

**Research Opportunity  
Announcement (ROA) OTA-25-007  
Limited Competition: The East Palestine, Ohio Train Derailment Study (OT2)**

## Overview Information

<b>Participating Organization</b>	<a href="#">National Institutes of Health (NIH)</a>
<b>Components of Participating Organization</b>	<a href="#">National Institute of Environmental Health Sciences (NIEHS)</a> <a href="#">National Center for Advancing Translational Sciences (NCATS)</a>
<b>Other Interested NIH Institutes, Centers, or Offices</b>	
<b>Research Opportunity Announcement (ROA) Title</b>	Limited Competition: The East Palestine, Ohio, Train Derailment Study (OT2)
<b>Activity Code</b>	<p><b>Other Transactions (OT2) Award mechanism.</b> This funding opportunity will use the Other Transactions Authority (OTA) governed by <a href="#">42 U.S. Code § 282 (n)(1)(b)</a>. Other Transactions (OT) awards are not grants, cooperative agreements or contracts and use an OTA, provided by law.</p> <p>Policies and terms for individual OT awards may vary between awards. Each award is therefore issued with a specific governing agreement, which is negotiated with the recipient and may be expanded, modified, partnered, not supported, or later discontinued based on program needs, changing research landscape, performance and/or availability of funds.</p>
<b>Research Opportunity Announcement (ROA) Number</b>	<b>OTA-25-007</b>
<b>Research Opportunity Announcement (ROA) Purpose</b>	The purpose of this Research Opportunity Announcement (ROA) is to invite new applications to establish a program to coordinate health-related research with public health department needs and clinical practice to respond to the health effects of the 2023 East Palestine (EP), Ohio train derailment. This program will involve non-traditional NIH partnerships to coordinate health-related research in evaluating the impacts of exposures to chemicals of concern on long-term health in East Palestine, Ohio and surrounding communities. Applications are sought to support a collaborative, community-driven, multi-phase program which will support approximately 5 years of planning, development, implementation, and coordination of community-engaged research and related activities to provide a comprehensive approach to address ongoing health concerns informed by the affected communities.

<b>Objective Review</b>	NIH will convene a panel with appropriate expertise to evaluate applications. See the <a href="#">Objective Review</a> section of this opportunity for further details.
<b>Eligibility</b>	See the <a href="#">Eligibility</a> section of this opportunity for further details.
<b>Funds Available and Anticipated Number of Awards</b>	<p>NIH intends to allocate up to \$10 million across five years [Fiscal Year (FY)25 through FY30] to fund approximately 1-3 awards.</p> <p>However, NIH procedures and OT mechanisms allow for significant flexibilities and adjustments, where necessary, to pursue catalytic and transformative initiatives. Award levels may change over time based on programmatic needs, funding availability, and recipient performance.</p> <p>Awards pursuant to this funding opportunity are contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.</p>
<b>Award Project Duration</b>	Project duration for applications submitted in response to this ROA is expected to be approximately 5 years. Individual projects may be added, extended or curtailed based on programmatic objectives, performance, and available funds.

<p><b>Application Submission Instructions</b></p>	<p>Applicants must submit applications via the <a href="#">NIH eRA ASSIST</a> system by 5:00 PM local time on the due date (see Key Dates below).</p> <p>To submit an application via ASSIST, the applicant organization must be registered in <a href="#">eRA Commons</a> (See Submission Instructions), <b>which may take two (2) weeks or more to complete</b>. Applicants should therefore begin the registration process as soon as possible. Once the organization is registered, the individual(s) with the roles of Signing Official (SO) and Principal Investigator (PI) must be affiliated with the organization and have eRA Commons credentials to complete the submission process. (If an individual plans to serve in both roles, they will need two separate sets of credentials.) Complete applications must be submitted via <a href="#">ASSIST</a> by the SO. Use <b>OTA-25-007</b> in the Opportunity Number field.</p> <p><a href="#">Here are instructions for submitting applications via the NIH eRA ASSIST system</a>. Technical assistance is available from the <a href="#">eRA Service Desk</a>.</p> <p>On the <a href="#">eRA Commons</a> home page, select the “Register Organization” link for more details.</p> <p><b>Submission and Contact Information.</b> Applications should be submitted by the proposing entity’s Signing Official via NIH eRA Commons ASSIST no later than <b>July 21, 2025</b> by 5 PM local time.</p> <p>If you encounter a system issue beyond your control that jeopardizes your ability to complete the submission process on-time, you must follow the <a href="#">Dealing with System Issues</a> guidance.</p>
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## Key Dates

<b>Post Date</b>	June 18, 2025
<b>Informational Webinar Dates (optional)</b>	
<b>Application Due Date</b>	July 21, 2025 by 5pm local time. Applications must be submitted via <a href="#">NIH eRA Commons ASSIST</a> . See Application Submission Instructions.
<b>Anticipated Review</b>	August 2025
<b>Earliest Start Date</b>	September 2025

## Agency Contacts

Potential applicants are encouraged to contact NIH to discuss the application process prior to submission.

