NIH RECOVER Initiative Frequently Asked Questions

This document contains triaged questions that have been populated by the NIH or submitted between **July 9, 2021 and July 30, 2021**.

This FAQ review covers the following topics regarding the Mobile Health Platform Research Opportunity Announcement OTA-21-015C:

1. Application Preparation and Submission

1.1 Q	**In responding to the Mobile Health Platform ROA OTA-21-015C, may an entity sub-contract to another entity for one or more parts of development?**
1.1 A	Yes, subcontracts are allowable for any and all activities under the ROA. Sub-awards must be fully justified and include normal budget documentation.
1.2 Q	**What information is required from consortium partners?**
1.2 A	Letters of support are acceptable.
1.3 Q	**My institution is part of a consortium. Should we submit a linked application or one application and administer activities through subawards?**
1.3 A	For a consortium, pre-existing or newly formed, it is advisable to submit a single application. Note that negotiations during the award process may modify the consortium.
1.4 Q	**When submitting to this announcement with sub-awardees, are we to include full subaward documents (budgets, justifications, statements of work, letters of commitment) for each site, or do we just include the "proposed" total for subawards and include the commitment letters only?**
1.4 A	It is recommended to include full subaward documents to include full budgets, justifications, biosketches and Consortium/Contractual Arrangement.
1.5 Q	**Should we submit letters of intent from all institutions that will be included in the proposal, or just include one letter from the Lead Institution?**
1.5 A	Although not required, you may include letters of intent in an additional appendix.
1.6 Q	**How would you like it clarified in the title which ROA I am applying for?**
1.6 A	When applying in ASSIST, please use the ROA number OTA-21-015. Do not include the final letter as the system will not recognize it. In the project title, however, you should specify you are applying to the OTA-21-015C ROA.
1.7 Q	**Can you describe the format and page restriction of all the components of the application?**
1.7 A	The page limit, as well as the required sections (e.g., project plan, budget, operational milestones, etc.) for each technical project plan, are specified in the corresponding ROA. There are, however, no document formatting requirements (e.g., fonts, margins, etc.). Clear and responsive content is the ultimate goal.

1.8 Q	**Will late applications be considered?**
1.8 A	No. Due dates for proposals are clearly indicated in each ROA.
1.9 Q	**Are external links allowed in applications?**
1.9 A	Yes, but reviewers will not be required to review all linked content within the document. Thus, applicants should use linked content sparingly and should be sure to include any critical content necessary for reviewers to evaluate how the applicant meets the requirements of the ROA in the main text of the document.
1.10 Q	**Does the page limit include references?**
1.10 A	References do not count towards the page limit.
1.11 Q	**Does the page limit include the bibliography?**
1.11 A	The bibliography does not count towards the page limit.
1.12 Q	**Is the budget justification part of the page limit?**
1.12 A	The budget justification does not count towards the page limit.
1.13 Q	**Are there formatting requirements for the budget?**
1.13 A	For budgets, we prefer but do not require the SF424. See the ROA for additional details regarding budget format and requirements.
1.14 Q	**How do we search for the ROA in ASSIST?**
1.14 A	When accessing ASSIST, applicants should enter in OTA-21-015, dropping the final letter in the ROA. Applicants should indicate which ROA they are applying to in the project title by including the complete ROA number (i.e., OTA-21-015C).
1.15 Q	**Are individuals with R35 funding able to apply for these opportunities?**
1.15 A	Yes, existing NIH grantees are eligible provided they can maintain the R35 minimum required effort level.
1.16 Q	**Can you advise whether this work will be open to for-profit private sector institutions to lead or will only academic/non-profit/public sector organizations be invited to submit?**
1.16 A	For-profit institutions, including small businesses, are eligible to apply. Please see ROA eligibility section of the ROA for additional guidance.
1.17 Q	**Can we leverage existing funding from the NIH?**
1.17 A	Existing NIH funding should only be used for the authorized purpose to which it was issued.
1.18 Q	**How should I handle overlap of science and/or budget between a ROA application and an R01 application that's been submitted?**
1.18 A	Applications should not contain overlap. Investigators should take care to remove overlapping elements prior to submission.
1.19 Q	**What is the expected timeframe for evaluation of proposals and notification of selected proposals?**

1.19 A	Proposals for the ROA are due on July 30. Selected applicants are expected to have virtual interviews in late August and/or early September. Awards are currently anticipated in September or October.

