



Research Opportunity Announcement
OTA-21-015C
REsearching COVID to Enhance Recovery (RECOVER) Initiative:
Mobile Health Platform

The NIH is soliciting applications in support of the goals of the REsearching COVID to Enhance Recovery (RECOVER) Initiative and Investigator Consortium. This Research Opportunity Announcement (ROA), OTA-21-015C, is for the Mobile Health Platform component of the Initiative.

Introduction

With this ROA, NIH is soliciting applications for the **Mobile Health Platform (MHP)** component of the REsearching COVID to Enhance Recovery (RECOVER) Initiative. The MHP will facilitate research that relies on the collection, annotation, harmonization, curation, and sharing of digital health data collected via mobile health technology by the RECOVER Investigator Consortium to complement and augment existing clinical, electronic health record (EHR), and other real-world data in an integrated manner.

Background on the RECOVER Initiative

Recovery from SARS-CoV-2 infection is extremely variable with many recovering quickly, while for other patients there are important post-acute sequelae. Reported symptoms among persons who have been infected with SARS-CoV-2 range from mild to incapacitating, may persist after recovery from acute disease, may involve multiple organs and systems, and can adversely affect overall quality of life. In some cases, new symptoms and findings are reported that appear linked to the timing of acute infection but emerge subsequently and evolve over time. The magnitude of the public health impact of these sequelae is currently unknown but potentially large, given the numbers of individuals across the age spectrum who have been and will be infected with SARS-CoV-2. It is a public health priority that we better understand and develop strategies to prevent and treat post-acute sequelae of SARS-CoV-2 infection (PASC) and that these strategies enable rapid innovation, evolution, and adaptation as more is learned about PASC and its potential impact on public health.

The goal of the trans-NIH RECOVER Initiative is to rapidly improve understanding of recovery after SARS-CoV-2 infection and to prevent and treat PASC. Toward these ends, the Initiative is designed to address these fundamental scientific questions:

- What is the clinical spectrum of and biology underlying recovery from acute SARS-CoV-2 infection over time?

- For those patients who do not fully recover, what is the incidence/prevalence, natural history, clinical spectrum, and underlying biology of this condition? Are there distinct phenotypes of patients who have prolonged symptoms or other sequelae?
- Does SARS-CoV-2 infection initiate or promote the pathogenesis of conditions or findings that evolve over time to cause organ dysfunction or increase the risk of developing other disorders?

The Initiative is designed to be a collaborative and inclusive approach for rapidly advancing our understanding of the recovery process and the epidemiology (including incidence/prevalence) and natural history (including duration) of PASC. Studies conducted will characterize: the clinical spectrum of recovery from SARS-CoV-2 infection, including the subset of patients who have symptoms of disease more than 4 weeks after infection with SARS-Cov-2; the individual, clinical, and contextual factors that contribute to the duration, types of symptoms, and severity of disease; phenotypes of patients who have prolonged symptoms or other sequelae; the impact of treatments for acute COVID-19 or for post-acute symptoms on the duration and severity of symptoms; and factors that impact the outcomes in patients infected by SARS-CoV-2.

At the heart of the Initiative is the rapid launch of the SARS-CoV-2 Recovery Cohort and SARS-CoV-2 Recovery Cohort Investigator Consortium.

The **SARS-CoV-2 Recovery Cohort** is a collaborative meta-cohort that will leverage ongoing fit-for-purpose cohorts, as well as new cohort studies, to chart the process of recovery in diverse adult and pediatric populations. This will include patients acutely infected with SARS-CoV-2 (acute cohort), as well as persons suffering from post-acute symptoms (post-acute cohort), along with appropriate control participants. The RECOVER Initiative will emphasize inclusive participation and leverage a variety of clinical platforms, including large-scale EHR/health systems-based cohort studies; large and long-standing longitudinal studies; COVID-19 clinical trials/networks; and COVID-19 clinics, registries, and observational studies. These will be augmented by utilization of mobile and digital health strategies for participant recruitment, data collection, and follow-up.

SARS-CoV-2 Recovery Cohort studies will characterize PASC symptoms and findings and their trajectory over time and across the lifespan. They will include investigator-initiated studies taking a variety of approaches to probe for evidence of tissue injury or organ system dysfunction or other conditions (e.g., immunologic, pulmonary, cardiac, neurologic/cognitive, metabolic, mental health). Some may focus on special populations including children, the elderly, pregnant or lactating people, or those with relevant comorbidities. Diversity in study populations will be necessary to generalize findings to the U.S. population affected by SARS-CoV-2 infection. Toward this end, RECOVER Initiative investigators are encouraged to collaborate where feasible with other relevant NIH initiatives (e.g., Rapid Acceleration of Diagnostics-Underserved Populations ([RADx-UP](#)), Community Engagement Alliance ([CEAL](#)) Against COVID-19 Disparities).