<b>Scientific/Research Contact</b>	<p>Toccara Chamberlain, MA <a href="mailto:Toccara.chamberlain@nih.gov">Toccara.chamberlain@nih.gov</a></p> <p>Ashlinn Quinn, PhD <a href="mailto:Ashlinn.quinn@nih.gov">Ashlinn.quinn@nih.gov</a></p> <p>Claudia Thompson, PhD <a href="mailto:Thompso1@niehs.nih.gov">Thompso1@niehs.nih.gov</a> National Institute of Environmental Health Sciences (NIEHS)</p>
<b>Financial/Agreements Officer Contact</b>	<p>Jennifer Cho <a href="mailto:Jennifer.cho@nih.gov">Jennifer.cho@nih.gov</a></p> <p>Stacia Fleisher, MPP <a href="mailto:Stacia.fleisher@nih.gov">Stacia.fleisher@nih.gov</a> National Center for Advancing Translational Sciences (NCATS)</p>

## Key Definitions

- Objective Review: A process where applications are assessed using a fair and unbiased evaluation of scientific and technical merit or other relevant aspects of the proposal.
- Other Transactions Authority (OTA): A unique type of authority that allows an agency to enter a legal agreement with a recipient organization that is not a contract, grant, or cooperative agreement ([Learn more about OTAs on the NIH website](#)).
- Partnership: An association of two or more entities with a commitment to an ongoing relationship to work toward common goals as established.
- Research Opportunity Announcement (ROA): Used to solicit applications for programs using [Other Transactions Authority](#).
- Operational Milestone: An objective, measurable event that is indicative of project progress occurring as proposed in the application.

## Program Background and Description

On February 3rd, 2023, a Norfolk Southern freight train derailed in East Palestine, Ohio. The train was comprised of 38 cars carrying hazardous materials including vinyl chloride, butyl acrylate, ethylene glycol, and benzene residue. Following the derailment, several railcars burned for more than two days, and emergency responders conducted controlled burns which raised concerns for the airborne release of hydrogen chloride and phosgene [1]. In the aftermath, the community reported a range of adverse symptoms including headaches, gastrointestinal illness, and increased stress. Community members further described the toll of the derailment during a two-day National Academies of Sciences, Engineering, and Medicine (NASEM) workshop [2].

Prior research has linked some of the released chemicals to adverse health outcomes. Vinyl chloride, for example, has been associated with liver toxicity [3]. Following the derailment, residents reported health symptoms including headaches and respiratory, skin, and eye irritation. Other health outcomes of concern to the community include but are not limited to: maternal and child health, psychological effects, immunological, respiratory and cardiovascular effects [2]. Multiple agencies responded to the incident to support clean-up efforts and community related health measures. Initial EPA air monitoring data suggested levels of potential concern for some air toxics including 1,1,2-Trichloroethane, acrolein, and naphthalene [4]. NIH organized and funded a National Academies workshop to identify ongoing community concerns, health-related findings, informational gaps, and health research needs going forward. In response, NIEHS has funded several exploratory awards to evaluate different research questions and concerns. Although these projects have served as strong informative foundational studies, additional knowledge gaps and community concerns remain.

This ROA supports the development of a vigorous, community-engaged, high impact research program to direct, implement, coordinate and sustain:

- robust community-engaged longitudinal epidemiological research to understand the health impacts of exposures on short- and long-term health outcomes including relevant biological markers of risk,
- public health tracking and surveillance of the community's health conditions to support health care decisions and preventive measures, and
- extensive, well-coordinated, communications among researchers, study participants, community stakeholders, health care providers, government officials, and others to provide a comprehensive approach to address the affected communities' health concerns.

## Advancing Research and Data - Objectives

NIH invites applications from individual organizations or multi-institutional teams to conduct community-engaged, high-impact research focused on the longitudinal health impacts following the EP train derailment among populations residing East Palestine, Ohio and other proximal residential areas within a 50-mile radius of the disaster. The overarching goal for this program is to create a program that is co-developed by the community, academic researchers and other stakeholders to address immediate health concerns, as well as to provide the infrastructure to enable an understanding of the long-term health impacts from exposure to the chemicals released as a result of the train derailment.

