East Palestine, Ohio Train Derailment Study

OTA-25-007

Questions and Answers

View the Research Opportunity Announcement:

https://www.niehs.nih.gov/sites/default/files/2025-06/NIEHS-East-Palestine-OT-ROA 508.pdf

General Information

- What is the purpose of this announcement?
 - The purpose of this Research Opportunity Announcement (ROA) is to invite new applications to establish a program to coordinate high-impact 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, multiphase 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.
- Whom can I reach out to with questions about this announcement:
 - All questions are welcome. Please reach out to the general mailbox at eproa@nih.gov. You can also reach out to individual team members: Toccara Chamberlain at toccara.chamberlain@nih.gov, Claudia Thompson at thompson at <a
- Can I request a meeting with a NIH Program Official to discuss my proposal?
 - To provide the most efficient response, please send your specific questions, with sufficient detail, to the ROA development team at eproa@nih.gov. Submitting questions to the preferred email address will allow program staff to consult with

one another before replying, to ensure consistency of our response. Any questions we receive that are likely to be relevant to other investigators will be posted to the Q&A page, so please check the Q&As before submitting to determine if your question has been answered previously. If your question remains unanswered, please contact us and we will do our best to accommodate your request to meet with a program official.

Key Dates

• What are the key dates in the timeline for planning our application?

Research Opportunity Announcement	June 18, 2025
Released	
Application Due Date	July 21, 2025, by 5:00 PM local time of
	applicant organization
Application Review	To begin on or about July 28, 2025
Award Negotiations	To begin on or about August 18, 2025
Applications Awarded	No later than September 30, 2025

- Will late applications and/or resubmissions be accepted?
 The submission date is July 21, 2025, by 5:00 pm local time of application organization.
- Will applicants with PIs and/or key personnel serving on NIH peer review panels (i.e., study sections) overlapping with the application submission timeline be granted additional time for submission?
 - No. Other Transactions are not subject to the grant policies regarding NIH peer review panels.
- Will there be additional submission deadlines for this opportunity beyond July 21, 2025?
 - At this time, there is only this funding opportunity with a deadline of July 21, 2025. Any future funding opportunities in future fiscal years as part of the East Palestine, Ohio Train Derailment Study will be separate from the current Research Opportunity Announcement (OTA-25-007) and subject to congressional appropriations and the agency's programmatic priorities.

Eligibility

- Are there any eligibility restrictions?
 - See the ROA for the list of eligible entities. 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.

- I think I/my organization could contribute to this effort, but we are not eligible to submit a complete application. How can we be involved?
 - Please feel free to reach out to eligible organizations who might be interested in partnering with you. At this time, we cannot accept applications from organizations not meeting eligibility requirements.

Other Transactions

- What is Other Transactions Authority (OTA)?
 - Other Transactions Authority (OTA) is 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. Policies and terms for individual OTs 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 (Learn more about OTAs on the NIH website).
- Are OT applications reviewed by the standard NIH peer review process?
 - Applications to Other Transactions Research Opportunity announcements such as this one, are not reviewed by the standard NIH peer review process, but use custom processes referred to as Objective Review.
 - Responsive full applications submitted in response to the solicitation, will be
 reviewed by subject matter experts (SMEs) via an objective review process.
 Objective review will involve the submission of written critiques by SMEs against
 the Review Criteria provided in the ROA, and interactive discussions between
 those experts and NIH staff. The SME's may include NIH staff and other federal
 staff. Written opinions may be solicited from experts external to the federal
 government.
 - Components of the full applications may be accepted into the final plan in whole, in part, or may be omitted. The outcome of each review could result in a

modified work plan for each application based on reviewers' comments and recommendations.

