

**Research Opportunity Announcement OTA-21-015E:
Research on Pathobiological Mechanisms Underpinning the Clinical Phenotypes, Symptomatic
Manifestations, and Multi-tissue/organ Pathology of Post-Acute Sequelae of SARS-CoV-2 Infection**

Purpose

This announcement encourages RECOVER investigators with expertise and insights germane to post-acute sequelae of SARS-CoV-2 infection (PASC) clinical pathobiology to apply for funding that would enable them to apply cross-disciplinary approaches and leverage RECOVER cohort participant enrollment, as well as samples and data collected as part of the RECOVER clinical protocol (under OTA-21-015B) to rapidly advance understanding of the biologic mechanisms underpinning the clinical phenotypes and symptoms of PASC, and the associated multi-tissue/organ pathology.

Background

To further the goals of the National Institutes of Health (NIH) Researching COVID to Enhance Recovery ([RECOVER](#)) Initiative, the agency is requesting proposals that address the urgent need to identify the pathobiological mechanisms that characterize the clinical manifestations and multi-organ/system injury resulting from SARS-CoV-2 infection. These effects can include multiple symptoms and multi-tissue/organ injury that persist long past the time that patients have recovered from the initial stages of COVID-19 (often referred to as long COVID) as well as new symptoms that arise after the time of initial infection and may evolve over time (e.g., MIS-C). These effects give rise to multiple, and as yet not well-defined, clinical phenotypes. Symptoms can persist for months and can range from mild to incapacitating. Symptoms can include fatigue, post exertional malaise, shortness of breath, difficulties with concentration and attention (“brain fog”), sleep disorders, fevers, gastrointestinal symptoms, anxiety, depression, headache, a variety of pain syndromes, postural orthostatic tachycardia, and others identified and as yet unidentified. The clinical phenotypes may also represent prodromes to future health threats (i.e., development of autoimmune diseases). While still being defined, these clinical and sub-clinical effects are collectively referred to as post-acute sequelae of SARS-CoV-2 infection (PASC).

Research Objectives

To make rapid progress in understanding the clinical manifestations of PASC and the mechanisms leading to the various symptoms, dysfunction of multiple organs and biologic systems, and phenotypes seen in PASC patients, the NIH encourages the submission of proposals to support these goals.

Examples of possible research to be proposed include but are not limited to the following:

- Studies of SARS-CoV-2 clearance in different tissues after acute infection, with focus on potential persistence of virus and its effects on organ function and chronic immune activation;
- Leveraging biospecimens from well-characterized PASC patient and controls developed within the RECOVER consortium to pursue in-depth characterization of immune response that could shed light on development of autoantibodies;
- Modeling of the interaction between pre-existing organ dysfunction/pathology (e.g., obesity, diabetes, hypertension) and the superimposition of viral infection/injury;
- Host and environmental factors and associated biological pathways (including the microbiome or existing cardiac, respiratory, metabolic, neurologic, or hematologic conditions) that predispose to development of, or resistance to, PASC;

- Time course and features of virus-host interactions leading to PASC, including the impact of SARS-CoV-2 infection on innate and adaptive immune responses;
- Host and environmental factors and the associated biological pathways that mediate the intensity and duration of the neurological, metabolic, immunologic, hematologic, and cardiopulmonary and vascular dimensions of PASC, including long-term host tissue responses, and affect recovery (e.g., modeling of viral infection on inflammation in the brain and CNS dysfunction);
- Biological effects/consequences of the virus-host interaction of SARS-CoV2 infection via ACE2 on modulating tissue/organ function over time including both short-term and long-term sequelae (e.g., mechanistic interplay between the ACE2-expressing neuroepithelial cells, the host-tissue pro-inflammatory milieu, the blood-brain-barrier and alterations in sensory neuron function in the pathogenesis of anosmia in PASC);
- Studies elucidating the pathogenesis of the varied sub-phenotypes of multi-organ dysfunction characteristic of PASC;
- Use of artificial intelligence or machine learning approaches to understand the clinical pathobiology of PASC, its manifestations, and potential prevention strategies;
- Cellular, metabolic, and immune factors as a result of viral infection as a trigger/sustainer of PASC symptoms and clinical phenotypes;
- Dynamics of innate and adaptive immune responses in PASC and implications for screening, diagnostic assay development, and predisposition to develop future immune dysfunctions; and
- Using single cell -omics and spatial -omics to systematically (unbiasedly) discover key individual cells and molecular pathways likely responsible for PASC symptoms, organ system dysfunction and sub-phenotypes. Discovery studies such as this may generate innovative hypothesis for future PASC-related studies.

