Research Opportunity Announcement OTA-21-015L: Pathobiology Studies Using Observational and Clinical Trial Resources

1. PURPOSE

The National Institutes of Health (NIH) invites applications for ancillary research studies that expand the Researching COVID to Enhance Recovery (RECOVER) Program's understanding of Post-Acute Sequelae of SARS-CoV-2 infection (PASC, or Long COVID).

This Research Opportunity Announcement (ROA) encourages research applications that leverage RECOVER's established infrastructure, including its curated and well-characterized repository of biospecimens, comprehensive data resources, observational cohort studies (Adult, Pediatric, and Autopsy), including long-term follow-up studies, as well as RECOVER Clinical Trials (CTs), to investigate the pathobiological mechanisms underlying persistent symptoms and organ-specific deleterious effects of Long COVID.

These studies, together with the complementary ancillary studies notice NOT-HL-25-027, are expected to help identify, elucidate, and validate key pathophysiological mechanisms, prognostic biomarkers, and potential therapeutic targets for individuals affected by Long COVID.

2. BACKGROUND, GOALS, AND SCOPE

The RECOVER Pathobiology Program has been instrumental in advancing understanding of the long-term, multifaceted consequences of SARS-CoV-2 infection. To date, three funding announcements have supported more than 60 research projects, including those supported under NOT-OD-22-038, aimed at uncovering the pathobiological mechanisms involved in the development and progression of Long COVID.

As the NIH RECOVER Initiative continues to evolve, there remains an urgent need to continue leveraging these resources to address RECOVER's Research Questions, pursue emerging opportunities identified on the RECOVER Ancillary Studies page, investigate the pathobiological underpinnings of Long COVID, and improve health outcomes for people affected by Long COVID.

As of June 2026, NIH is expanding this ROA to include biosamples collected as part of RECOVER Clinical Trials.

The research studies solicited under this ROA will address one or more of the following goals:

- Identify and validate key contributing factors such as molecular, cellular, microbiome, or other relevant signaling pathways as potential targets for therapeutic interventions.
- Expand upon RECOVER's foundational clinical and translational research.
- Utilize established biospecimens, clinical data, imaging studies, and other relevant resources already curated under the RECOVER observational and clinical trial protocols. In addition to the primary use of RECOVER resources, validation efforts from other well-curated non-RECOVER repositories (e.g., LIINC at UCSF, longitudinal cohorts).
- Propose observational or mechanistic approaches that complement—but do not duplicate—ongoing RECOVER Pathobiology efforts.

- Identify and validate biomarkers to assess risk, stratify patients, improve diagnosis of Long COVID, and monitor safety and efficacy of interventions for treatment of Long COVID.
- Address critical and emerging research gaps as identified in the RECOVER Gaps and Opportunities document.
- Develop and validate bioassays that can inform and be utilized in clinical studies of Long COVID.

This ROA complements the ancillary studies solicitation notice NOT-HL-25-027, which focuses on RECOVER multi-site observational cohort studies. While that notice also encourages ancillary studies to RECOVER-CT, this ROA is broader in scope, encompassing both RECOVER observational studies and RECOVER-supported clinical trials.

The goals of NOT-HL-25-027 are intended to support pathobiology studies that include at least one of the following:

- Propose studies whose goals are synergistic with the overarching aims of the RECOVER Program.
- Focus on long-term follow-up of individuals with Long COVID, including investigations on persistent symptoms and organ-specific deleterious effects that add scientifically supported clinical measurements or tests to the follow-up examinations or contacts of RECOVER Adult or Pediatric cohorts.
- Leverage existing RECOVER infrastructure, including biospecimen repositories, longitudinal clinical data (see RECOVER Ancillary Studies), and emerging innovative tools (e.g., Artificial Intelligence/Machine Learning (AI/ML)) to maximize and accelerate scientific discoveries.
- Utilize observational, mechanistic, or interventional study designs for long-term follow-up studies, as appropriate.

