National Institutes of Health

NIH PASC Frequently Asked Questions

This document provides answers to frequently asked questions (FAQs) on Post-Acute Sequelae of SARS-CoV-2 Infection (PASC). The FAQs cover the following topics:

This document will be updated periodically to include answers to frequently asked questions.

1. Initiative Scope

1.1 Q	**Why is this initiative happening so quickly?**
1.1 A	The SARS-CoV-2 pandemic is a dynamic and challenging public health emergency. Post-acute sequelae of SARS-CoV-2 infection (PASC) can range from mild to severe and are as yet not well understood. What we do know is that sequelae of SARS-CoV-2 infection present in different ways and can affect all organ systems. Therefore, PASC may not be a singular syndrome, but rather constitute multiple syndromes. It is critical that we quickly characterize PASC, so we can move toward effective treatments and preventive strategies that address the range of clinical sequelae.
1.2 Q	**Will this initiative support any clinical trials?**
1.2 A	Yes, our ultimate goal is to prevent and treat PASC; therefore, PASC clinical trials will be supported as part of this initiative. However, clinical trials will not be supported under the two initial ROAs (OTA-21-015A and OTA-21-015B). We will be issuing future ROAs focused on clinical trials.

2. Application Preparation and Submission

2.1 Q	**Can we leverage existing cohorts funded by the NIH?**
2.1 A	Yes, you can. Applications that can demonstrate an ability to rapidly enroll from an existing cohort, use data collected prior to the current pandemic, and which have clear capacity to perform cohort visits are encouraged.
2.2 Q	**In responding to the Core ROA OTA-21-015A, may an entity submit for one of the three cores as a prime and sub-contract to another entity for one or more of the other cores?**
2.2 A	Yes, subcontracts are allowable for any and all activities under the ROA. Sub-awards must be fully justified and include normal budget documentation.
2.3 Q	**How should I handle overlap of science and/or budget between a ROA application and an R01 application that's been submitted?**

2.3 A	Should an award be made under these ROAs, any overlap of science and/or budget with another NIH application will be addressed by our OT officers during the negotiation period and prior to award.
2.4 Q	**Can an R01 or other grant application that's already been submitted be retitled and submitted in response to the ROAs?**
2.4 A	While technically not prohibited, this approach would almost certainly not be optimally responsive to the ROAs without significant modification. The goals and scope of the ROAs are quite different from those for R01s and other grants.
2.5 Q	**How would you like it clarified in the title which ROA I am applying for?**
2.5 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, you should specify whether you are applying to the OTA-21-015A or OTA-21-015B ROA.
2.6 Q	**Can you describe the format and page restriction of all the components of the application?**
2.6 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.
2.7 Q	**Is there a separate specific aims page? Do the separate components of the research study ROA (OTA-21-015B) go in separately or together?**
2.7 A	A specific aims page is not required, the technical proposal must address the research questions. Each required section (i.e., technical project plan, budget, etc.) should be provided for each ROA component (i.e., recovery cohort, autopsy cohort, and EHR – and other Real-World Data-Based studies) within the same proposal.
2.8 Q	**Is there a threshold of number of active or retrospective cases that institutions need to have to participate and be funded?**
2.8 A	Yes, please see ROA OTA-21-015B for minimum requirements. Please also note that applicants proposing smaller samples should provide strong justification for their approach based on other considerations, e.g., special population characteristics, deep pre-infection phenotyping.
2.9 Q	**Are individuals with R35 funding able to apply for these opportunities?**
2.9 A	Yes, existing NIH grantees are eligible provided they can maintain the R35 minimum required effort level.
2.10 Q	**What information is required from consortium partners?**
2.10 A	Letters of support are acceptable.
2.11 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?**
2.11 A	Please see ROA eligibility section of the ROA for guidance.
2.12 Q	**Will applying for this opportunity as PI of our institutions Recovery Cohort use up ESI status?**