Budget

- What is the budget for this opportunity?
 - Applicants to the East Palestine, Ohio Train Derailment Study Research
 Opportunity can submit a budget up to \$2,000,000 total (direct + F&A) costs per
 year for up to 5 years. The budget should reflect the actual needs of the
 proposed project. The NIH may elect to negotiate any or all elements of the
 proposed budget.
 - Incremental funding will be provided for up to 12 months. Additional funding will be awarded based on completion of approved project milestones/activities and subject to the availability of funds.
- Can you provide guidance on indirect costs? Are there any restrictions?
 - Institutions with an established Facilities and Administrative (F&A) rate should use their Federally approved indirect rate to calculate indirect costs.
 Any non-Federal entity, including for-profit organizations, that does not have a current negotiated indirect cost rate, except for those non-Federal entities described in 2 CFR Part 200, Appendix VII, Section D(1)(b) may elect to charge a minimis rate of 15% of MTDC.
- How should the budget for the community-engaged activities be organized?
 - It is expected that at least 20% of the total budget will be committed to community-engaged activities. Research teams are allowed to adjust their community-engaged spending across the project term as long as they don't reduce below 10% in any given year and as long as the average remains 20% across the project term.
 - Budget justifications must be provided for all budget items and budget years.
 - Budgets must adhere to latest NIH salary limitation notice (<u>See Salary Cap Summary</u>/Guidance on Salary Limitation for Grants and Cooperative Agreements).
- If a multi-PI application involves PIs at different institutions, can they submit separate budgets for each institution or are they required to submit one overall budget?
 - Applicants that wish to submit a multi-PI, multi-institution application will submit a single application with one overall budget from the lead institution that includes the funding for each of the participating institutions and sites. Postaward, there will need to be an established agreement from the lead institution to the additional institutions or sites that will participate in the work.

- How should applicants structure and submit their budget and budget justification documentation?
 - Refer to the <u>Instruction Guide for OTA Submissions via eRA ASSIST</u> for detailed instructions on how to navigate the system and complete the application, including the budget section. In addition to a line-item financial budget with defined expense categories (see the Budget section of the ROA for additional information) applicants should provide a written narrative justification for all budget items.
- Is pre-award spending allowed under this OTA?
 - No, there will not be any pre-award access to funds.
- Is there a preferred format for the milestone-based workplan and budget?
 - No, there is no preferred format for these elements of the application. Please organize this information so it is clear how milestones link to timelines and to budget allocations.

Application and Submissions

- What are the important dates for the full application?
 - Applications must be submitted via Application Submission System & Interface for Submission Tracking (ASSIST) by July 21, 2025, at 5:00 pm (based on the local time of the applicant organization). Applications received past this date will not be accepted.
- Which applications will not be reviewed?
 - Applications not meeting the eligibility requirements in the ROA will not be reviewed. Applications deemed nonresponsive or incomplete will not be reviewed.
- How should I upload the application content into the ASSIST platform? There are limited fields to upload documents when compared to submitting a typical NIH grant.
 - The number of required and optional fields displayed within ASSIST is greatly reduced when submitting an application in response to a Research Opportunity Announcement (i.e., OTA-25-007) as compared to a typical NIH grant application. Any sections of the application that are not specifically requested in the fields in ASSIST should be uploaded in the Attachments field.
- For the specific aims page, are figures and tables allowed?
 - Yes, figures and tables are allowed.
- Are references part of the 30-page limit for the project plan?

- Yes, references are part of the page limitations for the project plan.
- Who should submit letters of support?
 - Generally, letters of support would be expected from collaborators receiving financial support outside the primary institution, and any other substantial collaborators. Letters of support are not needed from investigators at the applicant institution, nor from individuals who may be potential study participants.
- Can text links be used in the application to save space?
 - Yes, hyperlinks can be used in the application. Please limit your use to relevant links only.

Data Strategy, Management and Sharing

- What are the requirements of the NIH Data Management and Sharing (DMS) Policy?
 - Please visit https://sharing.nih.gov/data-management-and-sharing-policy for more information.

Other Q&A

- Can previous NIEHS or NIH officials serve on external advisory boards?
 - There is no policy against previous NIH officials serving on external advisory boards.
- How does the Data Management and Sharing Plan differ from the data management infrastructure referenced in the ROA?
 - NIH promotes the sharing of scientific data. Under the NIH Data Management & Sharing Policy, investigators are empowered to choose the most appropriate methods for sharing scientific data. This sharing is generally geared toward the scientific community at large (see https://sharing.nih.gov/data-management-and-sharing-policy for more details).
 - The data management infrastructure referenced in the ROA would feed into the Data Management section of the DMSP, but is specific to the East Palestine Train Derailment Study and is intended primarily to facilitate the study and to build a foundation for longer-term investigations into the exposure and health consequences of the derailment for the community of interest in your application.
- Are studies of occupational cohorts responsive to the ROA?
 - Yes, if the occupational cohort was affected by the East Palestine Train
 Derailment, this is a community that would be responsive to the ROA.