It is envisioned that the applicants for this highly competitive program will propose efficient, cross-disciplinary, and collaborative research teams to address their hypotheses and will have one or more of the following:

- Expertise in clinical assessment of SARS-CoV-2 infection and in elucidating the pathogenesis of the clinical manifestations of PASC;
- Expertise in similar post-infection disorders that share clinical manifestations with PASC and that may have similar protean symptomatology and share common pathobiological mechanisms;
- Expertise in the clinical manifestations of PASC based on experience or expertise in chronic viral infection, immune-autoimmune disorders, germane biological pathways, systems, organs, or diseases;
- Expertise and experience in cross-disciplinary clinical research focusing on tissue/organ/system dysfunction caused by other forms of tissue/organ/system injury relevant to multisystem symptomatology and organ/tissue dysfunction as observed in PASC; and
- Expertise and experience in using tissue and other biospecimens from COVID-19 and/or PASC patients to pursue biomarker discovery, in-depth phenotyping assays (e.g. immunophenotyping; -omics) and *in vitro* studies to gain mechanistic insights.

Supported research is expected to inform the diagnosis, prevention, mitigation, and/or treatment of PASC through elucidating: the pathobiological mechanisms and pathways underpinning post-acute sequelae, the molecular mediators of its protean symptomatology, and the possible multiple clinical clusters/sub-phenotypes. Toward these ends, supported research is expected to leverage and build upon—but should not duplicate—RECOVER cohort enrollment, samples, and data collected during the

protocol implementation. If necessary, additional samples and data previously collected outside the RECOVER study could also be utilized to confirm some of the findings.

Requirements

Proposals should have the potential to lead to rapid delineation of the pathogenesis of PASC clinical symptomatology, multi-organ dysfunction, and patients' sub-phenotypes in order to foster progress in diagnostic, therapeutic, and preventive avenues for PASC. To achieve those goals, applicants must pledge to rapidly share data and biospecimens with the NIH RECOVER (<https://recovercovid.org/>) data and biospecimen repositories and ultimately with the broader research community. A pledge of rapid submission of results for publication will also be a criterion for application consideration.

Application and Submission Information

Applications should be submitted using the eRA Commons ASSIST feature. All applications submitted in response to OTA-21-015E should include the following:

1. A Cover Page (single page) including the following:
 - a. The proposal title. Please ensure to reference the ROA# OTA-21-015E in the title of the proposal to ensure expedited processing.
 - b. The applicant's:
 - i. Legal entity name
 - ii. Address and contact information
 - iii. SAM # and expiration date
 - iv. DUN # and expiration date
 - v. EIN number
 - c. The name and contact information for the applicant's Principal Investigator (with eRA Commons account information)
 - d. List of key personnel with titles and affiliations
The name and contact information for the applicant's Business Official, the person authorized to negotiate and bind the applicant as a signatory to the Other Transaction agreement
 - e. The total cost proposed for each year
2. Research Strategy section is limited to 6 pages and should include the planned timeline, milestones, and deliverables for the proposed research.
3. Requests are for one year (an additional year could be considered with appropriate justification).
4. Fully justified, itemized budget with attached budget justification.

Proposed budgets should generally not exceed a maximum direct cost of \$500,000 per year. In addition, the maximum total costs should generally not exceed \$800,000 per year. A higher proposed budget could be considered if appropriately justified. The proposed budget must reflect the actual needs of the proposed project.

Applications nonresponsive to terms of this announcement will not be considered for review.

Review Process

The RECOVER Administrative Coordinating Center will coordinate the review of applications by NIH subject matter experts and external experts. Prioritization and funding decisions will be made by NIH.

Review Criteria

Only the review criteria described below will be considered in the review process:

Budget and Period of Support

NIH staff will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

Overall Impact

Given that the aim of these awards is to leverage the RECOVER cohorts to make rapid progress in understanding the mechanisms underpinning the manifestations of PASC, including the mechanisms responsible for the multi-organ/system dysfunction leading to the various symptoms of PASC:

- How might the proposed research increase understanding of the molecular pathways that underlie the long-term effects of SARS CoV-2 infection?
- In what way(s) do the applicants have expertise in understanding the clinical manifestations of PASC and similar post-infection disorders that may share clinical manifestations and mechanistic pathways with PASC?
- How are the applicants' hypotheses clinically relevant regarding the pathobiology of PASC, based on experience or expertise in pertinent biological pathways, systems, organs, or diseases?
- 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 do the applicants propose to develop cross-disciplinary and collaborative research?
 - For this particular announcement, note the following: A Multiple PD/PI leadership format is strongly encouraged. The application should include at least one PD/PI with expertise in SARS-CoV-2 clinical science and at least one PD/PI whose primary expertise is in clinically relevant cell biology, physiology, pathophysiology, pathobiology, and/or metabolism. The Multiple PD/PI leadership team might not have previously published together or otherwise have an extensive history of collaboration. The development of the project itself, as reflected in the quality of the preliminary data, the rigor of the approach, and the Multiple PD/PI leadership plan, can provide evidence of a strong and dedicated Multiple PD/PI team.
- 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?
- In what way has the proposed research set forth appropriate methodology and feasible project timelines, milestones, and deliverables?
- How do the applicants propose to rapidly share data and results with the broader research community, including, as appropriate, deposition into dbGaP, and how will they rapidly submit results for publication?