Given the heterogeneity of symptoms and findings involving multiple tissues and systems, understanding PASC will require a multidisciplinary approach. Toward this end, all study investigators under this initiative will work together in a **SARS-CoV-2 Recovery Cohort**

Investigator Consortium with the goal of immediately launching a multi-disciplinary collaboration to conduct rapid systematic screening and follow-up evaluations of SARS-CoV-2 infected individuals, to provide a resource for in-depth multi-disciplinary phenotyping, and to pool data and share biospecimens and data across studies. After award, Consortium investigators will be convened to rapidly develop a streamlined set of common core protocol elements (specific hypotheses, design elements, screening evaluations, exams, lab tests, functional assessments, imaging, digital health measures, patient-reported outcomes, common data elements etc.) and to provide a collaborative for multi-disciplinary phenotyping. Consortium investigators may also propose site- or study-specific hypotheses that, due to specific expertise or technology constraints, may only be possible in subsets of the consortium as sub-studies or ancillary studies. Successful applicants will be required to participate in collaborative protocol development and implementation.

Importantly, the Initiative also will leverage **EHR- and other Real-World Data-based approaches** to provide data and information on the incidence/prevalence of post-acute sequelae, PASC symptoms, imaging, and lab test results to inform the definition of PASC; describe patient demographics; identify comorbidities; define health care utilization patterns; provide real world data for comparative effectiveness studies, as well as reducing time and scope of potential clinical trial design and implementation; and inform PASC clinical characterization through health systems-based patient common data elements (CDEs). (See <https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence> for a description of real-world data.)

Exploratory clinical trials testing strategies to treat symptoms and prevent progression of SARS-CoV-2 infection to PASC are also a critical part of this initiative.

Also, critically important to understanding the pathology associated with PASC will be **Autopsy Cohort Studies** that will include in-depth histopathologic analysis of multiple organs and tissues, including brain, to identify tissue injury due to SARS-CoV-2 infection and/or its sequelae that lead or contribute to PASC.

RECOVER Initiative Structure

The research-related activities of the RECOVER Initiative will be supported by multiple components working closely together, including but not limited to:

- A **Clinical Science Core** to coordinate the investigator consortium; facilitate clinical protocol development, implementation, monitoring, and data analysis; foster the use of common data elements across groups; promote multi-disciplinary collaboration; and foster community engagement.
- A **Data Resource Core** to coordinate RECOVER data management, harmonization, integration, and sharing, and provide analytical tools and statistical support to the Clinical Science Core.
- A **RECOVER Biorepository Core** to receive, manage, and make available a diverse range of biospecimens derived from RECOVER Investigator Consortium studies.

- **Data Repositories** (e.g., Digital Health Data Repository, Clinical and Observational Data Repository) to deploy, manage and grow a robust, secure digital infrastructure.
- A **Mobile Health Platform** to develop customized mobile apps to collect PASC digital health measures in the Clinical Recovery Cohort studies.
- An **Administrative Coordinating Center** to provide central coordination and oversight.

This ROA requests proposals to implement and manage the Mobile Health Platform component of the RECOVER Initiative. The Mobile Health Platform will collaborate closely with the other components of the RECOVER Initiative to gather digital health data to augment the other data collected by the Recovery Cohort studies. The Clinical Science Core, Data Resource Core, and Biorepository Core are the subjects of a separate but related ROA: [OTA-21-015A](#). The research studies (Clinical Recovery Cohort Studies, Autopsy Cohort Studies, and EHR- and Other Real-World Data-based Studies) are also the subject of a separate but related ROA: [OTA-21-015B](#). Applicants are strongly encouraged to review these related ROAs in detail and to be familiar with their contents. The Data Repositories will be the subject of a separate ROA.

Consortium investigators will be required to develop, implement, and participate in a collaborative governance structure that includes community representatives and affected persons. All study investigators are required to rapidly and appropriately share data, software, and biospecimens (timeline to be determined by the RECOVER Governance Committee) and to consent participants for general research use of data, other medical information, and biospecimens.

This initiative supports NIH's longstanding commitment to making the results and outputs of NIH-funded research available to the public through effective and efficient FAIR data sharing practices. Consortium investigators will make research data and biospecimens available through the Clinical Science Core, Biorepository Core, and Data Resource Core at agreed upon milestones and upon completion of their study. Researchers will agree not to distribute controlled-access datasets and will acknowledge use of RECOVER datasets through citations in manuscripts and presentations.

Mobile Health Platform: Background and Objectives

RECOVER Initiative Clinical Recovery Cohort studies will utilize a variety of mobile health, digital health (e.g., wearable), and home testing technologies to collect intensive, longitudinal data on acute COVID and PASC symptoms, outcomes, and contextual constructs (e.g., environmental, social, and/or geographic determinants of health). These technologies can enable close to real-time and/or just-in-time data collection directly from patients away from clinical sites or in remote settings. The ubiquity of smartphones and growing use of wearable sensors can facilitate a better understanding of how recovery from SARS-CoV-2 and PASC is affecting various populations and, importantly, can help in reaching underserved, rural, and racial/ethnic minority groups who are affected disproportionately. The data collected from these technologies will be linked to and integrated with data collected from the Recovery Cohort studies.