Expectations for Collaboration with Patients and Community

Applicants are encouraged to consult the RECOVER Ancillary Studies page and the RECOVER Gaps and Opportunities document for community-identified priorities, and to describe concretely how patient and community perspectives will be incorporated at each stage of the proposed work. Applications should demonstrate that patients are treated as genuine partners across the full arc of the research, from shaping the question and design, through participation and engagement, to interpretation and dissemination of findings, so that the resulting study is both scientifically rigorous and meaningfully responsive to the needs of the PASC/Long COVID community. Specifically, applications should:

- Ground the research question in a known patient community priority, and show that patient input shaped eligibility criteria, procedures, and outcome selection.
- Select outcomes that reflect patients' lived experience, ideally co-developed with them, and design eligibility criteria that are inclusive and grounded in patient reality.
- Ensure the study is feasible and accessible, with accommodations for common PASC limitations, and include a realistic plan for engaging and compensating patients as partners throughout the study, not just at design or recruitment.

3. SPECIAL AWARD TERMS

The complete terms and conditions of each sub-agreement issued under this ROA are subject to negotiation and will be contained in the Other Transactions Agreement entered between the RECOVER Administrative Coordinating Center (ACC), on behalf of the NIH, and the Awardee. 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.

Publications, Authorship, and Collaboration

For studies involving RECOVER cohorts or resources, awardees are encouraged to have representation from the relevant RECOVER cohort(s) or infrastructure component(s) associated with that cohort (e.g., one per Hub/Core) to collaborate and serve as co-authors on associated manuscripts, provided they meet standard authorship criteria, such as International Committee of Medical Journal Editors (ICMJE), through meaningful intellectual contribution and participation in manuscript development. Implementation procedures will be developed to ensure authorship criteria are met and to minimize delays in the publication process. Additional details about this requirement will be provided by the RECOVER ACC and NIH OT Office.

4. LOWER TIER AGREEMENTS

With mutual consent of the Awardee and the NIH, the Awardee will be expected to issue sub-awards to entities identified and approved by the NIH under subsequent ROAs associated with this announcement.

5. ELIGIBILITY

Investigators from higher education institutions, government, nonprofit, for-profit, and other eligible institutions are encouraged to apply. Investigators from previously funded RECOVER Pathobiology studies are eligible to apply, and collaborations that integrate multidisciplinary approaches are particularly welcomed.

Applicant Organizations Required Registrations

Standard eligibility for OT may include:

Higher Education Institutions

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

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)

Local 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)

Federal Governments

- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations
- For-profit Organizations

Applicant organizations must complete and maintain the following registrations as described. All registrations must be completed prior to application submission. Registration can take 6 weeks or more; applicants should begin the registration process as soon as possible. Failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- **System for Award Management (SAM):** Applicants must complete and maintain an active registration, which requires renewal at least annually. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations that have not already been assigned a CAGE Code.
- **NATO Commercial and Government Entity (NCAGE) Code:** Foreign organizations must obtain an NCAGE code, in lieu of a CAGE code, in order to register in SAM.
- **Unique Entity Identifier (UEI):** A UEI is issued as part of the SAM.gov registration process. The same UEI must be used for all registrations and on the application.
- **DUNS Number:** Where requested in the application materials, applicants should provide the DUNS number and any associated expiration date information, if applicable, in addition to the UEI. Applicants should ensure that organizational identifiers are reported consistently across all submission materials.
- **eRA Commons:** Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registrations; all registrations must be in place by the time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.

Applicant organizations selected for award must have a valid Employer Identification Number (EIN)/Taxpayer Identification Number (TIN) and complete any required registrations necessary to receive federal funds, including enrollment in the HHS Payment Management System (PMS), as applicable.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (PD/PI)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the PD(s)/PI(s) is invited to work with their organization to develop an application for support.

6. AUTHORITY

This Research Opportunity Announcement (ROA) is issued with the goal of establishing an "Other Transactions" agreement or sub-agreement pursuant to **42 U.S.C. § 285b-3 and 42 U.S.C. § 282(n).**

7. SHARING OF DATA AND BIOSPECIMENS

The NIH expects and supports the timely release and sharing of research data from RECOVER-supported studies for use by other researchers to expedite the translation of research results into knowledge, products, and procedures to improve human health. See NIH Grants and Funding Scientific Data Sharing: Policies and Access to Data.