Eligibility

The following entities are eligible to receive an award under this ROA:

- *RECOVER Cohort Sites with fully executed contract with the NYU CSC*

Submission and Contact Information

Proposals should be submitted by the proposing entity's business official via eRA ASSIST not later than **January 31, 2022 by 5 PM EDT**. If applicants are not registered in eRA or experience difficulty with submission please contact NHLBI_OTA@mail.nih.gov for assistance. Inquiries can also be submitted to NHLBI_OTA@mail.nih.gov. Financial and administrative questions should be addressed to Kevin Heath, NHLBI Agreements Officer. Questions about the scientific scope of the studies should reference in the subject line the OTA number and specific research study component(s) in question to help route the inquiry as appropriate.

A note about eRA Registration

NIH uses the eRA Commons system to administer OT awards. If you are selected to participate you may need to submit additional information in eRA ASSIST, you will need to be registered in eRA Commons, which can take some time to complete – as many as several weeks in some cases. Therefore, if you are considering submitting a proposal and are not yet registered in eRA, it is highly recommended that you begin the process of registering your organization, Program Director/Principal Investigator (PD/PI) and Signing Official (SO) in eRA Commons as soon as possible to avoid possible award processing delays. To register, please follow the instructions via this website:

<https://public.era.nih.gov/commons/public/registration/registrationInstructions.jsp>.

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, the 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 SO will be prompted to electronically sign your registration request. (Please review your registration information carefully.)
7. Once your SO has electronically signed the request, your organization will be active in Commons and you may create and maintain additional accounts for your institution staff.

To complete the registration above, you may need to register for the following if you haven't done so already:

- Dun & Bradstreet Number (DUNS) - <https://fedgov.dnb.com/webform/>
- Employer Identification Number (EIN)- <https://www.irs.gov/businesses/small-businesses-self-employed/apply-for-an-employer-identification-number-ein-online>
- Small Business Administration (SBA) - <https://www.sbir.gov/registration>
- System for Award Management (SAM) - <https://www.sam.gov/SAM/>

RECOMMENDED SUBMISSION TIPS

1. **FILE FORMAT:** As a reminder, the eRA ASSIST submission system requires the use of non-fillable PDF forms. Please be sure the PDF forms you are using are not fillable. If you are unsure whether your document meets the submission requirement it is recommended to print the document using a PDF writer (using the Print option and selecting the PDF writer as your printer) or contact [the eRA Helpdesk](#).
2. **ADDING ATTACHMENTS:** Utilizing the eRA ASSIST option to upload multiple attachments will create a linked Table of Contents in your OT application based on the attachment file names in the order they are uploaded. Submitting in this manner will provide greater efficiency in the review of your application. Users may Click on the Add Attachment button pictured below for each attachment to be added.



As an example, the OT Office therefore recommends uploading multiple attachments using the following naming conventions in the following recommended order. Please note, the Attachment document must be saved or renamed using the File Name prior to upload:

| Attachment | File Name |
|---|-----------------------------------|
| Technical Plan | Technical Plan.pdf |
| List of Key Personnel and Biosketches | Key Personnel.pdf |
| Leadership Plan for Multi-PI applications (as applicable) | Leadership Plan.pdf |
| Milestones Plan (as applicable) | Milestones.pdf |
| Main Budget and justification | <Application Component>Budget.pdf |
| Subaward 1 Budgets and justification | Subaward_<SubName1>.pdf |
| Subaward 2 Budgets and justification | Subaward_<SubName2>.pdf |
| Letters of Support | Letters of Support.pdf |

3. **ADDITIONAL ATTACHMENTS:** If your application consists of any additional section not covered in the chart above, the OT office recommends that you submit the sections individually using the process referenced in #2 above. **Please be clear in the naming of files to indicate the content of each attachment.**
4. **REVIEW SUBMISSION:** At any point while preparing your application, you can click the “Validate Application” button to check business rules as well as preview the application image. This will ensure that the attachments appear as expected. Instructions for performing the validation can be found on page 12 of this document.
5. **SUBMISSION WALKTHROUGH:** For a complete walkthrough of the submission process please see the eRA OTA Submissions Instruction Guide on the following pages of this document.