The research team proposed in response to this East Palestine, Ohio Train Derailment Study ROA should include the relevant expertise, experience and collaborative partnerships that will address the primary objectives of the program:

- (1) conduct a health needs assessment by engaging organizations, networks, and researchers that are firmly connected to, actively working with, and/or embedded in communities proximal to the East Palestine train derailment disaster;
- (2) establish a scientifically rigorous and valid longitudinal study to assess health outcomes and risk associated from the environmental disaster;
- (3) provide training and educational materials as well as report-back of testing results and other findings to community members and local health providers; and
- (4) support the development and implementation of a health tracking system, in conjunction with data cyberinfrastructure. This system would leverage health care records (with participant consent) and research data in collaboration with health care providers and others, to identify health conditions, associated with the derailment, and understand factors that might guide health care decisions and public health interventions.

## Activities

The East Palestine, Ohio Train Derailment Study teams are expected to:

- **Conduct a community assessment of the health needs** for the communities impacted by the EP train derailment through the involvement of key stakeholders.
- **Develop a longitudinal high impact research study** to include:
  - a. Plans for cohort identification (including the target population and sampling frame) and a proposed study design considering the appropriate use of controls and/or range of exposed individuals.
  - b. Consideration of participant burden and description of a plan that balances scientific value with the needs, concerns, and capabilities of individual participants and the community at large. Appropriate participant compensation plans should be discussed in detail.
  - c. Valid assessment of environmental exposures of concern. As appropriate, objective measures using environmental and/or biological samples and industrial hygiene gold standard techniques should be utilized for concentration, exposure, and/or biological dose monitoring, characterization, and estimation.
  - d. Identification of appropriate and valid outcome metrics for health endpoints of interest. Health endpoints of interest must be clearly identified and could include, for example, reproductive and

developmental, mental health, cancer, immunological, neurological, respiratory and cardiovascular, and other disease indicators.

- e. Detailed analytical plan that incorporates appropriate epidemiologic and biostatistical methods to evaluate health impacts of chemical-specific exposures and/or chemical mixtures.
- **Develop plans for disseminating findings and materials** to community partners.
- **Develop a health research tracking system with data management infrastructure.**
- **Provide training and educational materials** for communities and local health care providers relevant to exposures and potential health outcomes of interest; to include report back of research findings from the longitudinal health study.
- **Develop plans for storage of biological and/or environmental samples for future sharing:** for example, to enable long-term follow-up for outcomes such as mortality, cancer incidence, and other outcomes with longer latency to disease detection.

**Throughout these activities, the teams are expected to:**

- **Ensure research studies are prioritized by community members, with consideration of populations with the greatest potential vulnerability** including, but not limited to, children, older adults, women of child-bearing age, workers and individuals with chronic health concerns.
- **Ensure ongoing engagement of community stakeholders** to be involved in planning activities, partnership identification and establishment of sustainable coalitions in support of the research, communications, evaluations, and associated East Palestine, Ohio Train Derailment Study activities. Examples include mental and behavioral health agencies and providers, schools, and healthcare systems.
- **Define and implement ethical standards that promote values essential to collaborative community-engaged research**, such as mutual respect, trust, accountability, transparency, fairness and protection of individuals and the community from unintended harms.
- **Collaborate with NIH and partners across the program** to ensure all parties can pivot as needed to address new research findings and community health needs in a timely manner.

## **Scope**

The East Palestine, Ohio Train Derailment Study intends to utilize rigorous scientific approaches to foster, coordinate, and sustain community engagement in support of research that identifies potential long-term health consequences of the EP train derailment. It will promote and support clinical practice and public health measures to prevent illness and improve recovery. An emphasis is being placed on health tracking and data management to provide the infrastructure needed to understand the long-term consequences of the derailment for these communities. It is expected that the study should leverage existing trusted partnerships, foster the development of new community collaborations, and leverage extant community resources and capabilities.

**Respondents/research teams should describe the following within their applications:**

- Track-record of community-engaged research work in the close vicinity of East Palestine, OH. Including but not limited to accomplishments working with various communities such as planning, evaluating, problem solving, user experience, project management, education and training, communication and quality management.

- Expertise in environmental health and/or disaster-related research.
- Experience and expertise in creating health tracking systems.
- Experience in developing, implementing, and managing a secure research and data/cyberinfrastructure that incorporates and maintains personal identifiers, clinical data, health records, exposure data, and other relevant information while protecting participant privacy and confidentiality.
- Experience identifying community partners as key stakeholders, and cultivating and maintaining relationships with community stakeholders to achieve mutually agreed upon objectives.
- Community-responsive strategies to overcome the limitations and challenges inherent to enrollment and retention of post-disaster cohorts.
- Provide a record of successful observational and/or clinical epidemiologic research activities.
- Incorporate interdisciplinary skillsets and expertise to achieve overarching programmatic goals, including experience in: chemical exposure assessment; advanced environmental health-relevant epidemiological research and design; and community-engaged research approaches.