2.12 A	ESI status will not be affected by awards issued under these ROAs.
2.13 Q	**If a group of centers wanted to propose studies related to diabetes in the Clinical Recovery Cohort Studies, is it advised that we apply as (a) part of our home institutions including a hypothesis related to diabetes or (b) a consortium comprised of investigators interested in diabetes from a number of institutions (10-20) and propose a series of hypotheses related to diabetes?**
2.13 A	Either approach is acceptable but go with whatever approach you think will generate the best science.
2.14 Q	**Do applicants have to apply for adult and pediatric populations, or one or the other?**
2.14 A	Applicants may apply for adult and/or pediatric populations. However, if you are applying for both, separate applications should be submitted. Applicants should review the thresholds described in the ROA to ensure the cohort(s) demonstrates access to adequate numbers of cases and comparators.
2.15 Q	**How do we search for the ROA in ASSIST?**
2.15 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-21-015A or OTA-21-015B).
2.16 Q	**If you use ASSIST, does that mean you don't need to go through eRA?**
2.16 A	Please submit your application through ASSIST as eRA will not recognize the OT number. Also, please submit your application to the email indicated in the ROA once uploaded into ASSIST.
2.17 Q	**If a core could be a sub-award to another core, then is it possible to propose a core that has a specific focus which would fall under the data core, such as a core to establish imaging protocols and oversee standardization of imaging of post-covid patients?**
2.17 A	Applications proposing to focus on just one part of a core are acceptable. However, we would prefer that such application activities be proposed as part of a sub-award under a complete core's proposal.
2.18 Q	**If we are only submitting to the Recovery Cohort Clinical Study without also submitting for a Core, can we simply reference how we plan to work with the cores in general (hard to give specifics until we know which cores are funded) or will there be preference given to proposals that apply for both the RCCS and a core?**
2.18 A	All three cores will be established as they are integral to the success of the program. All investigators will need to work with the three cores and should indicate in their proposals how they would intend to interface with the three cores. There is no preference for proposals that apply to both ROAs.
2.19 Q	**If we propose a multi-PI leadership team, is a standard MPI Leadership Plan document expected, or should this information be included in the technical project plan?**

2.19 A	The Standard MPI Leadership Plan document would be helpful to include but is not explicitly required. If you do include it, you may include it as an attachment.
2.20 Q	**Is late application allowed (2 weeks) for study section service?**
2.20 A	No. Due dates for proposals are clearly indicated in each ROA.
2.21 Q	**Can we use existing cohorts funded by the NIH?**
2.21 A	Yes, you could use an existing cohort, as long as it meets the criteria of the ROA.
2.22 Q	**Are external links allowed in applications?**
2.22 A	Yes.
2.23 Q	**Do the milestones go in the Budget section?**
2.23 A	The milestones plan must be included in the proposal. Applicants may choose where to include it in their application.
2.24 Q	**Does the 10-page limit include references?**
2.24 A	References don't count toward the 10-page limit.
2.25 Q	**Does the 10-page limit include the bibliography?**
2.25 A	No.
2.26 Q	**If submitting for all 3 cores, is there an upper limit of 10 pages per core, or is any breakdown allowed provided 30 pages is not exceeded?**
2.26 A	10 pages are allowed per core to describe the technical project plan.
2.27 Q	**Can a center planning 3 major research components include an overarching organization/administration/data management section within the 30-page limit?**
2.27 A	As each component will be evaluated individually, the organization, administration, data management needs to be described for each component.
2.28 Q	**If biosketches do not count toward page limit, may they be 5 pps or must they be constrained to 3 pp?**
2.28 A	It’s your choice, either is acceptable.
2.29 Q	**Is the budget justification part of the 10-page limit?**
2.29 A	No.
2.30 Q	**Are there formatting requirements for the budget?**
2.30 A	For budgets, we prefer but do not require the SF424. See the ROA for additional details regarding budget format and requirements.
2.31 Q	**My institution is part of a consortium, should we submit a linked application or one application and administer activities through subawards?**
2.31 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.

