award period, whichever comes first. NIH requires all applications submitted in response to this ROA to include a DMS Plan. The DMS Plan is expected to address the elements as described in Supplemental Information to the NIH Policy for Data Management and Sharing: Elements of an NIH Data Management and Sharing Plan (NOT-OD-21-014). For applications that aim to analyze existing data, DMS Plans should describe where and how other researchers can access that data to enable reproducibility and reuse. For this opportunity, the DMS Plan should reflect the goals of the program including respecting governance requirements for sharing the linked dataset/s. The DMS Plan will be reviewed and approved by NIH program staff prior to award. Awardees will be required to comply with their approved DMS Plan and any approved updates.

For human data, NICHD encourages the use of the Data and Specimen Hub (DASH), a centralized resource for researchers to store and access de-identified data from NICHD-funded studies. If use of DASH is not feasible, then NICHD expects awardees to share data through other equivalent broad-sharing data repositories.

NICHD ODSS also provides additional DMS Policy Resources.

Additional Items:

- A budget with justification (review the Budget section that follows this section for details)
- A letter of support from the applicant's organization indicating institutional commitment for the project (e.g., relaying support for contributions) including, but not limited to, support for training activities or PC-EMS-DSI meetings, licenses, and other resources; and preparations to enter into negotiated other transactions agreements
- Letters of support from proposed collaborators or parties who hold governance over data sources (e.g., health care partners, local police department, coroner's offices)
- A bibliography (not to exceed 1 page)

Budget (no page limitation): NICHD may elect to negotiate any or all elements of the proposed budget. Proposals must provide a realistic budget and cost estimate for performing the work for each year. Twelve-month budgets are expected not to exceed $400,000 total costs. Budgets will be reassessed as the projects proceed and may be increased or decreased depending on progress, the needs of the program, and funds available. Total budget for a 2-year proposal should not exceed $800,000 total costs.

The budget should address costs associated with the applicant's group, any collaborators, and data sources. The overall expected cost for each of the following categories should also be included: personnel, data sources/fees, software and platform, travel, funds for community partners (if applicable), subawards, other direct costs, and total cost (with indirect costs included). Provide a budget justification. Subawards need to provide details of cost breakdown.

Award Project Duration

The period of performance anticipated for this OTA will be a 24-month base period.

Submission Information

NIH uses the eRA Commons system to administer OTAs. If you are selected to participate, you may need to submit additional information in the eRA Application Submission System & Interface for Submission Tracking (ASSIST). You will need to

register in eRA Commons to do this. Applications to the PC-EMS-DSI may be submitted after the open date shown under the “Key Dates” section of this announcement. Applications **must** be submitted through eRA ASSIST site by **5 p.m. ET on December 6, 2024**. Paper applications will not be accepted. Applications from institutions must be submitted by an authorized organizational representative. Please review the “Resource only for OTA Users of ASSIST” section of eRA Training - ASSIST for additional guidance.

Upon receipt, applications are evaluated by NICHD for completeness, compliance with application requirements, and responsiveness. Applications that are incomplete, non-compliant, and/or nonresponsive will not be reviewed and the applicant will be so notified.

Section 6: Objective Review Information

Reviewer Process

Applications will undergo an objective scientific review. This ensures the assessment of scientific or technical merit of applications by individuals with knowledge and expertise equivalent to that of the individuals whose applications of support they are reviewing.

Reviewer Selection

This review will be conducted internally, with review panels representing expertise across fields such as prevention research, EMS and critical care science, transportation and crash professionals, injury and MVC science, health systems and services research, data science, and OT expertise.

Conflicts of Interest (COI)

Reviewers shall disclose any COI that might preclude their participation in the review process, as per NIH guidelines. Each reviewer must certify, under penalty of perjury (U.S. Code Title 18, Chapter 47, Section 1001), that, to the best of their knowledge, they have disclosed all COI they may have with the applications or research and development contract proposals; and they fully understand the confidential nature of the review process. COI of review panel members are appropriately managed during the review process in accordance with standard NIH policies.

Review Criteria

The objective review will consider:

1. The significance of the proposed work to address PC-EMS-DSI goals.
2. The innovation of project design and data science methodology proposed to create a valuable dataset/s that can be explored for the multi-faceted aspects of post-crash EMS care, and to test, apply, validate, and potentially strengthen NEMSIS data definitions in novel ways for improved understanding.
3. The rigor and quality of the plans to achieve the creation of the novel dataset/s using multiple data sources, ensuring pertinent governance and technical considerations are met.
4. The quality and fidelity of the proposed data science analysis and interpretation to analyze and test the dataset/s and to test, validate, and/or strengthen NEMSIS case definitions for post-crash EMS associations with health outcomes.
5. The feasibility of the project management plan, and the interrelated phases proposed, to achieve dataset/s development using disparate data sources and to conduct data science methodology within the dataset/s and NEMSIS case definitions.
6. The viability of the milestones and timeline proposed, and the soundness of contingency plans with capacity to course correct.
7. The expertise of senior/key personnel and team members with the proposed work to enable successful execution of the PC-EMS-DSI.
8. The suitability of the Resource Sharing Plan and the DMS Plan to support the PC-EMS-DSI goals, and whether these plans demonstrate appropriate plans for sharing models and de-identified data with the wider scientific community, and adherence to governance requirements.
9. The appropriateness of the proposed budget for the scope of work and justification of any third-party subcontracts.

Reviewers will be asked to provide scores and comments on applications. Funding decisions will be based on the outcome of application review and reviewer discussion. It is anticipated that one award will be made; however, this may vary depending on funds available and

applications received. Agreements for all awards will be negotiated with eligible entities whose applications are determined to be the most advantageous and provide the best value to the PC-EMS-DSI. Following the review of proposals, NIH may assemble teams from all or parts of applications to establish a PC-EMS-DSI team. Individual components from distinct applications may be selectively funded to achieve the goals set forth herein. Additionally, if, over the duration of the project, some of the components either gain relevance or lose relevance to programmatic goals, the funding for such components may be increased, decreased, or discontinued.

NIH reserves the right to:

- Invite all, some, one, or none of the Principal Investigators submitting applications in response to this solicitation to present their application in a web-based videoconference or teleconference
- Share applications between and among any applicant(s) as necessary for configuring teams, economizing work, and prioritizing activities
- Select for negotiation all, some, one, or none of the proposals received in response to this solicitation
- Accept proposals in their entirety or to select only portions of plans for award

Appeals of the objective review will not be accepted in response to this ROA.

ROA References

[1] CDC. (2023). Transportation Safety. Available at: https://www.cdc.gov/transportationsafety/

[2] CDC. (2022). Web-based Injury Statistics Query and Reporting System (WISQARS) Fatal Injury Data and 10 Leading Causes of Death. Available at: https://wisqars.cdc.gov

[3] NHTSA. (n.d.). NEMSIS. Available at: https://nemsis.org/

[4] NICHD. (n.d.). Record Linkage Implementation Checklist. Available at: https://www.nichd.nih.gov/sites/default/files/inline-files/Record_Linkage_Implementation_Checklist.pdf (PDF 238 KB)

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