NIH RECOVER Initiative Frequently Asked Questions

This document contains triaged questions that have been populated by the NIH or submitted after July 9, 2021.

This FAQ review covers the following topics regarding the Data Repositories Research Opportunity Announcement OTA-21-015D:

1. Application Preparation and Submission

1.1 Q	**In responding to the RECOVER Data Repositories ROA OTA-21-015D, 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 subawardees, 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	**Is a letter of intent required? What information should be provided in the letter of intent?**

1.5 A	Letters of intent are required for all Data Repositories and will be used to determine eligibility for further consideration. In the letter, applicants should describe participating institutions, repository or repositories to which you are applying and in no more than 2 pages address the following: 1. How the proposed solution meets the needs of the PASC Consortium with respect to fulfilling the requirements expected of the RECOVER Data Repository. 2. The team's prior experience deploying their solution in a variety of research contexts and experience working as part of a multi-institutional collaboration. 3. Technical proficiency with data management, privacy, security, accessibility, interoperability, providing a researcher platform for analytics, and adopting Consortium standards.
1.6 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?**
1.6 A	A letter of intent from the lead Institution is sufficient as long as it lists all of the institutions involved. In the letter of intent please include all key personnel with a percent effort at or above 25%.
1.7 Q	**How would you like it clarified in the title which ROA I am applying for?**
1.7 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-21-015D ROA.
1.8 Q	**Can you describe the format and page restriction of all the components of the application?**
1.8 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.
1.9 Q	**Will late applications be considered?**
1.9 A	No. Due dates for proposals are clearly indicated in each ROA.
1.10 Q	**Are external links allowed in applications?**
1.10 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.
1.11 Q	**Does the page limit include references?**
1.11 A	References do not count towards the page limit.
1.12 Q	**Does the page limit include the bibliography?**
1.12 A	The bibliography does not count towards the page limit.
1.13 Q	**Is the budget justification part of the page limit?**
1.13 A	The budget justification does not count towards the page limit.

1.14 Q	**Are there formatting requirements for the budget?**
1.14 A	For budgets, we prefer but do not require the SF424. See the ROA for additional details regarding budget format and requirements.
1.15 Q	**How do we search for the ROA in ASSIST?**
1.15 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-21-015D).
1.16 Q	**Are individuals with R35 funding able to apply for these opportunities?**
1.16 A	Yes, existing NIH grantees are eligible provided they can maintain the R35 minimum required effort level.
1.17 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?**
1.17 A	For-profit institutions, including small businesses, are eligible to apply. Please see ROA eligibility section of the ROA for additional guidance.
1.18 Q	**Can we leverage existing funding from the NIH?**
1.18 A	Existing NIH funding should only be used for the authorized purpose to which it was issued.
1.19 Q	**How should I handle overlap of science and/or budget between a ROA application and an R01 application that's been submitted?**
1.19 A	Applications should not contain overlap. Investigators should take care to remove overlapping elements prior to submission.

2. ROA Requirements: All Repositories

2.1 Q	**What is the distinction between the GUID and the Privacy Preserving Record Linkage?**
2.1 A	The GUID is a unique identifier that will be assigned to each study participant by the Data Resource Core. The PPRL, sometimes called a "hash algorithm," is a secure token-generating software designed to identify the same individual across studies and data sources to enable the same GUID to be assigned to all data for that individual across the repositories. The GUID may supplement study-specific participant identifiers, or a study may use GUIDs issued by the DRC as their participant identifier.
2.2 Q	**What metadata should be tracked as part of the provenance tracking process?**

2.2 A	Data provided to the repository either directly by a study or via the DRC will include a variety of metadata including where appropriate the data model and data dictionary that describe the dataset. For all submitted datasets, the repository must track the source and creator, as well as any data use limitations associated with the dataset. If the data were transformed from the original data model then the repository will be provided the original and transformed data + metadata, and must retain this data and metadata. If the repository transforms the data, it must retain all versions of the data and associated metadata, and create new metadata to describe the transformation performed, date/time of the transformation, and individuals responsible for the transformation. As datasets are provisioned to end users and analyzed, the repository should generate metadata to track each of these events, including the use of datasets in published results.
2.3 Q	**What is the role of the DRC vs. the repository in the curation of data?**
2.3 A	The role of the DRC in curation will vary depending on the capabilities of the specific repository. For example, a repository may have a well-defined and proven process and tools for syntactic and semantic harmonization of data. In this case it would make the most sense to have the repository execute this process rather than the DRC; i.e. the data may pass through the DRC or may be directly transferred from the studies to the repository with the DRC providing facilitation and tracking of the process. However, if the repository does not have such a capability, then the DRC would take the responsibility for harmonization.
2.4 Q	**What is meant by a "well-defined dataset"?**
2.4 A	A well-defined data set is a comprehensive dataset for which a DOI can be minted and then that DOI can be cited in a publication or other reporting of results. It may be an original raw dataset, or it may be the dataset used for a specific analysis. A well-defined dataset should be accompanied by a clear analytical protocol that will facilitate research reproducibility. The intent is that authorized investigators could reference that DOI in a request to access the dataset and reproduce or extend the analysis (assuming appropriate data access approvals).
2.5 Q	**What are the requirements with respect to FISMA and FedRAMP?**
2.5 A	Each repository is expected to be able to obtain a FISMA Authority to Operate (ATO) at the Moderate level within 90 days of award. The use of a cloud service provider with a FedRAMP ATO alone is insufficient to meet this requirement and the awardee must conduct a Security Assessment and Authorization (SA&A) process consistent with NIST guidance and the NIST Risk Management Framework. The cloud service provider must hold a FedRAMP ATO.
2.6 Q	**What is intended by the requirement to have the ability to associate an identifier such as a DOI with a workspace?**
2.6 A	The ability for an investigator to be able to reproduce an analysis completed by another investigator will be significantly aided by the ability to simply recreate the workspace used in the original analysis based on a citation of the workspace. Therefore a workspace must be able to be "archived" and associated with an identifier that enables it to be rapidly reconstituted including data, tools, workflows, including versions of software, data transformations etc.