2.32 Q	**Should we include specific details (inclusive of budget/budget justification) about data harmonization, or will that be the role of the NIH Data Resource Core?**
2.32 A	The Data Resource Core will play a key role in facilitating data harmonization across the Recovery Cohort. Applicants, however, should include in their budgets the funds needed to support data harmonization for their studies.
2.33 Q	**Will supplemental materials such as Facilities, Equipment, Enrollment Tables, and other Form F documents be accepted?**
2.33 A	Yes, those supplemental materials will be accepted.
2.34 Q	**How long will the recovery cohorts be followed? 1 year, 2 years, or longer?**
2.34 A	Details on the duration of follow-up will be determined after the awards are made, in collaboration with the larger Consortium group. Ideally subjects in the recovery cohort will be enrolled within the first 6-12 months so that they can be followed for at least 2-3 years.
2.35 Q	**Do we need to include a PHS Human Subjects and Clinical Trials Information Form in our initial proposal, or should this information be provided at the time of award?**
2.35 A	You do not need to include the PHS Human Subjects and Clinical Trials Information Form with your application.
2.36 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?**
2.36 A	Please include as much information about subawardees as possible.
2.37 Q	**Do you allow two investigators to serve as "multi-PIs"?**
2.37 A	Yes.
2.38 Q	**For autopsy cohort, autopsy SOP is required. Should the SOP be included in the 10-page "Technical Project Plan" or be submitted as a separate document without page limitation?**
2.38 A	The autopsy SOP can be an appendix and does not count towards the 10-page limit.
2.39 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?**
2.39 A	Although not required, you may include letters of intent in an additional appendix.
2.40 Q	**If an application includes all 3 components, should a separate multi-PI plan be included for each component? Or a single MPI plan integrating the three components?**
2.41 A	Either would be acceptable.

3. ROA Requirements: Core

3.1 Q	**What FISMA and/or FedRAMP compliance classification level is expected for the DRC?**

3.1 A	Any system hosted by the DRC must meet FISMA moderate compliance and receive an ATO from the NIH. If those systems are cloud-based, they must be hosted in a FedRAMP Moderate cloud service provider. However, if the DRC makes use of existing NIH cloud-based resources, such as the NHLBI BioData Catalyst, for all data work, then compliance is already assured.
3.2 Q	**I'm trying to decide whether to apply to the EHR/RWD Component or the DRC Component. What are the key differences that might help me decide which one to apply to?**
3.2 A	The Data Resource Core is much like a Data Coordinating Center and will be expected to handle the full breadth of data types collected across all consortium activities, including data harmonization, privacy-preserving data linkages across the consortium, etc. The EHR/RWD component addresses activities related to PASC data science, including development and validation of computable phenotypes, development and validation of analytical workflows, and other activities as outlined in the ROA. It is expected that there will be a close, continuous, and bidirectional relationship between the EHR/RWD component and the DRC.
3.3 Q	**Is this opportunity open to full time University faculty with part-time VA appointment? Can the application be based entirely on the VA population?**
3.3 A	Yes, university professors with VA appointments may apply. The ideal final study population will be assembled from participating studies to be a large, diverse, representative cohort across the lifespan, with populations at risk for PASC, populations with a broad spectrum of PASC symptoms and appropriate controls. All data and biospecimens will be prepared for sharing for general research use, so they must be collected under consents that permit this.
3.4 Q	**Should the biorepository propose a specific sample and aliquoting scheme in the application?**
3.4 A	This level of detail is not required but could be included.
3.5 Q	**What are the common data elements that will be utilized?**
3.5 A	PASC CDEs will be identified by the Consortium once it is established.
3.6 Q	**Will there be multiple sites selected to join as an integrated core or will there be one core for each of the core types listed?**
3.6 A	Only one site will be selected for each of the 3 cores identified in the ROA.
3.7 Q	**Are you developing a PASC protocol for the national brain repository?**
3.7 A	The PASC biorepository will be separate from the NIH NeuroBioBank.
3.8 Q	**Can we propose establishing a biomarker analysis as part of the Biospecimen Core?**
3.8 A	This is not required per the ROA, but certainly could be proposed.
3.9 Q	**Will the biorepository send sample collection kits directly to participants or will they need to be obtained from the clinical sites?**
3.9 A	The ROA states that the biorepository core will "Distribute instructions and kits for sample collection, preparation, labelling and shipping to PASC investigators." Thus,