## Roles and Responsibilities

### Recipient Roles and Responsibilities:

- Develop and address project specific milestones/activities and anticipate outcomes of the proposed research.
- Collect metrics to demonstrate impact and outcomes throughout the project period of performance as well as the potential for sustainability beyond the project time frame.
- Work with NIEHS to develop and execute a data sharing/use agreement. NIEHS and each East Palestine, Ohio Train Derailment Study recipient will reach mutual agreement on the data use process outlined in the final data sharing/use agreement.
- Provide representatives to participate in community advisory board meetings, Work Groups, Interest Groups and/or other ad-hoc meetings.
- Submit reports as requested by NIEHS.
- Actively participate in bi-monthly and/or quarterly project monitoring meetings with NIEHS.
- Adapt quickly and pivot as needed to respond to research findings.
- Collaborate with NIH and other identified partners as requested.

### NIH Roles and Responsibilities:

The NIH will actively engage with award recipients to establish the overall vision and capabilities for the program as well as provide evaluation, technical direction and oversight of the program.

Other Transactions Agreements Officer (OTAO) – the NIH employee responsible for legally committing the government to an OT award. The OTAO is responsible for negotiating and monitoring the financial and administrative requirements of the award, as well as terms and conditions. The OTAO is the focal point for receiving and acting on requests for NIH prior approval and is the only NIH official authorized to change the funding, duration, or other terms and conditions of award.

Other Transactions Agreements Specialist (OTAS) - the NIH employee with delegated responsibility for administrative and financial aspects of the award and is generally the first line of official OT

correspondence with the applicant and/or recipient.

Other Transactions Program Official (OTPO) - the NIH employee who provides day-to-day programmatic oversight and technical direction of individual awards, working closely with the OTAO. The OTPO ensures the successful implementation of the program by considering input from other federal experts, award recipients, and collaborators. The OTPO evaluates and reviews strategic planning activities and award performance, recommends approval and acceptance of deliverables to the OTAO, and, if warranted by progress or evolving program priorities, recommends budget adjustments to the OTAO. Additionally, the OTPO may propose creation, adjustment, or removal of milestones and deliverables.

## Eligibility

To expedite program establishment in response to this public health crisis, eligibility is limited to organizations that can demonstrate that they have substantively worked with East Palestine and surrounding communities affected by the Norfolk Southern train derailment. Eligible organizations are highly encouraged to leverage existing resources and expand on community partnerships and other forums for exchange that have been developed and verified since the train derailment. Research teams should have expertise in community engagement, multidisciplinary team research, epidemiological approaches, exposure assessment, secure data system development and management, report-back of research results to study participants, health communications, and demonstrated experience and interest in working to address the health impacts among communities impacted by disasters and health emergencies.

**If an organization fails to meet or justify how they meet the eligibility requirements, the application will be deemed non-responsive and will not be reviewed.**

### 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 domestic 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, including NIH Intramural Research Program (NIH IRP)
- U.S. Territory or Possession Other
- Independent School Districts
- Native American Tribal Organizations (other than federally recognized tribal governments)

Applicants may use a Multiple Principal Investigator (MPI) model which allows the applicant to utilize a collaborative approach of having more than one individual lead the project. If an MPI model is selected the applicant will need to select one individual to serve as the main contact for the application and provide an MPI Plan. The MPI Plan should include the individual roles and responsibilities as well as a plan for communication/collaboration and how conflicts will be resolved between the parties.

## Developing Applications

### Application Format

Applications will be accepted only from organizations listed in the Eligibility section of this announcement.

Applications must be prepared and submitted using [NIH's ASSIST](#) by the recipient Signing Official (SO). The organization must be registered in [eRA Commons](#) with one person designated as the Principal Investigator (PI) and one person designated as the SO. If an individual plans to serve in both roles, they will need two separate sets of credentials. Applicants should begin the registration process early as the entire process can take up to 2 weeks to complete. The SO's signature certifies that the applicant has the ability to provide appropriate administrative and scientific oversight of the project and agrees to be fully accountable for the appropriate use of any funds awarded for the performance of the OT award-supported project or activities resulting from the application. It is preferred, but not required, that all key personnel also be registered in eRA Commons prior to submitting an application.

Applications should be submitted on or before the "application due date" shown under the "Key Dates" section of this announcement in text-recognizable PDF (Adobe) format, use 11-point font with 1" margins and be single-spaced. The sections of the application **should be combined and uploaded as one attachment**, titled XXX\_PI\_Last Name\_ Org Name.pdf. In addition to the single pdf submission, applicants will be required to enter the abstract and specific aims sections into specified fields within ASSIST.

**All applications should include the following sections:** (1) Title page; (2) Abstract; (3) Specific aims; (4) Biosketches; (5) Background and Prior Experience; (6) Project Plan including a milestone-based workplan; (7) Data sharing plan; (8) Budget. If applicable, applications should also include the following sections: (9) letters of support.