Mobile health (also referred to as mHealth or remote patient monitoring) involves the application of wireless devices and sensors (including mobile phones) by consumers or providers, for monitoring health status or improving health outcomes (<https://doi.org/10.1016/j.amepre.2013.03.017>). Digital health involves technologies that use computing platforms, connectivity, software, and sensors for healthcare and related uses and include categories such as mobile health, health information technology, wearable devices, telehealth and telemedicine, and personalized medicine (<https://www.fda.gov/medical-devices/digital-health-center-excellence/what-digital-health>). Examples of how mobile/digital health technologies can enhance RECOVER clinical studies include:

- Providing frequent assessments of symptoms and behaviors, to help identify changes and trends in PASC over time.
- Enable time-series reports of symptoms and behaviors due to PASC that could inform whether treatments tested in clinical trials have desired beneficial effects.
- Capturing continuous physiological data with minimal burden on patients. Smartphones and wearable sensors can collect data automatically, such as number of hours of sleep or rest, step counts for physical activity, body temperature, heart rate fluctuations, etc.
- Collecting more granular data to understand disease and/or symptom trajectory. For example, devices can measure the number of hours of sleep or cognitive performance, and brief mobile CDEs can determine or infer the quality of sleep, subjective cognitive function, and subjective mental health states (e.g., mood states, abnormal perceptions) from the participant's perspective.
- Providing opportunities for collecting data that better represent people's actual day-to-day experiences, as opposed to data collected in the somewhat artificial environment of a study visit or healthcare visit.
- Enabling recruitment of and data collection from people who experience mild or moderate COVID-19 and/or PASC, with limited or no contact with the healthcare system, whose quarantine promotes the safety of patients and providers, and/or who have limited time or ability to travel and attend research study visits.
- Capturing patient-reported, person-centered PASC-related data. Devices can readily assess quality-of-life issues, such as sense of fatigue, mental health states (e.g., mood states), and ability to care for oneself, and how these change over time.
- Capturing social determinants of health and other real-world data that may be useful in understanding and addressing health inequities related to PASC.
- Gathering geospatial data. Knowing where and how long participants are in certain locations can let researchers link PASC symptoms with environmental and social context data (e.g., weather data, socioeconomic deprivation indices).
- Empowering and engaging patients by returning personalized information that provides value to the individual.

NIH's vision for the Mobile Health Platform (MHP) and for the Digital Health Data Repository (DHDR; solicited through [OTA-21-015D](https://www.fda.gov/medical-devices/digital-health-center-excellence/what-digital-health)) is that they work closely together and with the RECOVER Investigator Consortium to rapidly and flexibly deploy, manage, and grow a robust, secure digital infrastructure that can meet near-term and long-term needs of the Initiative. The

MHP will collect PASC-related mobile health data (CDEs, sensor data, etc.) from participants and will share this data with the DHDR to clean, curate, conduct QA/QC, store, and provide access to researchers. The infrastructure for both components will enable recruitment and engagement of participants, collection of standardized information from participants, and will make the data and its derivatives rapidly available to other members of the Consortium and to the research community where appropriate. Therefore, it is vitally important that the MHP and DHDR can nimbly adapt to the changing landscape of studies, measures, data types, and needs of the Initiative.

To address the fundamental scientific questions of the RECOVER Initiative, SARS-CoV-2 Recovery Cohort studies will need to contact/recontact participants and collect digital health data to augment existing clinical, EHR, and other real-world data. To facilitate consistency across the different cohorts, the RECOVER Investigator Consortium (including MHP investigators) are required to establish and adopt a standardized set of digital health measures (CDEs, sensor data, etc.) for assessing the trajectory of acute COVID-19 and PASC over time.

Once a core set of digital health measures has been defined, each SARS-CoV-2 Recovery Cohort study will be required to collect these measures, at a minimum, from their participants. The MHP being solicited through this Announcement will collaborate with the Clinical Science Core and Data Resource Core to provide each cohort study with a customized (study branding, study logo, etc.) mobile app for enabling collection of the core measures, as well as other standardized measures. Agreements with awardees will include appropriate data rights provisions to ensure that all mobile health and related digital data generated by the SARS-CoV-2 Recovery Cohort studies will be curated by, hosted in, and shared through the Digital Health Data Repository being solicited in OTA-21-015D

Although the specific details of the studies and measures to be supported by MHP are not known at the time of application, it is expected that the data collection strategy will be finalized soon after awards are made. The infrastructure for the MHP is required to be operational shortly after the time of award. The MHP should be ready to deliver customized apps to SARS-CoV-2 Recovery Cohort studies by the time those studies begin collecting data. Timeline and milestones will be negotiated accordingly.

In addition to delivering customized apps to the Recovery Cohort studies (up to 25 studies), the MHP may be expected to collaborate with the Clinical Science Core to develop a website/app to engage and assess populations beyond existing RECOVER cohort populations, reaching non-hospitalized, underserved, and underrepresented populations (i.e., RECOVER Patient Registry). The MHP will support this cohort in the same manner as the other RECOVER Initiative Recovery Cohorts. Based on direction from the Clinical Science Core, the MHP will facilitate recruitment of these additional participants, which may require programming of consent forms within the app(s) and development of recruitment strategies to reach participants outside of clinical settings (e.g., via social media advertisements). Participants in this registry could be recruited (with their permission) to participate in other PASC research studies.

Mobile Health Platform: Capabilities Sought

The NIH is soliciting proposals for adaptation and support of a scalable, configurable, and integrated Mobile Health Platform (MHP) to provide SARS-CoV-2 Recovery Cohort studies with customized (study branding, study logo, etc.) mobile applications and for enabling secure collection of PASC digital health measures. MHPs proposed for this initiative should have demonstrated experience and capabilities to support the following features. Applicants without existing capabilities in one or more listed areas below should describe how they will rapidly incorporate these capabilities into their platform before data collection.