	the biorepository will not send kits directly to participants. Sample collection kits will be sent to the clinical sites for distribution to appropriate participants.
3.10 Q	**Will the Biorepository core be responsible for molecular measurements, other assays, or processing samples (e.g. extracting DNA with associated QC, spinning blood tubes down for plasma and serum, etc.)?**
3.10 A	The Biorepository may be tasked with, and may contract out, some sample preparation and centralized assays for core protocols. Biorepository applicants should define what sample processing and assay resources, especially for routine procedures and measures, they can provide.
3.11 Q	**Is CAP accreditation sufficient for the Biorepository Core?**
3.11 A	The biorepository core applicant should state what accreditation(s) they have attained.
3.12 Q	**We are looking to apply to the Clinical Cohort on behalf of a consortium, with sites in/out of the US and across the age span. We will not be applying as a Data Core. Should we plan to arrange for our own data collection and queries and data submission to the Core via a clean data portal, or will the Cores be collecting data from our sites directly?**
3.12 A	The consortium will be expected to arrange for their own data collection, work with the CSC and DRC on data standards (CDEs) and pre-processing and submit data to the DRC via a clean data portal.
3.13 Q	**Will data Cores be obtaining patient outcomes or will applicants to the clinical cohorts be responsible for this?**
3.13 A	The clinical cohort investigators will be tasked with collecting data on patient outcomes.
3.14 Q	**Could you please clarify the expectation for sharing of biospecimens?**
3.14 A	PASC studies for which the biospecimens were collected or designated will have priority for their use. After that primary use, they will be made available to other researchers. Since biospecimens are limited resources, a specimen utilization oversight committee is anticipated that will review and adjudicate applications for sample access. PASC biospecimen reports and results will be made widely available through the data repository.

4. ROA Requirements: Research Studies

4.1 Q	**Will investigators in the Consortium have priority for use of the data?**
4.1 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. EHR and other Real-World Data will be made available upon release.
4.2 Q	**Will investigators implement their own proposed algorithms for phenotyping? Will investigators implement their own research programs? What is NIH's vision for the research questions submitted with the proposals for the Recovery Cohort?**