Instruction Guide for OTA Submissions

Use these instructions, together with the forms and information found in the funding opportunity announcement, to complete your application. The funding opportunity announcement (FOA) will include specific instruction and forms needed for your application submission. Remember that the FOA instructions always supersede these application instructions.

Prepare to Apply

NIH typically makes awards to organizations, not individuals. At the time of submission, the Program Director/Principal Investigator (PD/PI) and their organization must be registered at [eRA Commons](#). In addition to the PD/PI, an individual with the role of Signing Official (SO) is needed. If an application is awarded, additional registrations (e.g. [System Award Management](#)) will be required.

OTA applications must be submitted using NIH's [ASSIST](#) web-based application submission system. Users can access ASSIST directly or through eRA Commons. To complete the application, users must have access to a browser, a pdf generator, and Adobe Reader software.

Log into ASSIST using eRA Commons credentials (username and password)

Application Submission System & Interface for Submission Tracking (ASSIST)
Sponsored by the National Institutes of Health

Login

User Name

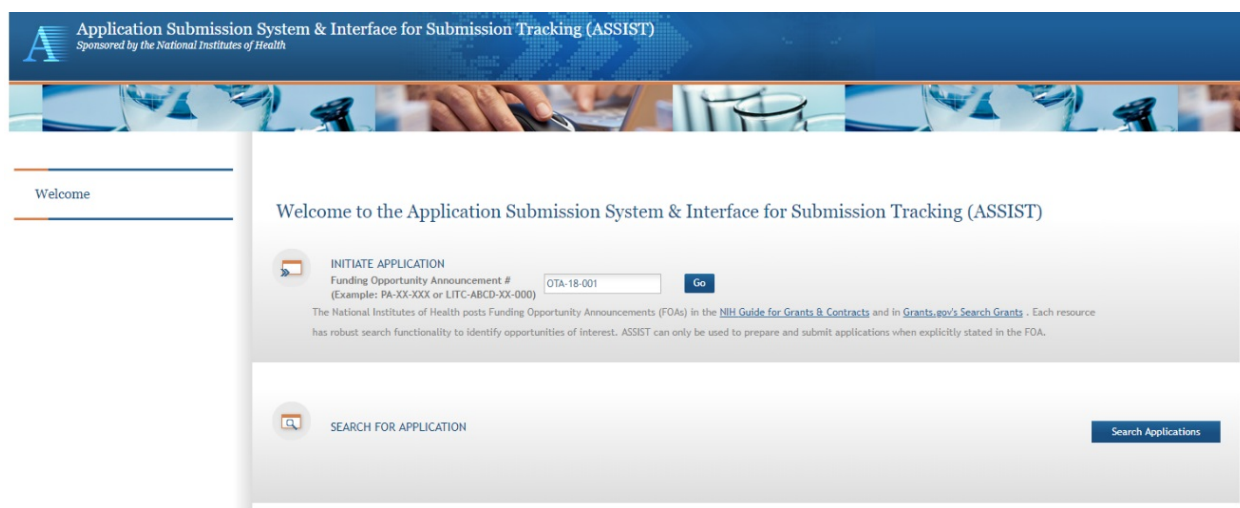
Password

[Forgot Password/Unlock Account?](#)

Note: Effective March 22, 2018: If you are registering a new entity in SAM.gov, you must provide an original, signed [notarized letter](#) stating that you are the authorized Entity Administrator before your registration will be activated. Read [FAQs](#) to learn more about this process change.

Note: When application and grant reporting submission delays occur because the applicant or recipient organization is officially closed due to a natural disaster or other emergency, the NIH will consider accepting late applications and reports, on a case-by-case basis. Please reference notice [NOT-OD-17-106](#) in the NIH Guide for Grants and Contracts for additional details.

Submit grant applications electronically to NIH and other Public Health Service Agencies...





The screenshot shows the ASSIST (Application Submission System & Interface for Submission Tracking) Welcome screen. At the top, a blue banner contains the ASSIST logo and the text "Application Submission System & Interface for Submission Tracking (ASSIST) Sponsored by the National Institutes of Health". Below the banner is a horizontal strip of images showing laboratory glassware and hands working with equipment. On the left, a sidebar with a "Welcome" link is partially visible. The main content area has a heading "Welcome to the Application Submission System & Interface for Submission Tracking (ASSIST)". It features two primary sections: "INITIATE APPLICATION" and "SEARCH FOR APPLICATION". The "INITIATE APPLICATION" section includes a form for "Funding Opportunity Announcement #" with the example "OTA-18-001" and a "Go" button. Below this, a note states that the NIH Guide for Grants & Contracts and Grants.gov's Search Grants are used for finding opportunities. The "SEARCH FOR APPLICATION" section includes a search bar and a "Search Applications" button.