## **1. Title Page (Limited to 1 page)**

The title page should include all the following information:

- A. Application title
- B. Applicant Organization:
  - a. Legal name and, if applicable, the legal name of all partners
  - b. Entity address and contact information
  - c. Name and contact information (including email and phone number) for the Principal Investigator who will serve as the application contact (with NIH Commons Account information), any Multiple Principal Investigators, and other key persons
- C. The name and contact information (including email and phone number) for the Applicant's Signing Official, the person authorized to negotiate and bind the Applicant as a signatory to the Other Transactions agreement
- D. Organization eligibility statement (limited to one paragraph)
- E. Total cost requested

## **2. Abstract (Limited to 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 individuals 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.

## **3. Specific Aims (Limited to 3 pages)**

State concisely the goals of the proposed research and summarize the expected outcome(s) for each activity being proposed, including the impact that the results of the research will have on those impacted by the train derailment. List succinctly the specific objectives of the proposed work for each activity being proposed.

## **4. Biosketches of Senior/Key Personnel and Other Significant Contributors (no more than 3 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-process/write-application/forms-directory/biosketch>, that is used for an NIH grant application is acceptable, but not required.

## **5. Background and Prior Experience in East Palestine (Limited to 1 pages)**

Provide evidence of current and/or recent engagement in East Palestine and/or surrounding communities affected by the Norfolk Southern train derailment.

## **6. Project Plan (Limited to 30 pages)**

Projects plans should be uploaded as searchable PDF format in a font size of 11 or 12 point and font type of

Arial or Times New Roman. Margins must be 1-inch wide (top, bottom, left, and right). The project plan must not exceed 30 pages in length. Excluded from the page limitation are cover sheets, letters from collaborators and consultants, and representation and certification documents.

The Project Plan should generally include the following elements:

- A. **Project Summary:** Description of the overall goals of the East Palestine, Ohio Train Derailment Study and the activities that will support its dissemination and implementation.
- B. Detailed description of how each objective will be met and how progress will be monitored. Applicants should describe how innovative practices and approaches will be used to accomplish the objectives.
- C. Milestone-based Workplan must include a description of operational milestones, completion criteria, and expected start and completion dates. An “Operational Milestone” is an objective, measurable event that is indicative of project progress occurring as proposed in the application. NIEHS with the assistance of NCATS, will review and approve the milestone-based work plan for inclusion in the OT Agreement.
- D. Financial Contingency Plan: Potential risks, mitigation strategies, and associated costs, including a description of a viable source to cover these costs.
- E. Team Organization: Team structure (including community members, representatives from community-based organizations, and/or other stakeholders), roles and responsibilities, leadership and communication plans.
- F. Resources and Environment: Resources available to the project and environment in which the activities will be performed.
- G. References from previous research or literature.

## 7. Data Management and Sharing Plan

NIH requires researchers to prospectively plan for how scientific data will be preserved and shared through submission of a Data Management and Sharing Plan. Applications should include a Data Sharing Plan outlining initial plans for how scientific data and accompanying metadata will be managed and shared. Applicants should include details on how data will be shared directly with community members as well as other program award recipients.

During negotiations funded recipients will refine this plan. Upon NIH approval of a Plan, NIH expects researchers and institutions to implement data management and sharing practices as they have described. Costs associated with data management and data sharing may be allowable under the budget for the proposed project.

Projects are subject to the [NIH Data Management and Sharing Policy](#), which requires that recipients submit a plan to manage and share data. Justified exceptions to sharing data are allowed, as noted in the Policy.

## 8. Budget (No page limit)

Proposed budgets must provide a realistic and well-justified cost proposal for performing the proposed work over a period of up to 5 years. Budgets for individual awards are expected to vary, depending on the proposed activities and resources. The budget must reflect the needs of the proposed work. It is expected at least 20% of the budget will be committed to community-engaged activities.

Incremental funding will be provided for up to 12 months. Additional funding will be awarded based on completion of approved project milestones/activities.

The budget proposal should include the following sections:

Detailed budget. Provide the overall expected cost for each of the following categories using a detailed, line-item budget approach, which rolls up into the following budget categories:

- Personnel
  - Budgets must adhere to latest NIH salary limitation notice (See [NOT-OD-25-025](#), Guidance on Salary Limitation for Grants and Cooperative Agreements)
- Equipment
- Travel
- Partners such as Subawards/subcontracts/consultants
  - Partners need to provide details of cost breakdown including both direct and indirect costs.
- Other direct costs
  - Include costs for participant compensation as appropriate.
- F&A (indirect) costs – if an applicant has an approved facilities and administrative costs rate agreement with the federal government, the approved rate should be reflected in the budget request. If the applicant does not have an approved facilities and administrative costs rate agreement, they may propose a rate for NIH review and consideration.
- Total cost (Inclusive of F&A/indirect costs)

Applicants should prepare a Gantt chart organized by activities that shows how the funding requested aligns to each of the proposed milestones in the milestone-based work plan.