4.2 A	It is anticipated that the applicants will submit hypotheses that will provide important input to the core protocol. These hypotheses will facilitate answering questions across broad populations with maximum power. Other hypotheses might guide more in-depth assessments conducted in individual studies or a subset of studies in the consortium. Ultimate decisions on which research questions will be pursued by the Recovery Cohort will be determined once the Cohort is established and the leadership prioritizes the science.
4.3 Q	**Are the adult and pediatric cohorts expected to use the same or similar CDEs?**
4.3 A	The objective of the consortium is to understand PASC across the lifespan. Having some CDEs in common, or which are comparable, will facilitate obtaining a continuous picture. However, there may be questions that require certain CDEs to be collected in some groups, but not in others.
4.4 Q	**Are international sites/cohorts allowed?**
4.4 A	Yes, international sites/cohorts are welcome as an applicant/proposer or as a sub-awardee.
4.5 Q	**Our local institution data can meet 200 PASC cases or exceed this by involving other institutions. What scale is more appropriate for this ROA?**
4.5 A	ROA OTA-21-015B notes that ”preference may be given to applicants capable of contributing … at least 200 PASC cases. An application may include a consortium of institutions or studies to achieve the numbers of cases needed. A suitable number of appropriate comparison participants should be included.” Institutions must also provide a suitable number of comparison participants. Applications can include other institutions to achieve or increase the number of cases and propose research hypothesis. If applicants can provide additional cases for more comprehensive study, that would further enhance the proposal. It should be noted that there are other factors to be considered, including the track record of recruitment, follow up and retention of the cohort by the institutions or the additional institutions, and the expertise of the investigators.
4.6 Q	**Can study subjects be paid for their time and trouble?**
4.6 A	Any compensation paid to study subjects participating in research conducted under OT-21-015B will need to be approved by an IRB.
4.7 Q	**With mass vaccination programs, how quickly do you expect investigators to enroll >1000 adults?**
4.7 A	We aim to assemble the recovery cohort as soon as possible. The ability to enroll will depend on many factors and some applicants may be able to leverage existing cohorts. Applicants with the ability to enroll the full cohort rapidly will be scored higher than those who require more time.
4.8 Q	**Is the required enrollment capacity of “1000 acute cases or 200 PASC cases” over 1 year, or the 4 years of the study?**
4.8 A	Given the urgency of the research topic and the need to follow the cohort for an extended period, applicants with the ability to enroll the full cohort rapidly (e.g., within less than 1 year) will be scored higher than those who require more time.

4.9 Q	**Do you expect the comparison group the "COVID-positive, PASC-negative", or do you expect to have some "COVID-negative" controls as part of the comparison groups?**
4.9 A	Suitable comparison participants may include individuals infected with SARS-CoV-2 who had a favorable recovery trajectory, or persons who did not have SARS-CoV-2 infection.
4.10 Q	**Is there a maximum number of patients that can be enrolled in the study?**
4.10 A	No, there is not a maximum number of patients for a cohort.
4.11 Q	**Is the Clinical Recovery Cohort limited to a patient cohort within the United States or could it include patients in the US + other countries together?**
4.11 A	No, it is not limited to the United States. However, the application should clearly describe plans for meeting the requirements for sharing data and biospecimen from all cohorts as outlined in the ROAs.
4.12 Q	**Is it acceptable that one institution submits a recovery cohort application for adults and one for children?**
4.12 A	Yes, this is acceptable.
4.13 Q	**If a proposal includes both adults and children, will you expect 200 adult PASC cases and 50 children PASC cases? Or some combination of both?**
4.13 A	Preference will be given to applicants capable of contributing at least 1000 cases of SARS-CoV-2 infection or at least 200 PASC Cases. For children, preference given to applicants capable of contributing at least 250 cases of SARS-CoV-2 infection or 50 PASC cases. For now, those are the goals and if an applicant applies, at least one of the criteria for adults or children will have to be met. Applicants proposing smaller samples should provide strong justification for their approach based on other considerations, e.g., special population characteristics, deep pre-infection phenotyping.
4.14 Q	**Would formation of a ME/CFS sub-cohort be acceptable to enable deep phenotype comparisons?**
4.14 A	We anticipate that applicants will propose to address specific hypotheses in the overall group and subgroups of PASC participants and the investigator consortium will develop an overall protocol and sub studies to address these questions.
4.15 Q	**Can you include very specialized groups like those requiring extracorporeal life support?**
4.15 A	As outlined in the ROA, one goal is to determine whether the initial presentation and severity of COVID-19 is associated with severity, pattern, time of onset, metabolic dysfunction or other characteristics of PASC and long-term consequences. As such, you can include those who had required extracorporeal life support. However, inclusion of this group must also be viewed in the context of providing at least 200 PASC cases and suitable comparison participants.
4.16 Q	**Do we need our own sample collection for the recovery cohort study?**
4.16 A	Applicants will be rated more favorably if they have capacity to collect patient specimens.