2. ROA Requirements: Mobile Health Platform

2.1 Q	**What technologies being used by other components of the PASC initiative should be supported by the Mobile Health Platform?**
2.1 A	Technologies including wearable devices, sensors, smartphone apps, and data repositories may be supported through multiple aspects of the PASC Consortium. Specifically, the Digital Health Data Repository (DHDR) will host the digital health data being collected by the Mobile Health Platform apps and other PASC-related apps as appropriate. The DHDR scope will include data ingestion and storage, data curation, and computation and analysis, while maintaining appropriate privacy and security of the data. In addition, individual clinical cohort sites may propose and provide use of wearable devices, sensors and/or smartphone apps that may complement Mobile Health Platform activities.
2.2 Q	**Are there device and app integrations that are preferred for the MHP to support for the PASC initiative?**
2.2 A	The ROA requires 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. 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. The applicant must propose and justify which device(s) will be used.
2.3 Q	**My platform does not have all the capabilities listed in the ROA. Can I still apply?**
2.3 A	Applicants without existing capabilities in one or more of the listed areas should describe how they will rapidly incorporate these capabilities into their platform.
2.4 Q	**The clinical studies ROA indicates international sites are allowed. Does this mean platforms must be General Data Protection Regulation (GDPR) compliant?**
2.4 A	NIH recommends that US investigators wishing to collaborate with European Economic Area (EEA) researchers on NIH-funded or -conducted research consult with their legal counsel and potential partners on General Data Protection Regulation's (GDPR) obligations as well as any other potential implications for cooperation.
2.5 Q	**Will the MHP do more than support the existing PASC clinical study cohorts?**
2.5 A	In addition to supporting existing PASC clinical study cohorts, the MHP may be expected to collaborate with the Clinical Science Core to develop a website/app to engage and assess populations beyond existing PASC cohort populations, reaching non-hospitalized, underserved, and underrepresented populations (i.e., PASC Patient Registry). The MHP will support this cohort in the same manner as the other PASC 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.
2.6 Q	**Is the MHP responsible for harmonizing sensor data?**
2.6 A	The PASC Digital Health Data Repository (DHDR) will be responsible for harmonizing all data, including sensor data. However, the MHP awardee will be responsible for participating in the process to define sensor data standards and harmonization processes.
2.7 Q	**Does NIH have a preference for which consumer wearable device is procured and distributed by the MHP?**
2.7 A	Proposed wearable devices should be validated commercial or research-grade devices that collect information relevant to PASC such as heart rate, skin temperature, oxygen saturation, physical activity, and sleep. The applicant must propose and justify which device(s) will be used.
2.8 Q	**How long should I plan to manage upkeep of the Mobile Health Platform post-deployment?**
2.8 A	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.
2.9 Q	**Who will have priority access to the data generated from the Mobile Health Platform?**
2.9 A	In this program, high priority will be given to making the data available to the broad research community as soon as possible. For the clinical recovery cohort data, there will be a very short period during which investigators in the consortium will have access to data before they are available for general research use.
2.10 Q	**Will the Mobile Health Platform be expected to gain eConsent for existing pediatric cohorts?**
2.10 A	The MHP should be capable of supporting participant consenting processes for both adult and pediatric populations. The need for additional consenting/ eConsenting with be determined based on the existing consents for any existing study compared to the needs of the PASC Consortium research.
2.11 Q	**The MHP ROA requests that the platform be usable, accessible, and culturally appropriate for diverse populations. What populations are high priority? Does the MHP need to be suitable for all these populations?**
2.11 A	The priority populations are those disproportionately impacted by the coronavirus pandemic, including Black/African Americans, Hispanic/Latino Americans, American Indians/Alaska Natives, and Native Hawaiians/Pacific Islanders; sexual and gender minorities; people living in nursing homes, jails, rural areas, and/or underserved urban areas; and people experiencing homelessness. (See RADx-UP priority populations: https://www.nih.gov/research-training/medical-research-initiatives/radx/radx-programs#radx-up.) The MHP should serve many PASC Initiative studies. Therefore,