Application Submission System & Interface for Submission Tracking (ASSIST)
Sponsored by the National Institutes of Health

Welcome

Welcome to the Application Submission System & Interface for Submission Tracking (ASSIST)

 **INITIATE APPLICATION**
Funding Opportunity Announcement #
(Example: PA-XX-XXX or LITC-ABCD-XX-000)
The National Institutes of Health posts Funding Opportunity Announcements (FOAs) in the [NIH Guide for Grants & Contracts](#) and in [Grants.gov's Search Grants](#). Each resource has robust search functionality to identify opportunities of interest. ASSIST can only be used to prepare and submit applications when explicitly stated in the FOA.

 **SEARCH FOR APPLICATION**

Initiating the Application

On the ASSIST Welcome screen, enter the OTA ROA number in the Funding Opportunity Announcement # field and then click 'Go'.

The Initiate Application screen contains several required elements: At a minimum the Application Project Title must be entered, and the Lead Applicant Organization must be selected from the drop-down menu.

The Contact PD/PI fields may be pre-filled from Commons Username using the button or entered manually. These fields will be available to edit in the application once it has been initiated.

Once required fields have been satisfied, press the “Initiate Application” button to create an application record.

Home > Search for Applications > Initiate Application

Initiate Application for ROA #: OTA-18-005

Home > Search for Applications > Application Information

Hide Navigation Show Help

Application Information

Application saved

Summary OTA Core

Application Information

Application Identifier: 955437
Application Project Title: test
PD/PI Name:
Organization: WHATSAMATTA U
Project Period:
Status: Work in Progress Submit Application "Submit Application" is only active for Signing Officials

Contact Project Director/Principal Investigator

Enter PD/PI Information below or

First Name:
Middle Name:
Last Name:

Pre-fill Application from Username Clear

Initiate Application Cancel

Navigating the Application

Each application in ASSIST receives a unique Application Identifier at creation. This value is displayed on the Application Information Summary page and can be used as a search key on the Search for Applications screen if returning to work on the application at a later time.

Home > Search for Applications > Application Information

Hide Navigation Show Help

Application Information

Application saved

Summary OTA Core

Application Information

Application Identifier: 955437
Application Project Title: test
PD/PI Name:
Organization: WHATSAMATTA U
Project Period:
Status: Work in Progress Submit Application "Submit Application" is only active for Signing Officials

Actions are available on the left-hand side of the screen. The Summary screen and any constituent forms in the application are loaded as tabs to the right of the action menu.

Navigate to the OTA Core form by clicking the grey tab for the form. The currently active tab will be highlighted in blue.

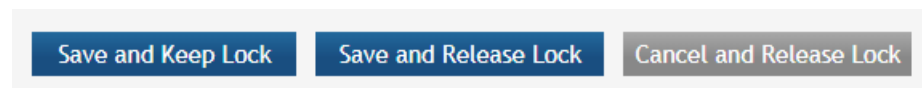
Completing the Application Form

All fields marked by an asterisk (*) are required.

All attachments should be in the format of a PDF file.

Click on “Edit” button to begin data entry. In the “edit” mode, data entry by other users is blocked until the lock-holder either releases the lock or it expires.

At the bottom of the form there are several saving options:



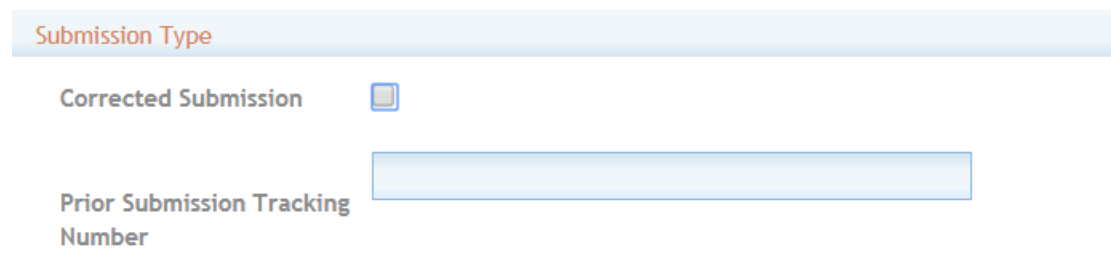
Three buttons are displayed in a row. The first button is blue with white text and says "Save and Keep Lock". The second button is blue with white text and says "Save and Release Lock". The third button is grey with black text and says "Cancel and Release Lock".