4.17 Q	**Can the "acute cohort" be inpatients?**
4.17 A	Yes.
4.18 Q	**Who does "patient representatives" refer to in the context of this ROA?**
4.18 A	"Patient representatives" are patients who have experienced SARS-CoV-2 infection and who will be engaged in the development of the PASC Consortium and Initiative.
4.19 Q	**Can subcontract sites be international, or only US based institutions?**
4.19 A	Yes, subcontract sites can be international.
4.20 Q	**How can an investigator join the investigator consortium? By invitation?**
4.20 A	All institutions awarded to participate in the Recovery Cohort ROA will be asked to provide representatives to the Consortium and the various Consortium workgroups.
4.21 Q	**Can we propose studies that would be conducted on the entire meta-cohort or some subset thereof, or should we propose studies of cohorts we have already established?**
4.21 A	The research questions pursued by the Consortium will be a combination of common and site-specific hypotheses.
4.22 Q	**Would an application proposing a study using an existing observational study of COVID-19 positive subjects but with relatively narrow focus (physiologic data applied analytics) be responsive to the ROA? Or should a broader approach be proposed (e.g., additional measures/variables)?**
4.22 A	Applications will be more competitive if the applicants can contribute to the overall protocol as well as to meritorious sub studies.
4.23 Q	**Is the use of virtual interventions desirable?**
4.23 A	This ROA does not support interventional studies.
4.24 Q	**Is inclusion of pediatric and adult populations necessary or just encouraged (and could we budget separately for our pediatric collaborators)?**
4.24 A	It is not necessary to have both pediatric and adult populations.
4.25 Q	**Do any of these ROAs apply to studying mindfulness meditation in adolescents?**
4.25 A	The current ROAs are intended to characterize the long-term effects of SARS-CoV-2 infection on individuals of all ages. Clinical intervention studies will be the subject of future ROAs.
4.26 Q	**Does this ROA allow for funding of investigating treatment of post-acute sequelae of SARS-CoV-2 infection, such as fatigue, sleep disorders, muscle weakness and pain etc.?**
4.26 A	The current ROAs are intended to characterize the long-term effects of SARS-CoV-2 infection. Clinical intervention studies will be the subject of future ROAs.
4.27 Q	**Is there any interest in post-vaccination COVID-19 phenotypes?**
4.27 A	The current ROAs are intended to characterize the long-term effects of SARS-CoV-2 infection. Activities proposed in response to this ROA should be linked to this overarching concept.

4.28 Q	**Does PASC cohort need to be defined by clinical symptoms, or can the cohort be identified by biomarkers?**
4.28 A	The SARS-CoV-2 Recovery Cohort will characterize PASC manifestations and their trajectory over time and across the lifespan, thus for this application, the cohort needs to be defined by clinical symptoms or with clearly defined biometric abnormalities.
4.29 Q	**Will documentation of prior SARS-CoV-2 infection require a positive SARS-CoV-2 PCR result or would individuals who had a compatible syndrome and were SARS-CoV-2 antibody-positive (with no history of vaccination) be acceptable?**
4.29 A	It is recommended that the PI propose a case definition for the cohort that seems optimal for the proposed hypothesis. However, the PI should be flexible as the approach may need to evolve as the science evolves and the PI should be able to utilize the approach(es) adopted by the Consortium.
4.30 Q	**Are "EHR/other real-world data" studies listed under OTA-21-015B meant to focus more towards infrastructure, tooling, resource, software development, or hypothesis testing?**
4.30 A	Applicants should describe high-impact hypotheses, methods for testing those hypotheses, and very importantly, how the proposal will support and advance resource development for use by the other members of the consortium and by the wider research community.
4.31 Q	**Our group is conducting secondary data analysis using two large EHR cohorts, but we will not be able to upload the data due to ownership restrictions. Can we still apply?**
4.31 A	An application could be submitted. To be competitive, applicants would need to make very clear the specific value of the data and associated analyses enabled by the data, as well as how the data could be made as rapidly and widely accessible as possible.
4.32 Q	**Can you clarify the following ROA OTA-21-015 B language: "For applicants proposing to use EHR-based approaches, applicants describe their intention to transfer data to the National COVID Cohort Collaborative (N3C) or another secure NIH-approved OTA-21-015B repository." Would access, similar to the distributive system of analysis in OHDSI for example, be acceptable under the ROA requirements?**
4.32 A	The intent is to have secure, rapid sharing of as much data as possible to as wide a group as is possible. Applicants should make clear to evaluators how their approach achieves that goal. Proposals that only permit data to be accessed by the applicants themselves may not be seen as top tier in terms of competitiveness. Proposals that can only permit access to the data by members of the consortium will likely not be as competitive as those that can securely provide access to data both within and outside the consortium. We encourage applicants to think as creatively as possible to achieve these goals and to provide evaluators with sufficient detail to assess the data sharing approach.