	suitability for a broad range of populations that are impacted disproportionately from COVID-19 will be viewed as a strength.
2.12 Q	**Are applications including new sensor development efforts encouraged?**
2.12 A	No. Applicants should plan to leverage existing sensor devices.
2.13 Q	**Is it the responsibility of the MHP to select the controlled vocabularies, ontologies, and CDEs (bioinformatic infrastructure) that individual RECOVER investigators will employ to realize the desired harmonization and sharing" of digital health data obtained from a constellation of devices? Or is the role (cost) of the MHP limited to "governance" of vocabularies, ontologies, and CDEs that are developed by individual RECOVER investigators?**
2.13 A	Selection of controlled vocabularies, ontologies, and CDEs for digital health data will be a joint effort led by the Clinical Studies Core and Data Resource Core. The Mobile Health Platform, Digital Health Data Repository, and Investigator Consortium will participate in that effort.
2.14 Q	**Does ROA OTA-21-015C provide funding for the development of a COVID-19 detection device?**
2.14 A	No. This ROA is not soliciting applications for a COVID-19 detection device. Investigators are encouraged to explore other NIH COVID-19 funding opportunities
2.15 Q	**How will data sharing of mobile health data be governed?**
2.15 A	Working in collaboration with the Clinical Science Core, the Data Resource Core will lead the data sharing agenda and coordinate data sharing with the Consortium investigators, data repositories and the Mobile Health Platform.
2.16 Q	**What obligations, activities, and costs would the Mobile Health Platform (MHP) be responsible for in relation to other RECOVER components, including reporting to the Clinical Science Core and conducting data transfers to a Data Resource Core, Biorepository Core, Data Repositories, and the Administrative Core?**
2.16 A	The MHP will be a subaward to the Clinical Science Core and will be expected to collaborate and integrate across the sites and Cores. The MHP should be prepared to transfer data to the Digital Health Data Repository, including preparation of the data for transfer. As data are being collected through the MHP, they will need to be shared with the clinical sites for analysis, as specified in the ROA.
2.17 Q	**To what extent should the application outline an approach that is integrated with the existing funded PASC studies, the Data Resource Core, and other funded Cores?**
2.17 A	Integration and collaboration across the PASC studies and Cores is essential to the success of the RECOVER Initiative. Although space is limited, to the extent possible investigators should highlight how their approach will facilitate integration. This could be addressed for example by providing a high-level outline of proposed strategy for integration of the MHP with the studies and Cores.

3. Proposal Budget

3.1 Q	**How many PASC clinical cohorts are expected to be awarded and should the MHP include the cost for each mobile platform deployment in the budget?**
3.1 A	The number of PASC clinical cohorts is yet to be determined. Budgets should estimate 25 site-specific MHP deployments, although the actual number is to be determined and will be based on actual needs.
3.2 Q	**Are detailed budgets required for subawards?**
3.2 A	Yes, detailed well-justified budgets are required for subawards.
3.3 Q	**Is there a maximum budget that can be requested for the respective ROAs?**
3.3 A	No, but we strongly encourage realistic and well-justified budgets.
3.4 Q	**What is the budget scope? How much detail is needed?**
3.4 A	The budget should be based on the needs of the proposed work and strongly justified. An SF424 detailed categorical budget, or similar documentation, is recommended. A detailed budget justification is also required. Sub-awards should also include detailed budgets and justifications.
3.5 Q	**Can budgets be renegotiated?**
3.5 A	The complete terms and conditions of each OT agreement or sub-agreement issued under this ROA--including the budget--are subject to negotiation and will be contained in the agreement between the NIH and the awardee.
3.6 Q	**When you say to use the SF424 for the budget, do you mean the standard R&R budget template or the SF424A non-construction budget template?**
3.6 A	The standard SF424 form is recommended for budgets. In addition to this, the Timeline and Tasks section of the application should list the budget for each task being proposed in the first year.
3.7 Q	**Are indirect costs allowed?**
3.7 A	Yes, applicants should use their current negotiated F&A rate.
3.8 Q	**Does the NIH Salary cap apply to OT awards, as it does for NIH grant?**
3.8 A	Yes, the NIH salary cap applies to OTA awards.
3.9 Q	**Should investigators budget for network service and device cost for participants that cannot afford mobile device services (i.e. smart phone and internet)?**
3.9 A	Yes, investigators can budget for this in their proposal. If doing so, please provide a breakdown of cost per person for devices and/or cellular/internet services.
3.10 Q	**Are the 25 sites referenced in the Mobile Health Platform ROA OTA-21-015C announcement 25 physical facilities or 25 Consortium members where each member may see patients at several different physical sites?**
3.10 A	For the purposes of the budget, please treat the 25 consortium members as if each member may see patients at multiple physical sites. Please also note the complete terms and conditions of each OT Agreement or sub-agreement issued under this ROA--including the bugdet--are subject to negotiation and will be contained in the Agreement entered between the NIH and the Awardee.