The MHP will include the following functionalities:

- 1) Maintaining integrity, confidentiality, privacy, and security of participant study data collected through the MHP. The MHP may require the creation and maintenance of System(s) of Record (SOR) to securely contain personally identifiable information (PII). The SORs will adhere to a Federal Information Security Management Act (FISMA)-moderate level of security controls. Specifically, the MHP will:
 - a) Incorporate evolving data security standards and best practices, as well as conform to regulations that ensure privacy, confidentiality, integrity, and security, particularly for data capture and data transfer.
 - b) Provide data storage that complies with Health Insurance Portability and Accountability Act (HIPAA) and FISMA standards, and is Federal Risk and Authorization Management Program (FedRAMP) authorized to ensure privacy and security if cloud-based.
 - c) Be compliant with [21 CFR Part 11](#) (section D) including but not limited to the following:
 - User access controls must be in place to ensure entries come from the study participant.
 - Data elements must be associated with an authorized data originator.
 - If mobile technology transmits data automatically, the technology should be identified as the data originator.
 - Source data collected directly from a participant should be stored long-term in the sponsor's electronic data capture (EDC) system and not in the mobile technology.
- 2) Procurement of consumer wearable devices and distribution to subsets of participants in the Clinical Recovery Cohort studies. The MHP will provide training and support for wearable device setup and troubleshooting.
 - a) The applicant must propose and justify which wearable device(s) will be used.
 - b) Budgets should include the costs for procuring and deploying up to 10,000 wearable devices across sites. Deployment costs could include but are not limited to: training and support, wearable device software licenses, and postage for mailing/returning wearable devices.
- 3) Ability to deploy the MHP on multiple interfaces, including smartphones (e.g., iOS, Android) and tablets, mobile and desktop web browsers, etc.

- 4) Integrated PASC study management system with interfaces for participants and study staff that can assist with:
 - a) Participant recruitment, consenting, and onboarding.
 - b) Real-time data collection and reports.
 - c) Ticketing system to track and respond to technical issues with the MHP and/or sensor devices deployed by the MHP.
 - d) Making the digital health data collected through the MHP available to the Recovery Cohort investigators in near-real-time or just-in-time, so that the investigators can perform analyses that combine the digital health data with the clinical data they are collecting in the same patients.
 - e) Return of individual results to participants, as appropriate.
 - f) Contacting participants via email, text/SMS, and mobile system alerts for push notifications/alerts and survey questions (i.e., CDEs) and responses.

- 5) Collection of a standardized and/or harmonized set of common data elements and digital health measures for assessing the trajectory of acute COVID-19 and PASC over time. The MHP will support the Clinical Science Core and RECOVER Investigator Consortium to develop and validate this set of measures, including the data elements, temporality of assessment, and on-screen display of questions. These measures are likely to evolve as more is learned about recovery from SARS-CoV-2 infection and PASC. The measures should include:
 - a) Core questions about the symptoms experienced by patients to chart recovery or worsening over time in symptoms and quality of life.
 - b) Sensor data from consumer wearable devices (provided by the MHP or owned already by participants) that can capture certain clinical measures as well as specific symptoms or clusters of symptoms that patients are experiencing (e.g., heart rate, respiration rate, blood oxygen, activity levels, cough, sleep patterns, actigraphy, temperature, anxiety, menstrual changes).
 - c) Geospatial data, which will enable patient data to be linked with environmental and social context data (e.g., weather data, socioeconomic deprivation indices).
 - d) Integration of data from COVID-19 testing, including serial at-home COVID-19 antigen testing to monitor possible reinfection.

- 6) Support for multiple, concurrent studies across the RECOVER Investigator Consortium, including multiple clinical study designs, with customized study deployments and study experience.
 - a) Budgets should include costs for deploying the MHP in up to 25 sites.

- 7) Tools and strategies to engage participants (feedback, sharing of findings, return of individual results, computer-adaptive surveys [i.e., CDEs], etc.) to enhance retention, as well as support for systems that enable real-time optimization of participant engagement strategies (e.g., A/B testing).

- 8) Collection of participant data from multiple sources (mobile CDEs, wearable devices, mobile-friendly electronic health records, etc.) across multiple studies and track unique identifiers from participants and their devices, as well as relevant metadata such as version information where available.
 - a) For any mobile CDEs that will be collected at multiple time points and have already been captured from participants prior to deployment of the MHP, the MPH will need to import those captured CDEs (e.g., from REDCap) and merge them with future CDEs collected through the MHP.

- 9) Integration with validated commercial or research-grade devices (including consumer wearable devices) that collect information relevant to PASC such as heart rate, skin temperature, oxygen saturation, physical activity, and sleep.
 - a) The applicant must list all sensor integrations their technology currently supports and how they will achieve any planned or proposed integrations, including how long it typically takes to integrate new sensors.
 - b) Applicants are strongly encouraged to consider proposing tasks for working with the participating cohorts to assess and report the ethical, legal and social implications (ELSI) of their data collection methodology, use of personal devices for research, and any bias or disparities introduced.

- 10) Ability to support digital integration of serial at-home COVID-19 testing (e.g., reminders to test, testing instructions, capture of results).