4.33 Q	**For the EHR- and Other Real-World Data-based Studies, if some data partners cannot share data but have large COVID and PASC cohorts, can convert to the common data model, and can run analyses on them locally, can they be included in an application if they provide other unique advantages?"**
4.33 A	Researchers can propose this model; however, applicants should provide a compelling justification for why data cannot be shared and the unique value this PASC cohort brings to the program.
4.34 Q	**First, I am wondering if a decision has been made concerning the potential inclusion of data from the VA EHR given the requirements that all VA data remain behind the VA firewall. Hence, it will not be possible to provide individual level data to the consortium, but parallel analyses would need to be conducted behind the VA firewall. Despite this limitation, the comprehensive VA EHR provides a remarkable opportunity for real time longitudinal cohort creation and would be very responsive to the EHR-/Other Real-World Data-based Studies.**
4.34 A	Researchers can propose this model; however, applicants should provide a compelling justification for why data cannot be shared and the unique value this PASC cohort brings to the program.

5. Proposal Budget

5.1 Q	**Is there a maximum budget that can be requested for the respective ROAs?**
5.1 A	No, but we strongly encourage realistic and well-justified budgets.
5.2 Q	**What is the budget scope? What kind of detailed budget application is needed?**
5.2 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.
5.3 Q	**Can budgets be renegotiated once a master protocol is developed?**
5.3 A	Yes. The ability to negotiate and develop optimal strategies and adapt them as needed is a hallmark of Other Transactions Authority (OTA). We ask for realistic, strongly justified budgets, but it is possible these will be renegotiated based on consortium needs and other dynamics. For example, some proposal components may not be funded, other parts may be descoped/expanded, milestone schedules may need to be adjusted to align with master protocols or other strategies, and proposers may be asked to become sub-awardees of another applicant as part of a reorganized consolidated proposal that is funded.
5.4 Q	**Will there be flexible future funding for awardees to incorporate common procedures as decided upon by the investigator consortium into protocols? For example, if the investigator consortium decided that cardiac MRI is important, and that was not in the initial submitted budget for a particular awardee, will there be additional funding for those types of procedures?**
5.4 A	We recognize that initially proposed budgets may need to be adjusted via negotiation in order to accommodate common protocol elements decided by the consortium.