The overarching goal of this ROA is to lead to rapid delineation of Long COVID pathobiology to foster progress in diagnostic, therapeutic, and preventive avenues for this condition. To achieve this goal, awardees must pledge to rapidly share data and biospecimens, where not prohibited (e.g., Tribal data sovereignty), with the NIH RECOVER data and biospecimen repositories and ultimately with the broader research community.

Award recipients will work closely with RECOVER on data-sharing activities to advance the science of Long COVID research across the country.

8. KEY DATES

Applications will be accepted on a rolling basis throughout the period that this ROA remains open. Applications may be batched for review at the discretion of the NIH based on programmatic priorities, application volume, and other relevant considerations.

The NIH anticipates making award decisions and issuing awards approximately quarterly; however, the timing and frequency of application reviews and awards are subject to change at the NIH's discretion.

This ROA will remain open until the NIH determines that the objectives of the program have been met or that the opportunity should otherwise be closed. If the NIH anticipates closing this ROA, the announcement will be updated to include an anticipated close date. Except in limited circumstances, the

NIH will provide a minimum of eight (8) weeks' notice prior to the close date to allow prospective applicants sufficient time to prepare and submit applications.

9. DATA AND SAMPLE REQUEST

Prior to submitting a full application, applicants must request confirmation of availability of the data and samples required for their proposed research.

- For applications involving **RECOVER Observational & Tissue Pathology** samples, use the Observational Biospecimen Request Form.
- For applications involving **RECOVER Clinical Trial (RECOVER-CT)** samples, use the Clinical Trials Biospecimen Request Form.

Requests will be assessed to confirm availability of the specified data and samples, and applicants will receive a binary response (available / not available), with clarification provided as applicable. Applicants with confirmed availability will be invited to submit a full application.

10. APPLICATION FORMAT AND REQUIREMENTS

Materials submitted under this ROA must meet the following format requirements: no less than 0.5-inch margins on all sides and no less than 11-point font, except in formulas, legends, tables, and image descriptions. URLs should not be included except where specifically requested or where included in biosketch or reference/citation materials.

This ROA encourages collaborative research between different research groups within or outside of RECOVER teams. Applicants are encouraged to discuss their research plans with a representative from the RECOVER Pathobiology Program Scientist team, recoverpathbio@nih.gov, and the RECOVER Administrative Coordinating Center, recoverreviews@rti.org, to ensure that the proposed research is aligned with the overall RECOVER program objectives.

The application should clearly and fully demonstrate the proposer's capabilities, knowledge, and experience, and should justify the proposed budget. The application should develop a plan to support analysis and reporting of the projected number of biospecimens based on participant selection criteria and sampling time points (see RECOVER Ancillary Studies). The actual number of biospecimens and time points used may be reduced or eliminated based on interim analyses, recruitment, or other considerations.

Application must include the following required sections:

- Cover Page
- Abstract / Project Summary
- Specific Aims
- Project Plan
- Appendix

Each of these sections will be submitted electronically via the REDCap link provided below.

Cover Page

The Cover Page, completed in REDCap, must include:

- The application title
- The applicant's legal entity name, address and contact information, SAM UEI number and expiration date, DUNS number and expiration date (where applicable), and EIN number
- The name and contact information for the Principal Investigator(s) (maximum 3)
- List of key personnel with titles and affiliations (maximum 10)
- The name and contact information for the Awardee's Business Official, the person authorized to negotiate and bind the Awardee as a signatory to the Other Transactions agreement
- The total cost proposed

Abstract / Project Summary

The Abstract is limited to 1 page. It is a succinct and accurate description of the proposed work and must 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.

Specific Aims

The Specific Aims is limited to 3 pages. It must state concisely the goals of the proposed research and summarize the expected outcomes, including the impact that the results of the proposed research will have on the research field(s) involved. List succinctly the specific objectives of the proposed research.