Additionally, the applicant should provide the following detailed information in the budget justification.

- Proposed Cost Share contribution, if applicable. Cost sharing is encouraged but not required.
- Plan for issuing timely payments to community/primary care partners (if applicable). The plan should detail how processes may differ for different partner types/agreements.
- Description of community partners, including partner type (public health departments, community service organizations, academia, grassroots organizations, social service systems, faith-based organizations, health systems, safety-net clinics, schools, and other partners.
- For manuscripts published in journals that are not immediately open access, applicants should include costs to pay for immediate open access.

#### **9. Letters of Support (No page limit)**

Letters of support for all collaborators/other significant contributors, consultants and sub-award sites should be provided. Letters should describe the type of contribution, collaboration or consultation that will be provided. Letters that are written for the sole purpose of endorsement should not be included and will not be considered during review. However, a list of previous collaborators (limited to one page) who may be contacted as references as to demonstrate the applicants' history of collaborative work with the East Palestine and surrounding communities affected by the train derailment to justify eligibility should be included, as applicable.

## **Human Subjects Protections**

For research involving human participants, NIH has specific requirements for research staff, and policies regarding research conduct, safety monitoring, and reporting of information about research progress. If funded, all human subjects research must be approved by an Institutional Review Board (IRB) and be conducted under a Federal Wide Assurance (FWA). Before engaging in any human subjects research, recipients must obtain Federal Wide Assurance (FWA) from the DHHS Office for Human Research Protections (OHRP) (<https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwf/fwaf-fwa-protection-of-human-subject/index.html>), and comply with 45 CFR 46 (<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>), and, as applicable, any relevant FDA regulations (e.g., 21 CFR 11, 50, 54, 56, 312, and 812) (<https://www.fda.gov/medical-devices/medical-device-databases/code-federal-regulations-title-21-food-and-drugs>) governing the protection of human subjects and the conduct, management, and oversight of clinical trials.

Recipients will need to provide to the NIH OTAS and OTPO evidence of an active FWA prior to the commencement of any human subject research activities contemplated under this Agreement. Further, recipients must comply with all applicable laws and regulations relating to the privacy and confidentiality of human subjects.

In addition, for research involving human participants, recipients will be required to provide the number of participants they plan to recruit, and NIH will monitor progress made towards recruiting that number.

## Objective Review

Recipients will be selected through an objective review process. The level of funding towards any awards made will depend on the quality and scope of the proposals received and the availability of the funds. Agreements for awards will be negotiated with eligible organizations whose proposals are determined, through the review, to be the most advantageous and provide the best value to the government.

Applicants are encouraged to be creative and innovative in leveraging their track record of community-engaged research in disaster (natural and man-made) impacted communities.

Recipients will be selected through an objective review process that will evaluate the following criteria: 1) proposal responsiveness to the objectives of this research opportunity announcement; 2) innovation of the specific proposed strategies; and 3) feasibility and rapid potential impact of proposed activities.

### Review Process

Responsive applications will be reviewed by subject matter experts. The subject matter experts will include NIH and other federal staff, and external expertise as needed. The objective review process will use review criteria (described below) to guide the subject matter reviewers on the assessment of applications, the preparation of written evaluation summaries, and the discussions between those experts and NIH program staff.

Applicants will not receive written feedback on their application based on the objective review. However, if resources allow, NIH may provide feedback in a post review discussion call if requested by the applicant. NIH will not accept an appeal of the objective review or funding decision outcomes.

### Review Criteria

Individual subject matter experts will review and assess each application taking into account the following:

For each of the following criteria, reviewers will indicate a rating of a) highly likely, b) moderately likely, or c) unlikely:

1. Proposal responsiveness to the objectives of this funding opportunity as outlined in the Advancing Research and Data-Objectives section.
2. Innovation of the specific proposed strategies.
3. Feasibility and rapid potential impact of proposed activities as described in the Milestone-based Workplan.

**Assessment of Overall Impact:** Reviewers will provide an assessment of whether the overall proposed activities are likely to have a high, medium, or low potential impact.

Additionally, reviewers will be asked to identify key aspects of applications that merit additional interest:

1. **Components:** Laudable activities within applications that independently have potential to significantly advance the program.
2. **Areas for Improvement:** Identification of independent activities proposed that might be improved.