Save and Keep Lock: saves data and restricts data entry access to current user

Save and Release Lock: saves data and releases form to other users

Cancel and Release Lock: does not save data and releases form to other users

Submission Type: If the application is being resubmitted after correcting errors/warning, check “Corrected Submission” and enter prior submission tracking number as it appears in the footer of the prior submission.



The "Submission Type" section contains two items. The first is a checkbox labeled "Corrected Submission". The second is a text input field labeled "Prior Submission Tracking Number".

1. **Applicant Information**

1. Applicant Information

| | |
|---------------------|---|
| * Organization Name | <input type="text"/> |
| Department | <input type="text"/> |
| Division | <input type="text"/> |
| * Street 1 | <input type="text"/> |
| Street 2 | <input type="text"/> |
| * City | <input type="text"/> |
| County | <input type="text"/> |
| State | <input type="text"/> |
| Province | <input type="text"/> |
| * Country | <input type="text" value="--- Select Country ---"/> |
| Zip/Postal Code | <input type="text"/> |

Organization Name: This field is required. Enter the name of the organization for the SO

Contact and Address fields: Enter the field data for the Applicant Organization as each label indicates. The Organization Name, Street 1, City, and Country are required fields. The State and ZIP/Postal Code fields will become required upon Country selection of United States. Note that ZIP/Postal Code must be entered in ZIP+4 (nine-digit postal code) format. Province is enabled for all non-US countries and required for Canada.

2. **Employer Identification (EIN) or (TIN):** Enter either the organization's Taxpayer Identification Number (TIN) or Employer Identification Number (EIN) as assigned by the Internal Revenue Service. If your organization is not in the United States, enter 44-4444444. Your EIN may be 12 digits, and if this is the case, enter all 12 digits.

2. Employer Identification (EIN) or (TIN)

Employer Identification

3. Descriptive Title Of Applicant's Project

* Descriptive Title of
Applicant's Project

4. Project Period

Start Date



End Date



3. **Descriptive Title of Applicant's Project:** This field is required. The descriptive title is limited to 200 characters, including spaces and punctuation.
4. **Project Period:** Enter the proposed start date of the project.
The **Start Date** is an estimate. The project period should not exceed what is allowed in the ROA.
The **End Date** is an estimate and must occur in the future of the Start Date.
5. **Project Director/Principal Investigator (PD/PI) Contact Information**
The PD/PI is the individual responsible for the overall scientific and technical direction of the project. In the eRA Commons profile, the person listed here must be affiliated with the applicant organization entered in "1. Applicant Information".

If submitting an application with multiple PD/PIs, the main or primary PD/PI should be entered in the first or top section as the Contact PD/PI. The "Add Additional PD/PI" button may be used to add other PD/PIs. Following data entry, the user may "Edit" or "View" the PD/PI entries; Additional PD/PI entries can also be individually removed from the application.

If the FOA requires a [leadership plan](#) for a [multi-PD/PI application](#), provide the rationale for choosing a multiple PD/PI approach. The governance and organizational structure of the leadership team and the research project should be described, including communication plans, processes for making decisions on scientific direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PD/PIs and other collaborators.

If budget allocation is planned, the distribution of resources to specific components of the project or the individual PD/PIs should be delineated in the Multiple PD/PI Leadership Plan. In the event of an award, the requested allocations may be reflected in a footnote on the Notice of Award.

The attachment should be attached as a PDF file.

5. Project Director/Principal Investigator Contact Information

Enter the Contact PD/PI's contact information below.

| Contact PD/PI Name | Organization Name | Action | |
|--------------------|------------------------------------|--------|------|
| ! | UNIVERSITY OF CALIFORNIA SAN DIEGO | Edit | View |

Additional PD/PI

Additional PD/PIs may be added using the Add Additional PD/PI button.

Add Additional PD/PI

| Entry # | Additional PD/PI Name | Organization Name | Action |
|---------|-----------------------|-------------------|--------|
|---------|-----------------------|-------------------|--------|

Nothing found to display.

Leadership Plan

Add Attachment

Delete Attachment

View Attachment

Summary

OTA Core

OTA Core > Contact PD/PI Record

OTA Core - Contact PD/PI Record

OTA Core v1.0 ?

Edit

Expand

Credential, e.g., agency login

Populate fields from Credential

Prefix

--- Select Prefix ---

* First Name

Middle Name

* Last Name

Suffix

--- Select Suffix ---

Position/Title

Department

* Organization Name

Division

* Street 1

Street 2

* City

County/Parish

State

CA: California

Province

* Country

USA: UNITED STATES

Zip/Postal Code

Phone Number

Fax Number

* Email

Save and Keep Lock

Save and Release Lock

Cancel and Release Lock

Credential, e.g. agency login: enter the eRA Commons user name for the PD/PI. This field is not required to save the form, however the Commons user Identification is for the Contact PD/PI at the time of submission.