Project Plan

The Project Plan is limited to 5 pages and must address the following five elements:

1. Significance and Innovation

- Describe the scientific premise, including consideration of its strengths and weaknesses, the study hypothesis, rationale, and the importance of the problem or critical barrier to progress the proposed project addresses.
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice.
- Describe how the application challenges current research or clinical practice paradigms, including any novel theoretical concepts, approaches, methodologies, instrumentation, or interventions and their advantages over existing alternatives.

2. Approach

- Describe the overall strategy, methodology, and resources, and how they will be integrated into the study design, including synergies with other ongoing studies and the overall program, cohort selection, longitudinal follow-up procedures, detection methodologies, statistical analysis, and outcome measures.
- Provide a description of the precise analyses planned, along with available information about sensitivity and specificity of technologies selected, and the type and amount of biospecimens or data requested from RECOVER.

- Include preliminary data on feasibility, limits of detection, and sample pre-analytic considerations. Applicants are expected to be fully familiar with the relevant RECOVER protocols.

3. Technical Approach, Analysis Plan, and Data Management

- Describe the statistical analysis and data management plans for raw data generated within the proposed research, including quality assurance procedures for all proposed assays, data harmonization for batch effects, and work performed at different research sites, if applicable.
- Describe procedures for biospecimen selection and transfer to research site(s), and, if a multi-site or multi-laboratory approach is selected, a feasible workflow for sharing samples released from the Long COVID Biorepository Core (BRC).
- Demonstrate that the proposed statistician or statistical analysis team has the skill and experience to evaluate the hypotheses in the Specific Aims. Utilization of biostatistics, data management, and/or bioinformatics core facilities at the hub site is permitted for observational cohort applications.
- Include plans for data sharing that detail the types of data to be managed and shared, related tools, software, and/or code needed to access or analyze the data, and plans for data preservation and access in accordance with the NIH Scientific Data Sharing Policy and RECOVER Sharing Data for Broader Impact policies and processes.

4. Project Timeline and Milestones

- Provide a project plan with measurable milestones and deliverables based on the listed aims and objectives for the requested period of support, including a feasibility assessment addressing potential challenges and proposed mitigation strategies.
- For applications involving the observational cohort, provide a timeline aligned with long-term follow-up objectives and milestones.
- For applications involving RECOVER Clinical Trials, expected timelines and milestones appropriate to the clinical trial resources requested. Information about RECOVER Clinical Trials can be found at trials.recoverCOVID.org.

5. Investigator(s)

- Describe the experience of key personnel supporting the planning and implementation of activities described in the ROA, including expertise in relevant analytic modalities, platforms, and methodologies on biospecimens, imaging procedures, and other examination components, as well as expertise in data analysis and management, statistical methods, AI/ML, or bioinformatics. NIH biosketches for key personnel must be provided in the Appendix.
- Provide examples of prior project experience relevant to research areas described in this ROA. Each example should include the total funding awarded, dates of award, contact information for a sponsor able to serve as a reference, and a brief description of the project and its relevance to this ROA. Applicants proposing long-term follow-up studies must demonstrate prior work with multi-center clinical research, consortia, or networks.

6. Environment

- Describe the organizational resources available to perform the proposed effort, including project administration, staffing, and quality control. Explain how the scientific environment contributes to the probability of success.

Note on Resource Sharing and Human Subjects: NIH considers sharing of research resources an important means to enhance the value of NIH-sponsored research; refer to NIH Grants and Funding Scientific Data Sharing: Policies and Access to Data. If the proposed project requires engagement in human subjects research, the proposer must obtain a Federalwide Assurance (FWA) and comply with all applicable laws and regulations. These items will be addressed during the post-submission review and award negotiation process and need not consume project plan page space.

Appendix Items

The technical plan may be supported by the following required and supplemental materials as Appendix Items. These materials do not count toward the page limits and should not be used to circumvent required application sections.

Required:

- References or list of citations
- Senior/Key Personnel biosketches (conform to the most recent NIH format requirements)
- Other Support for Senior/Key Personnel in the Common Form format; use SciENcv to prepare the form

If applicable:

- An existing manual of operations from a prior or ongoing externally funded project serving as external core resource or cohort

Budget and Project Period

The Budget section must provide a realistic, fully justified project period, and the budget and cost must reflect the actual needs of the application for performing the work specified in the ROA.