5.5 Q	**For OTA-21-015B, if I apply for more than one component, should I submit one budget or a budget for each component?**
5.5 A	A budget for each component is required per the ROA.
5.6 Q	**When you say 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?**
5.6 A	The standard SF424 form is recommended for budgets. The milestone payment schedule should be submitted separately.
5.7 Q	**Is cost-sharing mandatory or voluntary? Will it be considered during merit review?**
5.7 A	Cost-sharing is not mandatory, but we do welcome it in proposals. It will be considered.
5.8 Q	**Are indirect costs allowed?**
5.8 A	Yes, and the most current rate on file should be used.
5.9 Q	**While the typical $500,000 ceiling does not apply, are there parameters on the number of Senior and Key personnel that can be proposed?**
5.9 A	There is no limit on number of key personnel (senior or otherwise) that can be proposed.
5.10 Q	**Is the NIH Salary cap require to be used, as it is for NIH grant or are the individuals full salaries able to be used, as they are used for NIH contracts?**
5.10 A	Yes, the NIH salary cap applies to OTA awards.
5.11 Q	**Should budgets for software providers be included as part of the budget for core service providers?**
5.11 A	If this question is referring to paying software providers as subcontractors or as a purchase, the costs should be included as part of the other core service providers.
5.12 Q	**Should payments at each milestone be related to specific costs, or is unlocking the next year's proposed budget more appropriate?**
5.12 A	Milestones don't necessarily need to be tied to specific costs. Rather, a percent of the total budget can be aligned with groupings of certain milestones and deliverables that are expected to be completed by a specific date. Once those milestones and deliverables are achieved, the next "tranche" of funding would become accessible.
5.13 Q	**Is the milestone driven budget just a way for the sites to get reimbursed or is it in addition to the traditional budget which is also being requested?**
5.13 A	The milestone budget should be presented as percentages of the total budget which can be aligned with groupings of certain milestones and deliverables that are expected to be completed by a specific date. The milestone-based budget is also a tool to monitor progress in achieving milestones.
5.14 Q	**For the budget: is there a $600,000 limit per year or a total ceiling on the award, or is there a process to request a larger budget? For the Milepost-based payment system, we imagine that there would be some ongoing encumbrances (salary support for the personnel doing the work and enrolling and**

	phenotyping subjects, and for statistical support) versus some encumbrances that fit well as one-time expenses. Are we advised to budget the ongoing expenses separate from the mileposts?
5.14 A	There is no dollar limit that requires additional approval. All budgeted expenses should be broken out into tranches in the milestone plan.
5.15 Q	**Are detailed budgets required for subcontractors?**
5.15 A	Yes, detailed well justified budgets are required for subcontractors.
5.16 Q	**Are LOI's, scopes of work, budgets and budget justifications required for subcontract sites?**
5.16 A	Strong budget justifications are needed for both the prime awardee and any sub-awardees proposed.

6. Proposal Review and Award Processes

6.1 Q	**Will preference be given to cohorts with certain kinds of pre-existing data, e.g., positive PCR test, pre-infection data, EHR?**
6.1 A	The ideal final study population assembled across participating studies will be a large, diverse, representative cohort across the lifespan, with populations at risk for PASC, populations with a broad spectrum of PASC symptoms and appropriate controls. To answer some questions, broad and deep characterization of measures of interest before exposure will be important. For other questions, knowing the timing of the infections will be important to understand the natural history and spectrum of responses to the virus. We anticipate balancing considerations of sample size and power, diversity and inclusion across the lifespan, inclusion and timing of a range of PASC symptoms, breadth and depth of pre-and post-infection data collection, and ability to conduct appropriate follow-up examinations.
6.2 Q	**If I apply to one of the ROAs for more than one component (for example, if I submit proposal for the Clinical Recovery Cohort and the Autopsy Cohort), will the components be reviewed together or individually?**
6.2 A	Each component within a multi-component proposal will be evaluated individually for merit. It is possible that not all components proposed in an application will be selected for negotiation/funding.
6.3 Q	**Is the CSC responsible for contracting and paying the steering committee and any other working group members?**
6.3 A	Yes.
6.4 Q	**When do you anticipate making awards for OTA-21-015A and OTA-21-015B?**
6.4 A	Initial awards for OTA-21-015A OTA-21-015B are anticipated to be made in April/May.

7. Application and Funding Profile

7.1 Q	**Are national labs eligible to participate?**
7.1 A	Yes. In addition, applicants are encouraged to review the eligibility criteria included in the ROAs.