Complete the personal information for the PD/PI.

Contact and Address fields: Enter the field data for the PD/PI as each label indicates. The Organization Name, Street 1, City, and Country are required fields. The State and ZIP/Postal Code fields will become required upon Country selection of United States. Note that ZIP/Postal Code must be entered in ZIP+4 (nine-digit postal code) format. Province is enabled for all non-US countries and required for Canada.

Following data entry, Save changes. To return to the main form use 'Save and Release Lock' or click the 'OTA Core' breadcrumb under the blue 'OTA Core' form tab.

6. Business Official Contact Information

6. Business Official Contact Information

| | |
|---------------------|--------------------------|
| Prefix | --- Select Prefix --- ▼ |
| * First Name | <input type="text"/> |
| Middle Name | <input type="text"/> |
| * Last Name | <input type="text"/> |
| Suffix | --- Select Suffix --- ▼ |
| Position/Title | <input type="text"/> |
| Department | <input type="text"/> |
| * Organization Name | <input type="text"/> |
| Division | <input type="text"/> |
| * Street 1 | <input type="text"/> |
| Street 2 | <input type="text"/> |
| * City | <input type="text"/> |
| County | <input type="text"/> |
| State | <input type="text"/> |
| Province | <input type="text"/> |
| * Country | --- Select Country --- ▼ |
| Zip/Postal Code | <input type="text"/> |
| Phone Number | <input type="text"/> |
| Fax Number | <input type="text"/> |
| * Email | <input type="text"/> |

By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances* and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 218, Section 1001)

** I agree ☐

Complete the information for the Business Official Contact.

Contact and Address fields: Enter the field data for the Business Official as each label indicates. The Organization Name, Street 1, City, Country, and Email are required fields. The State and ZIP/Postal Code fields will become required upon Country selection of United States. Note that ZIP/Postal Code must be entered in ZIP+4 (nine-digit postal code) format. Province is enabled for all non-US countries and required for Canada.

Assurances: The applicant organization is responsible for verifying its eligibility and the accuracy, validity, and conformity with the most current institutional guidelines of all the administrative, fiscal,

and scientific information in the application, including the Facilities and Administrative rate. Deliberate withholding, falsification, or misrepresentation of information could result in administrative actions, such as withdrawal of an application, suspension and/or termination of an award, debarment of individuals, as well as possible criminal and/or civil penalties. The signer further certifies that the applicant organization will be accountable both for the appropriate use of any funds awarded and for the performance of the grant-supported project or activities resulting from this application. The grantee institution may be liable for the reimbursement of funds associated with any inappropriate or fraudulent conduct of the project activity.

Check “I agree” to provide the required certifications and assurances.

7. **Estimated Project Funding:** Enter the total federal funds, including Direct Costs and F&A (Indirect Costs) requested for the entire project period.
8. **Human Subjects:** Answer yes or no to the question regarding involvement of human subjects. If yes, indicate whether the studies are exempt from Federal Regulations. If required by the ROA, select the Human Subject Clinical Trial Information Form from the “Optional Forms” in the left navigation pane. Follow instruction in the SF424 instruction guide for this specific form.

8. Human Subjects

* Do you anticipate studies involving human subjects (Y/N)? ☒ Yes ☐ No

If YES to Human Subjects

Is the project exempt from Federal regulations? ☒ Yes ☐ No

If yes, check the appropriate exemption number. ☐ 1 ☐ 2 ☒ 3 ☒ 4 ☐ 5 ☐ 6 ☐ 7 ☒ 8

Actions ?

MANAGE ACCESS

ADD OPTIONAL FORM

PREVIEW APPLICATION

VALIDATE APPLICATION

VIEW STATUS HISTORY

UPDATE SUBMISSION STATUS

9. **Cover Letter:** The cover letter is for internal use only. It should be included any special considerations or explanatory details regarding the submission of the application. The letter should include the application title.

10. **Attachments:** attach PDF file in accordance with the FOA and/or specific instructions using the “add attachment” button. The attachment should be in the format of a PDF file. If multiple attachments are added, each should have a unique file name. To delete an uploaded attachment, check ‘Delete on Save’

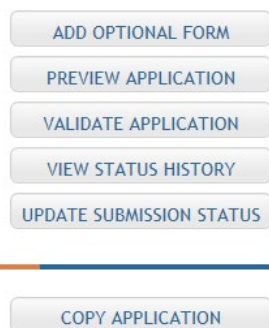
and the file will be removed upon next save. Individual attachments can be replaced or updated by clicking the ‘Update’ button of the corresponding row.