Budgets may be up to **$800,000 total costs per year** for up to a **2-year period of performance.** Applicants applying to leverage data and biospecimens that are readily available in RECOVER should plan for a project period of up to 12 months; requests for a 2-year period must be accompanied by strong scientific justification.

Budget materials must be submitted via the REDCap link provided below.

Include, for each prime award and each subcontract:

- A detailed budget for each budget period of up to 12 months. The detailed budget Standard Form 424 (Research & Related) is highly encouraged for ease of review and consistency in cost category information.
- A Budget Justification is required to accompany each detailed budget. Include the Fringe Rate for personnel costs and Indirect Cost Rate and date of negotiated rate agreement, as applicable to your institution. The budget justification should provide cost-basis detail for non-personnel cost categories represented in the budget.

Requests for **travel are not permitted** under this ROA. Requests for capital expenses for instruments or equipment are also not permitted. The NIH Salary Cap must be strictly observed for all budgets. Effective January 11, 2026, the salary limitation is $228,000.

11. APPLICATION SUBMISSION INSTRUCTIONS

Applications must be submitted electronically via the designated NHLBI internal submission system, REDCap. The required application information must be entered by the PI or their designee on the form provided at the REDCap link below. A code will be provided for return access to the REDCap form. The completed application form must be submitted by an organizational Signing Official via REDCap. Applications that are nonresponsive to the terms of this announcement will not be considered for review.

REDCap application submission link: RECOVER Pathobiology Studies Using Observational and Clinical Trial Resources - OTA-21-015L

12. APPLICATION RESPONSIVENESS AND SELECTION CRITERIA

Applications that are noncompliant, whether due to missing required elements or inclusion of materials not permitted under the ROA, may be administratively withdrawn as nonresponsive.

***Common grounds for withdrawal**:*

- Missing required attachments or application components
- Noncompliance with page or budget limitations
- Submission proposing approaches or project types explicitly excluded in this ROA
- Submission through an incorrect system or channel
- Applications submitted without prior approved Data and Sample Request
- Failure to meet applicant eligibility requirements
- Failure to comply with formatting requirements outlined in this ROA and the submission portal

13. REVIEW AND SELECTION CRITERIA

Applications that meet eligibility requirements will be reviewed by external subject matter experts using the merit-based criteria outlined in this announcement. All applications undergo an objective assessment of scientific and technical merit in accordance with the Federal Advisory Committee Act (FACA).

The outcome of review may result in a modified work plan, with application components accepted in whole, in part, or omitted entirely. This modified work plan, as shaped by the review process, will serve as the blueprint for final negotiated terms and milestones for resulting awards. The following criteria will be used to evaluate and select applications for award:

Overall Impact: Reviewers will provide an overall impact score reflecting their assessment of the likelihood that the project will advance understanding of the mechanisms underlying Long COVID manifestations, including those responsible for multi-organ and multi-system dysfunction and associated symptoms.

In consideration of the scored review criteria and additional review criteria below, reviewers will assess how well the project leverages NIH RECOVER Observational, Tissue Pathology, or Clinical Trial cohorts, associated resources, and potential synergies with ongoing studies. An application does not need to be strong in all categories to be judged likely to have major scientific impact.

Factor 1. Importance of the Research

Significance

- Evaluate the importance of the proposed research in the context of current scientific challenges and opportunities, either for advancing knowledge within the field, or more broadly. Assess whether the application addresses an important gap in knowledge in the field, would solve a critical problem, or create a valuable conceptual or technical advance.
- Evaluate the rationale for undertaking the study, the rigor of the scientific background for the work (e.g., prior literature and/or preliminary data) and whether the scientific background justifies the proposed study.
- Specific to this ROA:
  - How significant or compelling are the proposed hypotheses?
  - Will the proposed studies address one or more emerging research challenges identified on the NIH RECOVER Ancillary Studies website?
  - How might the proposed research increase understanding of the molecular pathways that underlie the long-term effects of SARS-CoV-2 infection, including its resolution?
  - In what way does the proposed research have the potential to inform the diagnosis, prevention, mitigation, and/or treatment of PASC through elucidating the clinical pathogenetic mechanisms of PASC and the identification of associated clinical pathways?