- 11) Support for recruitment and retention of participants remotely and in person for PASC data collection, including recruitment of targeted populations outside of established clinical studies and beyond clinical contexts.

- 12) Flexible and configurable remote, electronic participant consenting/assenting and onboarding processes that allow participants to be contacted for new studies. Where appropriate, the platform should store contact information for participants in case there is a need to recontact them.

- 13) Configurable CDEs engine that includes:
 - a) Ability to deploy a standardized/harmonized set of digital health measures that will be collected across all Clinical Recovery Cohort studies.
 - b) Ecological momentary assessment (EMA) including a customizable task queue for real-time mobile CDEs that are triggered (e.g., based off location) or scheduled.
 - c) Randomization engine of CDEs including the number of questions and the specific questions to be asked as to reduce respondent burden.

- 14) The MHP will use standards-based methodologies, when available and appropriate, to support interoperability and exchange of data across studies, with the Digital Health Data Repository, and with the Data Resource Core. The Data Resource Core will coordinate data

flow, indexing and linkage of all digital health data. Data standards for cross-study interoperability may include but are not limited to Open mHealth. Specifically, the MHP will:

- a) Facilitate the standardization and/or harmonization (i.e., usage of common data elements) of RECOVER Initiative digital health data, including mobile technologies, wearable devices, sensors and internet technology for health, healthcare and clinical research, and others as needed.
- b) Secure and harmonize data exchange with participants and their devices, recognizing they may be using many different providers, connection protocols and devices.
- c) Exchange all data collected through the MHP, including data obtained through device and app integrations, with the Digital Health Data Repository using appropriate privacy and security safeguards, such as widely recognized encryption protocols like IPsec and TLS/SSL, and using appropriate standards for harmonization and interoperability, such as FHIR.
- d) Be easily adapted to support a wide range of standardized and validated measures and instruments (in addition to the standardized/harmonized set of digital health measures that will be collected across all Clinical Recovery Cohort studies).
- e) Design and customize the MHP in a manner that enables the data it collects to be combined with the clinical data collected by the Recovery Cohort (i.e., clinical cohort and EHR/Real-World Data studies), through the Data Resource Core via privacy-preserving record linkage.

15) The MHP will be usable and accessible to a wide variety of diverse audiences. Ideally, the MHP will have been tested with these audiences to ensure population-specific usability. All web-based technologies must work on responsive templates. All MHP-supported interfaces must be Section 508 compliant in accordance with HHS regulations

(<https://www.hhs.gov/web/section-508/>). The MHP will:

- a) Be accessible to and usable by people with a range of physical, cognitive, mental health, and sensory disabilities, including low vision, color blindness, hearing impairment, and tremors. Content will be written at an 8th grade readability level, to the extent possible, to be accessible to a broad U.S. population with a range of health literacy levels.
- b) Support multi-lingual interfaces (English, Spanish, etc.), with culturally adapted translations vetted through testing with native speakers. Applicants should justify their proposed language offerings based on anticipated target populations.
- c) Provide culturally adapted, audience-specific MHP interfaces that meet the needs and preferences of vulnerable and racial/ethnic minority groups, especially those disproportionately affected by COVID-19 (e.g., African Americans, Hispanics/Latinos, American Indians/Alaska Natives, Native Hawaiians and Other Pacific Islanders).
- d) Provide audience-specific interfaces that meet the needs and preferences of a wide range of age groups, including adolescents and older adults.

16) The MHP will support customized implementations across multiple concurrent, scalable studies of tens of thousands of total participants and with follow-up of participants for up to 4 years post-infection and collaborate with the Data Resource Core, Clinical Science Core, and the other RECOVER Initiative components to:

- a) Support the development of study protocols, manuals of operation, data and safety monitoring plans, and data entry/case report forms.
- b) Provide technical support to accelerate the stand-up, management, and close-out of studies using the MHP.
- c) Support transition of sites to use of MHP, including sites with and without existing mobile/digital data collection interfaces.
- d) Develop and implement an identity management system utilizing unique identifiers for participants and associated devices that supports multi-level data linkage.
- e) Develop and execute strategies to support digital/online recruitment of targeted participants outside of existing cohorts and clinical settings (e.g., focus-group tested social/digital media recruitment advertisements). This may be done in collaboration with a RECOVER Patient Registry and the Clinical Science Core.
- f) Help customize and provide eConsent for respective studies.
- g) Facilitate training of Consortium members and study staff to support use of the MHP technologies and apps.
- h) Rapidly respond to technical support requests from study staff and participants.
- i) Create regular summaries/reports of studies including data integrity, participant activity, and any technical issues encountered.
- j) Work with RECOVER Investigator Consortium members to identify additional feature needs. Establish a roadmap of feature development and implementation for features prioritized by the Consortium.
- k) Develop, implement, and comply with Consortium policies and processes in collaboration with the RECOVER Investigator Consortium and RECOVER Initiative leadership.
- l) Track and ensure integrity and secure transmission of all study data to the Digital Health Data Repository.

Special Award Terms

The complete terms and conditions of each OT Agreement or sub-agreement issued under this ROA are subject to negotiation and will be contained in the Agreement entered between 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.