Review outcomes are likely to include recommendations that could facilitate dialogue or site visits between applicants and federal staff, leading to modifications of the milestones/activities submitted to NIH. Components of the applications may be accepted into the final plan in whole, in part, or may be omitted. The modified tasks and milestones, as shaped by the objective review process, will serve as a framework for the final negotiated terms for the resulting awards.

## Negotiations

Based on the objective review, NIH will select a subset of applicants and/or subsections of applications to negotiate award terms. Final funding decisions will be based on the outcome of the objective review and negotiations between the selected recipients and NIH. Agreements for all awards will be negotiated via video conference, site visit, and/or teleconferences.

NIH reserves the right to:

- Select for negotiation all, some, one, or none of the proposals received in response to this ROA,
- Segregate portions of resulting awards into components and their associated budget that differ from those that have been proposed,
- Accept proposals in their entirety or to select only portions of proposals for award,
- Fund projects in increments and/or with options for continued work at the end of one or more phases,
- Fund projects of two or more applicant entities as part of a reorganized, consolidated consortium operating under an article of collaboration, teaming arrangement, or other means acceptable to the NCATS,
- Request additional documentation (certifications, etc.), and
- Remove proposers from award consideration should the parties fail to reach a finalized, fully executed agreement, or the proposer fails to provide requested additional information in a timely manner.

If a limited number of responsive applications are received and/or there are significant gaps in the research areas proposed, NIH may determine a need to invite additional organizations to submit an application for consideration after the posted due date. Invited applications will undergo an internal review process based on the criteria specified above.

## Financial and Risk Assessment

As is standard for OT programs, all applicants will be subject to financial analysis and risk assessment conducted by NIH staff.

## Special Award Terms

The complete terms and conditions of each Other Transactions (OT) award issued under this ROA are subject to negotiation and will be contained in the OT Agreement entered between NIH and the recipient. This Special Award Terms section is provided for informational purposes only to provide prospective applicants with an understanding of key expectations and terms that may differ from traditional NIH award mechanisms (e.g., cooperative agreements/grants or procurement contracts). All terms and conditions of award will flow down to any partners (e.g., subrecipients, collaborators) participating in the OT award.

The funding mechanism of this ROA is OTA. The use of OTA will support NIH taking a flexible approach to negotiate award terms and conditions. The OTA award mechanism allows significant

ongoing involvement from NIH Program Staff and allows NIH to alter the course of projects in real-time to meet overarching program goals. This may mean an awarded activity could be expanded, modified, or discontinued based on Program needs, achievement of agreed-upon activities, or availability of funds. During the funding period, performance will be reviewed on an ongoing basis with course corrections taking place where necessary. As a result, NIH reserves the right to fund projects in increments and/or continue or discontinue work at the end of each phase.

NIH expects publications resulting from the NIH studies to be immediately available to the public upon publication. Recipients should plan to coordinate with journals in advance to pay for immediate open access. Prior to publication, award recipients are encouraged to alert their Other Transactions Program Official and Agreement Specialist of upcoming manuscripts to ensure coordination of communication and outreach efforts.

### **Potential Addition of Partners for Award**

With mutual consent of the applicant and NIH, successful proposers might be asked to develop partnerships with entities identified and approved by NIH. This might be the case if NIH determines during objective review that an applicant does not have sufficient capacity to conduct their proposed project, that applicant may be asked to partner with another applicant to provide the support needed to begin work on the applicant's project.

### **Post Review Submission of Milestones and Timeline**

NIH will review and approve the proposed milestone-based work plan agreed upon during negotiations for inclusion in the OT Agreement. Those selected for funding will:

- Produce and submit a written final plan with self-identified milestones and a timeline to be agreed upon with NIH staff (may be informed by negotiations); and
- Achieve milestones/activities as defined in a binding, written agreement to be developed and agreed upon by NIH and the recipient.

## **Payment**

The OT award will use the Payment Management System (PMS) operated by the DHHS Program Support Center. Payments by PMS may be made by one of several payment methods, including SMARTLINK II/ACH, cash request, or by cash request on a reimbursement basis as specified in the terms of the Agreement. Generally, payments align with achievement of milestones and a payment schedule will be negotiated prior to issuance of the award to minimize the amount of time elapsing between the transfer of funds from the Federal Government and disbursement by the recipient. NIH and/or applicants may negotiate non-milestone-based payment structures for part or all of the award period.

## **Reporting**

The terms and conditions of award will address this requirement as appropriate based upon the final negotiated and agreed upon budget.

### **1. Financial and Progress Reports:**

- Recipients will be asked to provide regular progress reports to the OT Program Official and Agreements Officer. The frequency and types of technical and financial reports (e.g., Federal

Financial Reports) required will be specified in the Agreement document, and will include, at minimum, financial status reports that will establish the burn rate for the project and a bi-annual progress report.