Innovation

- Evaluate the extent to which innovation influences the importance of undertaking the proposed research. Note that while technical or conceptual innovation can influence the importance of the proposed research, a project that is not applying novel concepts or approaches may be of critical importance for the field.
- Evaluate whether the proposed work applies novel concepts, methods or technologies or uses existing concepts, methods, technologies in novel ways, to enhance the overall impact of the project.

Factor 2. Rigor and Feasibility

Approach

- Evaluate the scientific quality of the proposed work. Evaluate the likelihood that compelling, reproducible findings will result (rigor) and assess whether the proposed studies can be done well and within the timeframes proposed (feasibility).

Rigor:

- Evaluate the potential to produce unbiased, reproducible, robust data.
- Evaluate the rigor of experimental design and whether appropriate controls are in place.
- Evaluate whether the sample size is sufficient and well-justified.
- Assess the quality of the plans for analysis, interpretation, and reporting of results.

- Evaluate whether the investigators presented adequate plans to address relevant biological variables, such as sex or age, in the design, analysis, and reporting.
- For applications involving human subjects or vertebrate animals, also evaluate:
    - the rigor of the intervention or study manipulation (if applicable to the study design).
    - whether outcome variables are justified.
    - whether the results will be generalizable or, in the case of a rare disease/special group, relevant to the subgroup.
    - whether the sample is appropriate and sufficiently diverse to address the proposed question(s).
- Specific to this ROA:
    - How are the applicants' hypotheses clinically relevant regarding the pathobiology of Long COVID, based on experience or expertise in pertinent biological pathways, systems, organs, or diseases?
    - Is the proposed approach optimally designed to test the proposed hypotheses?
    - In what way has the proposed research set forth appropriate methodology and feasible project timelines, milestones, and deliverables?

Feasibility and synergy:

- Evaluate whether the proposed approach is sound and achievable, including plans to address problems or new challenges that emerge in the work. For proposed studies in which feasibility may be less certain, evaluate whether the uncertainty is balanced by the potential for major advances.

For applications involving RECOVER Clinical Trial (RECOVER-CT) samples:

- Is the proposed approach feasible, appropriately leverages existing RECOVER-CT data and biospecimen resources, and avoids redundancy with ongoing RECOVER-CT efforts?
- Does the application demonstrate synergy with and alignment to overarching RECOVER-CT program objectives?
- Is the proposed analytical approach appropriate for the type, volume, and clinical characteristics of available RECOVER-CT specimens, including compatibility with established collection protocols, storage conditions, and trial design ?
- Does the applicant demonstrate adequate understanding of the RECOVER-CT trial design, data linkage requirements, biospecimen handling procedures, and applicable regulatory and governance frameworks?
- Is the proposed timeline and resource plan realistic given access, processing, and approval requirements, including anticipated lead times for sample retrieval, data linkage, or committee review?
- Are participant privacy protections, de-identification standards, and data security requirements for clinical trial specimens and linked data adequately addressed?

For applications involving RECOVER Observational and tissue pathology samples:

- Is the proposed research aligned with RECOVER program objectives, demonstrates synergy with ongoing programs, and avoids potential overlap with ongoing RECOVER efforts?
- Does the proposed approach make strategic use of existing RECOVER data, biospecimen resources, or established cohorts, rather than duplicating existing infrastructure or data collection?
- Is the proposed analytical approach appropriate for the type and volume of available specimens or data?
- Does the applicant demonstrate adequate understanding of RECOVER data structures, biospecimen handling requirements, and access procedures?
- Is the proposed timeline and resource plan realistic given the access and processing requirements of the requested materials?

Patient representatives will consider whether:

- The study addresses something the PASC patient community genuinely needs answered.
- The study's eligibility criteria include the right patients with PASC.
- Things being measured in the study are what actually matters to patients with PASC.
- The study is realistic for patients to participate in, including those most affected by PASC.
- Would you or patients you know consider taking part in this study.
- Were patients genuinely involved in designing this study.
- There is a solid, realistic plan to keep patients meaningfully involved for the full duration of the study.