Lower Tier Agreements

With mutual consent of the Awardee and the NIH, the Data Resource Core will be expected to issue sub-awards to entities identified and approved by the NIH under ROAs associated with the RECOVER Initiative.

Negotiation

The 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 and/or milestones 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, which can consist of more than one milestone;
- 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 NIH;
- Fund proposers as sub-awardees of a separate Coordinating Center entity to be established by the NIH;
- 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.

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. § 282(n).

Eligibility

The following entities are eligible to apply under this ROA:

Higher Education Institutions

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

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)

For-Profit Organizations

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

Other

- Federally Funded Research and Development Centers (FFRDC) and University Affiliated Research Centers (UARC) are eligible to apply and/or participate as partnering organizations subject to any agency sponsor related requirements and restrictions on eligibility.

Proposal Format and Requirements

The proposal should clearly and fully demonstrate the proposer’s capabilities, knowledge, and experience. Applicants should provide a budget assuming an award term of four years to be

funded on an annual basis. Proposals should include a Cover Page, an Executive Summary, a Timeline and Tasks for the first year, a Project Plan, and a Budget.

The Cover Page (1 page max) should include:

- A. The proposal title. **Please ensure to reference the ROA# OTA-21-015C 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
- E. 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
- F. The total cost proposed for each year

The Executive Summary (1 page max) should describe:

- A. How the proposed solution meets the needs of the RECOVER Investigator Consortium with respect to fulfilling the requirements expected of the MHP
- B. The team's prior experience deploying their solution in a variety of research contexts and experience working as part of a multi-institutional collaboration
- C. Technical proficiency with data privacy, security, accessibility, interoperability, and adopting Consortium standards

The Timeline and Tasks for the first year (1 page max) should include a summary of major tasks to be accomplished in the first 12 months of the proposed project. Each major task should include:

- Timeline
- Milestones and benchmarks
- Deliverables
- Budget for the task (the sum of all the task budgets should match the total budget being requested for the first year)

The Project Plan (10 pages max) should include:

A. Technical Approach

The proposal should describe how the applicant will meet the specific responsibilities of the MHP, as described in the "*Mobile Health Platform: Capabilities Sought*" section of this ROA. The proposer must demonstrate its understanding of the RECOVER Initiative and component(s) being proposed by clearly showing a grasp of the range and the complexity of

the work. This section should include a detailed project plan that includes milestones and deliverables for each phase of the MHP implementation, with a particular focus on early steps needed to rapidly stand up key functions and capabilities (e.g., customized MHP apps available within 2 months of award, depending on Recovery Cohort study requirements). Proposers should demonstrate a conceptual understanding of the challenges specific to the tasks required in the ROA and suggestions for overcoming these. Applicants must address specific processes and procedures for how they will achieve the required integration with the other components and for resolving any areas of disagreement. This includes rapid sharing of resources.

B. Key Personnel Experience

Proposers should demonstrate experience of key personnel supporting the planning and implementation of activities described in the ROA. Please provide resumes describing key staff who will be assigned to manage performance and supervise the work for each task and subtask (as appropriate). These resumes will be reviewed to evaluate whether the individuals possess the required experience to perform the specific tasks. Resumes should be no more than three (3) pages in length and will not count toward the page limits.

C. Management/Staffing Plan

Proposals should detail how the applicant will provide the necessary project administration, organization, and staff to ensure quality control, compliance with ROA expectations, and necessary staffing adjustments. In addition, proposers must demonstrate the ability to simultaneously manage multiple tasks within set time periods.

D. Past Experience

Proposers should provide multiple examples of prior project experience serving as a mobile health platform (or in similar capacity), as described in this ROA. Each example should include the total funding awarded and dates of award, contact information for a sponsor able to serve as a reference, and a brief description of the project itself, including how the project was analogous to the needs identified in this ROA with respect to the work being proposed. Applicants will need to demonstrate prior work with clinical consortia or networks AND competency associated with the work being proposed.

The Budget should address the following:

The Budget section must provide a realistic, fully justified annual budget and cost proposal for performing the work specified in the ROA over a period of 4 years. NIH prefers applicants use an SF424 template to complete the categorical budget, but this is not required. Budget information and any related administrative documentation shall not count toward the total proposal page limit.

The Budget should provide the overall expected cost for each of the following categories:

- Personnel
- Materials and supplies (including up to 10,000 wearable devices and associated costs)

- Equipment
- Travel
- Subawards/subcontracts/consultants
- Other direct costs
- Total cost (with indirect costs included)
- Proposed Cost Share contribution

For budgeting purposes, applicants can assume customized deployments of the MHP across 25 sites.

Objective Review Process

Applications will be evaluated in two stages. The first stage will be based on technical evaluation of the written proposals and will be done by a committee of subject matter experts. In the second stage, a subset of applicants will be invited to participate in an interview. The purpose of the interview stage is to clarify details from the written application. The interviews will be conducted via a videoconferencing platform. NIH will not support any costs associated with these interviews.