- A final Federal Financial report is required for all Other Transactions Awards. A final progress report that summarizes the project and tasks will be required at the end of the Agreement period.

The reports shall be prepared and submitted in accordance with the terms and conditions requirements.

2. i-Edison: Agreement terms and conditions will contain a requirement for patent reports and notifications to be submitted electronically through the i-Edison Federal patent reporting system at <https://www.nist.gov/iedison>.

## Questions and Answers

Responses to Questions about this ROA will be posted here:

[https://www.niehs.nih.gov/research/programs/east\\_palestine/ep\\_research\\_opportunity](https://www.niehs.nih.gov/research/programs/east_palestine/ep_research_opportunity)

## Submission and Contact Information

For best consideration, applications should be submitted in ASSIST **July 21, 2025, by 5 PM local time**.

Financial and administrative questions should be addressed to Jennifer Cho, NCATS Agreements Officer, by email at [jennifer.cho@nih.gov](mailto:jennifer.cho@nih.gov).

Technical and program specific questions should be addressed to Toccara Chamberlain, NIEHS, by email at [toccara.chamberlain@nih.gov](mailto:toccara.chamberlain@nih.gov).

## eRA Registration

NCATS (the NIH Institute that will administer awards) uses the eRA Commons system to administer OT awards. Therefore, prior to submitting your application via eRA ASSIST, it is essential that your organization, Principal Investigator (PI), and Signing Official are registered at eRA Commons. It is desirable, though not required, that other key personnel are also registered at eRA Commons. Please plan to complete the registration process early to avoid application submission problems. To register, please follow the instructions via this website:

<https://public.era.nih.gov/commonsplus/public/registration/initRegistration.era>.

1. Complete the online Institution Registration Form and click Submit.
2. The NIH database will send you an email with the link to confirm your email address.
3. Once your email address is verified, NIH will review your request and let you know of the result via email.
4. If your request is denied, you will get an email notifying you of the reason.
5. If your request is approved, you will get an email with your Commons User ID and

temporary password.

6. Log into Commons with the temporary password and the system will prompt you to change temporary password to a permanent one. Your Signing Official will be prompted to electronically sign your registration request. (Please review your registration information carefully.)

7. Once your Signing Official has electronically signed the request, your organization will be active in Commons, and you may create and maintain additional accounts for your institution staff.

Once you have established an eRA account, the next step in the process is to formally submit your application in ASSIST, which is a component of the eRA system.

Complete applications must be submitted under **OTA-25-007** via NIH eRA Commons ASSIST no later than the ***“Application Due Date”*** shown at the top of this notice, by 5 pm local time of the applicant organization.

Full applications must be submitted via the NIH eRA ASSIST system.

Applications must be prepared and submitted using NIH’s eRA ASSIST.

Applicants must submit the full application via the NIH eRA Commons ASSIST system no later than **Monday, July 21, 2025**, by 5 pm local time of applicant organization. Here are instructions for submitting via the NIH eRA ASSIST system including specific guidance for OTAs: <https://www.era.nih.gov/help-tutorials/assist/era-training-assist.htm>. Technical assistance is available from the eRA Service Desk: <https://www.era.nih.gov/need-help>. If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Dealing with System Issues guidance.

Please note to receive an award, you **may** need to register for one or more of the following if you haven’t done so already:

- **System for Award Management (SAM):** <https://sam.gov/content/home> – Applicants must complete and maintain an active registration, which requires renewal at least annually.
- **Unique Entity Identifier (UEI):** A UEI is issued as part of the SAM.gov registration process.
- **eRA Commons:** Once the unique organization identifier (UEI after April 2022) is established organizations can register with eRA Commons (<https://www.era.nih.gov>) in tandem with completing their full SAM and Grants.gov registrations.

## References

- [1] Environmental Protection Agency. (2025, April 24). *East Palestine, Ohio Train Derailment*. <https://www.epa.gov/east-palestine-oh-train-derailment>
- [2] National Academies of Sciences, Engineering, and Medicine. 2024. Public health research and surveillance priorities from the East Palestine train derailment: Proceedings of a workshop—in brief. Washington, DC: The National Academies Press. <https://doi.org/10.17226/27441>.
- [3] Bolt, H. M. (2005). Vinyl Chloride—A Classical Industrial Toxicant of New Interest. *Critical Reviews in Toxicology*, 35(4), 307–323. <https://doi.org/10.1080/10408440490915975>.
- [4] Oladeji, O., Saitas, M., Mustapha, T. et al. (2023). Air Pollutant Patterns and Human Health Risk following the East Palestine, Ohio, Train Derailment. *Environmental Science & Technology Letters*, 10(8), 680-685. <https://doi.org/10.1021/acs.estlett.3c0032>