Factor 3. Expertise and Resources

Investigator(s)

- Evaluate whether the investigator(s) have demonstrated background, training, and expertise, as appropriate for their career stage, to conduct the proposed work. For Multiple Principal Investigator (MPI) applications, assess the quality of the leadership plan to facilitate coordination and collaboration.

Specific to this ROA:

- To what extent do the applicants have expertise and experience in cross-disciplinary clinical understanding of tissue/organ/system dysfunction caused by other forms of tissue/organ/system injury relevant to multisystem dysfunction in PASC?
- How well do the applicants propose to develop cross-disciplinary and collaborative research?

Environment

- Evaluate whether the institutional resources are appropriate to ensure the successful execution of the proposed work.

Scored Review Criteria

Reviewers will consider Factors 1, 2, and 3 in the determination of scientific merit and provide an overall score. In addition, Factors 1 and 2 will receive a score, and Factor 3 will be rated sufficient/insufficient.

- **Factor 1.** Importance of the Research (Significance and Innovation)
- **Factor 2.** Rigor, Technical Approach, and Feasibility (Approach)
- **Factor 3.** Expertise and Resources (Investigator(s) and Environment)

Additional Review Criteria (scored within Overall Impact, not separately)

As applicable for the project proposed, reviewers consider the following additional items while determining scientific and technical merit, but do not give criterion scores for these items, and should consider them in providing an overall impact score.

- **Protections for Human Subjects:** For research that involves human subjects, evaluate justification for involvement and proposed protections per 45 CFR Part 46 guidelines and Guidelines for the Review of Human Subjects.
- **Biohazards:** When the proposed research includes Biohazards, evaluate whether specific materials or procedures that will be used are significantly hazardous to research personnel and/or the environment, and whether adequate protection is proposed.
- **Data Sharing:** Evaluate the Data Management and Sharing Plan, and how well applicants propose to rapidly share data and results with the broader research community, including deposition into dbGaP or BioData Catalyst, and plans for rapid publication of results.

Additional Review Considerations (not scored)

As applicable for the project proposed, reviewers consider each of the following items, but do not give scores for these items, and should not consider them in providing an overall impact score.

- **Authentication of Key Biological and/or Chemical Resources:** For projects involving key biological and/or chemical resources, evaluate the brief plans proposed for identifying and ensuring the validity of those resources.
- **Budget and Period of Support:** Evaluate whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

Final award decisions will be made by the RECOVER SPO based on scientific priority and merit, potential impact on Long COVID research, availability of funds and requested budget, and programmatic balance.

NIH RECOVER staff will review the proposed budgets and budget justifications to ensure that the budget proposed is reasonable and the proposed project duration is justified. Applicants may be required to provide supplemental information or clarifications during the review process.

14. CONTACT AND ADDITIONAL INFORMATION

For inquiries regarding the scope of this ROA, submission instructions, or further details about RECOVER resources, please contact the RECOVER Administrative Coordinating Center at recoverreviews@rti.org.

Additional guidance, FAQs, and application resources are available on the RECOVER Funding page: https://recovercovid.org/funding.

Requirements Prior to Award Issuance

If an application is selected for potential award, the NIH may request additional documentation from the applicant prior to award issuance. Such materials may include, but are not limited to:

- Updated biographical sketches
- Current and pending Other Support information
- Other documentation deemed necessary to support final award determinations

15. NEGOTIATION

NIH reserves the right to:

- Select for negotiation all, some, one, or none of the applications received in response to this ROA.
- Segregate portions of awards into components and their associated budget and/or milestones that differ from those proposed.
- Accept applications in their entirety or select only portions of applications for award.
- Fund projects in increments and/or with options for continued work at the end of one or more phases, which can consist of more than one milestone.
- Fund projects in increments with options to terminate activities based on evolving data, needs, or priorities of the initiative.
- Request additional documentation, including certifications.
- Remove proposers from award consideration should the parties fail to reach a finalized, fully executed agreement, or if the proposer fails to provide requested additional information in a timely manner.

Date: 2026-08-06