All applications will be evaluated using the following criteria:

1. Investigative Team

- Are the PI(s) and other key personnel well-suited to their roles in the Mobile Health Platform component of the RECOVER Initiative?
- Does the proposed applicant team provide requisite expertise to complete the tasks specified in this ROA, including but not limited to, mobile platform development and implementation across a variety of operating systems (e.g., iOS, Android, and web) and study designs, data security and privacy, data harmonization and standards (e.g., Open mHealth), diverse recruitment and retention?
- Does the applicant(s) have experience managing and integrating mobile technology and associated mobile data as part of a complex consortium?
- Is there strong evidence of the team's ability to build high-impact collaborations and make a sustained contribution to a high-profile, complex program using mobile health technology?
- Does the past experience of the team demonstrate a capability to rapidly stand up multiple new mobile studies through collaboration with other institutions and successfully complete studies according to timeline and study objectives?
- Has the team shown commitment to including diverse populations in mobile health studies and supporting their needs and preferences in the design and usability of the platform?

2. Approach

- Will the platform be scalable and configurable to support recruitment through follow-up of multiple, concurrent observational studies and clinical trials, with different populations and outcomes?
- Will the infrastructure for the platform be operational shortly after the time of award and nimbly adapt to the changing landscape of studies, measures, data types, and needs of the RECOVER Initiative (e.g., ability to rapidly integrate new devices, customize to different studies, and/or develop new study protocols)?
- Does the approach provide a high level of interoperability, security, and privacy? Will data storage and transmission be compliant with government standards?
- Will the proposed MHP facilitate the collection, annotation, harmonization, curation, and sharing of core measures and other digital health data? Does the platform have the flexibility to leverage commonly used measures, data and metadata standards, models and schemas?
- Does the proposed platform have the existing infrastructure to capture digital data relevant to the RECOVER Initiative, including wearable sensors and device integrations, electronic consent management, ePROs (e.g., real-time or just-in-time assessments), and passive sensing through smart phones (e.g., geolocation, multimedia content)?
- Can the platform support diverse studies and the participants that comprise them through features such as tailored interfaces and configurations (e.g., multi-lingual interfaces), accessibility (e.g., support for vision impairment), usability, and engagement strategies? Will the platform be acceptable and culturally appropriate for diverse populations who may be experiencing health disparities?
- To what extent can the platform return information to participants and keep them engaged with the platform through the study period?
- Are there plans and adequate resources to collaborate with Consortium members on study design and to provide training and technical support for Consortium members and study participants?
- Are the proposed timeline, plans, methods, techniques, and procedures for the project sound, feasible, and realistic?

3. Integration

- To what degree does the application address the data integration, consortium coordination, and community engagement needs of this ROA?
- To what extent will the proposed design and technical approaches of the proposed MHP lead to effective harmonization of solutions, tools, and products in collaboration with the RECOVER studies, Data Resource Core, and Clinical Science Core?

- To what extent does the application specify resources, personnel time, and flexibility to efficiently work with the RECOVER Digital Health Data Repository and the Data Resource Core?

4. Environment

- Are the institutional/organizational support, facilities, equipment, and other physical resources available to the investigators adequate for the project proposed? Is the proposed MHP appropriate for the RECOVER Investigator Consortium and able to comply with FISMA-moderate security requirements?
- Will the proposed MHP benefit from unique features of the scientific environment or collaborative arrangements?
- Will the institutional resources support a platform for engaging diverse researchers and participants?

The following will be considered when making funding decisions:

- Scientific and technical merit of as determined by objective review.
- Availability of funds.
- Relevance and complementarity of the application to RECOVER Initiative priorities.
- Evidence that the applicants are committed to goals and policies of the RECOVER Initiative, including confidentiality, publications, sharing of information and resources, and collaboration.
- Evidence of previous productive, cooperative, collaborative technology development taking into consideration the needs of end users.
- Evidence that the application will contribute to the diversity of technical and intellectual approaches and to the overall goals of the Initiative.

Non-Responsive Applications

An application will be considered non-responsive to this ROA if it: 1) proposes a generic mobile app and/or platform without consideration of specifically how the technology will be integrated with the RECOVER Recovery Cohort Studies, relevant data repositories, Clinical Science Core, and Data Resource Core; 2) proposes a mobile app and/or platform that does not meet the minimum privacy and security standards specified for the MHP; or 3) proposes the de novo development of a mobile app and/or platform.

Non-responsive applications to this ROA will not be reviewed.

Submission and Contact Information

Proposals must be submitted via eRA ASSIST under OTA-21-015 and simultaneously emailed to NHLBI_OTA@mail.nih.gov no later than **5 PM EDT on July 30, 2021**. The ROA # OTA-21-015 should be entered into the system when submitting via ASSIST.

Technical issues or questions concerning submission of applications via eRA ASSIST should be submitted to the [eRA Help Desk](#). Additional guidance is provided below regarding submission of applications.

Other inquiries can be submitted to NHLBI_OTA@mail.nih.gov, with financial and administrative questions addressed to Kevin Heath, NHLBI Agreements Officer and technical questions addressed to Audie Atienza, Scientific Program Lead. Prospective applicants are encouraged to contact RECOVER program officials before the application deadline, via the email address above, to ensure that proposals meet the goals of the Initiative.

Applicants are encouraged to register for the [Technical Assistance Webinar](#) to be held on July 15, 2021, at 5PM ET.

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:

1. Dun & Bradstreet Number (DUNS) – <https://fedgov.dnb.com/webform/>

2. Employer Identification Number (EIN) – <https://www.irs.gov/businesses/small-businesses-self-employed/apply-for-an-employer-identification-number-ein-online>
3. Small Business Administration (SBA) – <https://www.sbir.gov/registration>
4. 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 below.