9. Attachments

Attachments Add Attachment

| Attachment File Name | Delete on Save | Update Attachment | View Attachment |
|----------------------|--------------------------|---------------------|-------------------|
| Equipment.pdf | <input type="checkbox"/> | Update | View |

Actions ?



ADD OPTIONAL FORM

PREVIEW APPLICATION

VALIDATE APPLICATION

VIEW STATUS HISTORY

UPDATE SUBMISSION STATUS

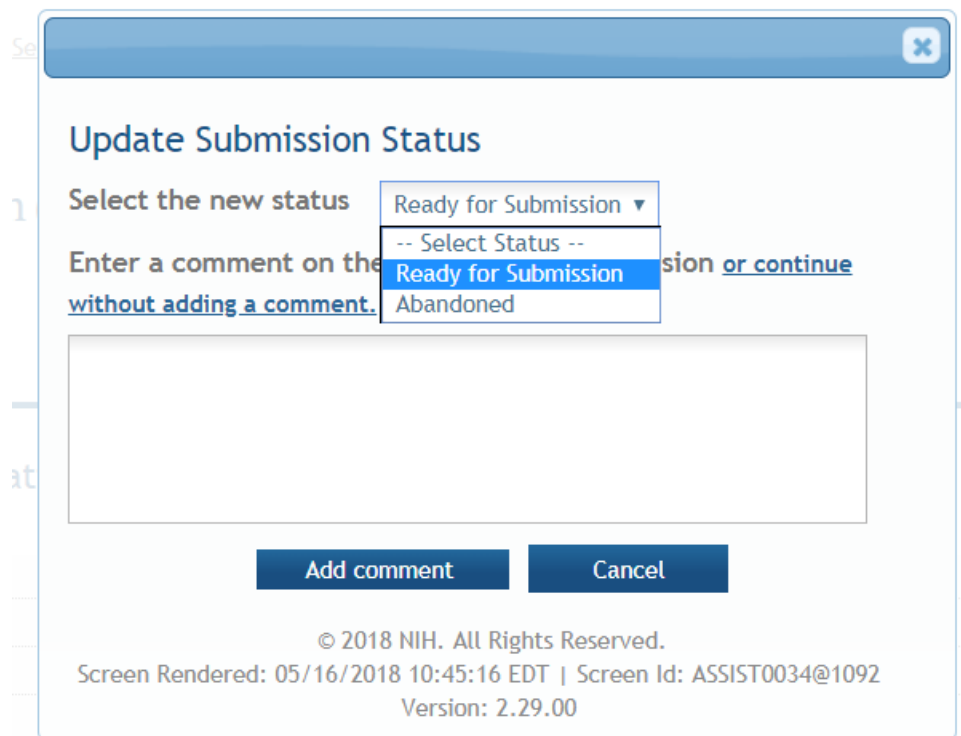
COPY APPLICATION

Submitting your Application

Validating your application: Select “Validate Application” from the left-hand panel to check your application for business errors and warning. Errors must be corrected prior to submission. Warnings will not stop prevent your application from being submitted.

Preview Application: presents the PDF version of the application. This is a view of the assembled image is nearly identical to that the reviewers/evaluators will assess.

Update Submission Status: Prior to submission, the status must be updated to “Ready for Submission” which will also perform additional validations against business errors prior to changing the status. Click “Add Comment” or “continue without adding a comment” to continue.



Update Submission Status

Select the new status Ready for Submission ▼

-- Select Status --

Ready for Submission

Abandoned

Enter a comment on the application or continue without adding a comment.

Add comment Cancel

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Screen Rendered: 05/16/2018 10:45:16 EDT | Screen Id: ASSIST0034@1092
Version: 2.29.00

Submission

Once the application has been placed in “Ready for Submission” status, the Signing Official will be able to click “Submit Application”. After a confirmation that the SO does wish to submit the application, it will be sent to NIH for processing. The status can be viewed and updated by clicking the “View Submission

Status Details” hyperlink next to the application status.



Application Information

| | |
|----------------------------|---|
| Application Identifier: | 21115 |
| Application Project Title: | Clinical Center for All of Us NIH Program |
| PD/PI Name: | AARONS, GREGORY |
| Organization: | |
| Project Period: | |
| Status: | Ready for Submission Submit Application |
| Status Date: | 2018-05-16 10:50:09.000 PM EDT Submit Application |

Notice:



Are you sure you want to submit the application?

Yes

Go Back

Follow the status of your submission in eRA Commons