3. ROA Requirements: Imaging Data Repository

3.1 Q	**What imaging modalities are anticipated for the Imaging Data Repository? What are the expected organs and systems to be imaged?**
3.1 A	The SARS-CoV-2 Recovery Cohort studies may potentially generate medical imaging data from a wide range of modalities, from established clinical imaging (radiography, computed tomography, and magnetic resonance imaging) to more specific and early-stage imaging modalities. PASC has been shown to impact a wide range of organs and systems, from the brain to limb extremities. It is expected that data relevant to a variety of organs and system including but not limited to cardiopulmonary, neurological, or abdominal systems, will be generated in the framework of SARS-CoV-2 Recovery Cohort studies. The Imaging Data Repository is expected to be extensible and versatile, ensuring that data from diverse imaging modalities and organ systems can be ingested, stored, and analyzed.
3.2 Q	**Are there additional requirements for de-identification of medical images?**
3.2 A	In addition to data and metadata de-identification steps common to all repositories, the medical imaging repository will provide for image and image metadata level de-identification and deploy tools and procedures to minimize the risk of re-identification. One specific concern to be addressed is re-identification by facial reconstruction.
3.3 Q	**What data formats are expected to be submitted?**
3.3 A	DICOM is the most widespread data format in medical imaging, and it will likely be a major component of the data format mix to be ingested. In addition, the imaging repository is expected to provide support for additional data formats, for example, Brain Imaging Data Structure (BIDS)-formatted data. When transformed data is submitted, the original data and metadata, clear of all identifiable information, is to be submitted in parallel (4.2A, above)

4. ROA Requirements: Pathology Data Repository (PDR)

4.1 Q	**What imaging modalities are anticipated for the PDR?**
4.1 A	Bright field and immunofluorescent images should be anticipated to be housed in the PDR. Multiplex IHC and multiplane image support should be anticipated.
4.2 Q	**What image formats will be submitted?**
4.2 A	A diversity of formats should be anticipated for submission. Whole Slide Image formats from multiple vendors, as well as photomicroscope image formats should be supported.

5. ROA Requirements: Digital Health Data Repository (DHDR)

5.1 Q	**The ROA references standards multiple times. What is the expectation for the DHDR if there is not a standard?**
5.1 A	In cases where a single, preferred standard is not available, the DHDR applicant should recommend and justify the best available and/or most widely used approach.
5.2 Q	**What are the roles of the Mobile Health Platform (MHP) (ROA OTA-21-015C) and the Digital Health Data Repository (DHDR) (ROA OTA-21-015D) with respect to data flow?**
5.2 A	The MHP and DHDR will work closely together (and with the PASC 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 infrastructure 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. While the MHP and the DHDR will function collaboratively, they will each lead distinct aspects of the digital infrastructure. Specifically, the MHP will develop customized mobile apps for enabling the collection of digital health data via mobile health technology by the PASC Investigator Consortium to complement and augment existing clinical, electronic health record (EHR), and other real-world data. The 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. Both the MHP and the DHDR will be responsible for maintaining appropriate privacy and security of the data.

6. Proposal Budget

6.1 Q	**Are detailed budgets required for subawards?**
6.1 A	Yes, detailed well-justified budgets are required for subawards.
6.2 Q	**Is there a maximum budget that can be requested for the respective ROAs?**
6.2 A	No, but we strongly encourage realistic and well-justified budgets.
6.3 Q	**What is the budget scope? How much detail is needed?**
6.3 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.
6.4 Q	**Can budgets be renegotiated?**
6.4 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.

6.5 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? And is the milestone payment schedule to be submitted in addition to the standard budget form?**
6.5 A	The standard SF424 form is recommended for budgets. The milestone payment schedule should be submitted separately.
6.6 Q	**Are indirect costs allowed?**
6.6 A	Yes, applicants should use their current negotiated F&A rate.
6.7 Q	**Does the NIH Salary cap apply to OT awards, as it does for NIH grant?**
6.7 A	Yes, the NIH salary cap applies to OTA awards.