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)



The screenshot shows the top header of the ASSIST system with the title "Application Submission System & Interface for Submission Tracking (ASSIST)" and the NIH logo. Below the header is a navigation bar with a "Login" link. The main content area is split into two columns. The left column contains a login form with fields for "User Name" and "Password", and buttons for "Login" and "Cancel". Below the form is a link for "Forgot Password/Unlock Account?". The right column contains two "Note" sections. The first note states that as of March 22, 2018, users registering in SAM.gov must provide a signed notarized letter. The second note explains that late applications may be accepted in cases of natural disasters or emergencies. At the bottom right of the page is a large blue button that says "Submit grant applications electronically to NIH and other Public Health Service Agencies..."



The screenshot shows the "Welcome" page of the ASSIST system. The header is identical to the previous screenshot. Below the header is a navigation bar with a "Welcome" link. The main content area features a large heading "Welcome to the Application Submission System & Interface for Submission Tracking (ASSIST)". Below this heading is a section titled "INITIATE APPLICATION" which includes a text input field for the "Funding Opportunity Announcement #" (with the example "OTA-18-001") and a "Go" button. A small informational note below this section explains that FOAs are posted in the NIH Guide for Grants & Contracts and Grants.gov's Search Grants. At the bottom of the page is a section titled "SEARCH FOR APPLICATION" with a search icon and a "Search Applications" button.

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.

Research Opportunity Announcement: RECOVER Mobile Health Platform
OTA-21-015C

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 

 **ROA INFORMATION:** * Required field(s)

ROA Number:	OTA-18-005
Opportunity Title:	OT Research Opportunity Test June
Offering Agency:	National Institutes of Health
Opportunity Open Date:	
Opportunity Close Date:	
Agency Contact:	NIH Contact
Application Identifier:	

Application Project Title *
(describe title in 200 characters)

Lead Applicant Organization: * ---- Choose Organization ----

Lead Applicant Organization Address:

Contact Project Director/Principal Investigator

Enter PD/PI Information below or Pre-fill Application from Username Clear

First Name:

Middle Name:

Last Name:

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.

Research Opportunity Announcement: RECOVER Mobile Health Platform OTA-21-015C

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:

Save and Keep Lock Save and Release Lock 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.

Submission Type

Corrected Submission

Prior Submission Tracking Number

1. Applicant Information

1. Applicant Information

* Organization Name

Department

Division

* Street 1

Street 2

* City

County

State

Province

* Country

Zip/Postal Code

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.

- 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.

Research Opportunity Announcement: RECOVER Mobile Health Platform
OTA-21-015C

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.

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](#)

The attachment should be attached as a PDF file.

Summary **OTA Core**

OTA Core > Contact PD/PI Record

OTA Core - Contact PD/PI Record

OTA Core v1.0 ?

Expanded

Credential, e.g., agency login	<input type="text"/>	<input type="button" value="Populate fields from Credential"/>
Prefix	<input type="text" value="--- Select Prefix ---"/>	
* First Name	<input type="text"/>	
Middle Name	<input type="text"/>	
* Last Name	<input type="text"/>	
Suffix	<input type="text" value="--- 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/Parish	<input type="text"/>	
State	<input type="text" value="CA: California"/>	
Province	<input type="text"/>	
* Country	<input type="text" value="USA: UNITED STATES"/>	
Zip/Postal Code	<input type="text"/>	
Phone Number	<input type="text"/>	
Fax Number	<input type="text"/>	
* Email	<input type="text"/>	

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	<input type="text" value="--- Select Prefix ---"/>
* First Name	<input type="text"/>
Middle Name	<input type="text"/>
* Last Name	<input type="text"/>
Suffix	<input type="text" value="--- 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	<input type="text" value="--- 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.

Actions ?

- ADD OPTIONAL FORM
 - PREVIEW APPLICATION
 - VALIDATE APPLICATION
 - VIEW STATUS HISTORY
 - UPDATE SUBMISSION STATUS
-
- COPY APPLICATION

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

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.

Se

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at

Update Submission Status

Select the new status

Ready for Submission ▾

-- Select Status --

Ready for Submission

Abandoned

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

Add comment

Cancel

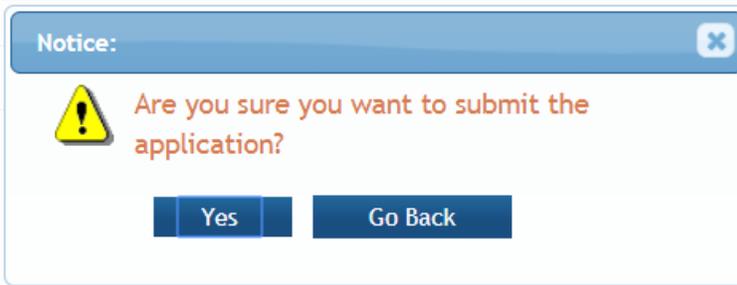
© 2018 NIH. All Rights Reserved.
Screen Rendered: 05/16/2018 10:45:16 EDT | Screen Id: ASSIST0034@1092
Version: 2.29.00

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



[Follow the status of your submission in eRA Commons](#)