RADX-UP PHASE III PRE-APPLICATION WEBINAR
Q&A NOTES

Date: 3/15/2022
Time: 1:00pm – 3:00 pm EST

Frequently Asked Questions (FAQs)

1. **Do proposals submitted to RFA-OD-22-005 and RFA-OD-22-006 have to be linked to an existing parent award, RADx-UP award, or collaborate with existing RADx-UP investigators?**

   No. There is no requirement for proposals submitted to RFA-OD-22-006 or RFA-OD-22-005 to be linked to or associated with current NIH awards, RADx-UP projects, or RADx-UP investigators. RFA-OD-22-005 and RFA-OD-22-006 are funding opportunities to solicit new projects. NIH refers to these RFAs as Phase III funding opportunities because this is the third funding cycle the program has undergone.

2. **Will previous RADx funding be weighted when considering proposals for funding for RFA-OD-22-005 and RFA-OD-22-006?**

   No. There will be no prerequisite for, or preference given to investigators with existing RADx-UP awards. Projects will be evaluated based on merit and innovation of their submitted proposal. Please see “Section V. Application Review Information” of both RFAs for scored criteria. NIH encourages proposals from new investigators, as well as collaborations with underserved communities in locations that RADx-UP does not have existing projects.

3. **Does the PI need to be part of a center grant to apply to RFA-OD-22-005 and RFA-OD-22-006?**

   No. PIs can be from many types of different institutions and are not required to be part of an existing NIH center grant. Please see "Section III. Eligibility Information" for details. The main restriction is that foreign institutions/components are not allowed.

4. **Are small businesses eligible to apply to RFA-OD-22-005 and RFA-OD-22-006?**

   Yes. Small businesses are eligible to submit proposals to RFA-OD-22-005 and RFA-OD-22-006. Please see “Section III: Eligibility Information” for the full list of eligible institutions. The principal investigators must have the skills, knowledge, and resources necessary to carry out the proposed research. For institutions/organizations proposing multiple program directors/principal investigators, please follow instructions for the multiple program director/principal investigator policy in the Senior/Key person Profile (Expanded) component of the S424 (R&R) application guide.

5. **Are there study design requirements? Could you please describe preferences for study design?**

   Yes. The study design must be appropriate to accomplish the proposed project aims and research questions. Please refer to RFA-OD-22-005 and RFA-OD-22-006 for study designs that may be appropriate.

6. **Can you clarify the earliest start date for RFA-OD-22-006?**

   Yes. The earliest start date is anticipated to be December. Participating institutes are anticipated to receive the approved funding plan for the FOA in later October or early November to begin processing awards.

7. **Would social, ethical, and behavioral implications (SEBI) research related to wastewater testing for SARS-CoV-2 be eligible?**

   Yes, but the proposed research must be related to and focused on at least one SEBI outcome.

8. **Do projects need to focus on BOTH underserved AND COVID-19 vulnerable populations?**

   Yes. The proposed population(s) must be underserved and COVID-19 vulnerable.

9. **Would a retrospective study of underserved populations be eligible for RFA-OD-22-005 and RFA-OD-22-006?**

   Yes. Retrospective research is eligible. Please review the funding opportunity announcements to ensure that the requirements and responsiveness criteria are met.

10. **Who is the appropriate NIH contact to reach out to for RFA-OD-22-005 and RFA-OD-22-006?**

    Each funding opportunity has a list of NIH contacts appropriate to reach out to for grants management and scientific areas of interest. The appropriate NIH contact will be dependent on the scientific focus area for the project.

11. **Can you comment on appropriate primary outcomes and measure of success? Should these measures be the number of tests completed or another metric dependent on COVID-19 rates?**

    Primary COVID-19 testing outcomes should align with your research aims. Please make the strongest justification for which outcomes are most important.

12. **Can the principal investigator be a Clinical Research Coordinator or a Law Professor?**

    Yes, provided the PI has the appropriate qualifications and background to conduct the study. PIs can have many different backgrounds and the appropriateness of a given background is dependent on the study proposed. The research team composition needs to have the appropriate expertise to answer the proposed research questions. If multiple PIs are proposed, the required multi-PI model needs to be clearly presented per the SF424 requirements.

13. **Is qualitative research acceptable for RFA-OD-22-005? Are research aims that require more normative, historical, or ethical modes of inquiry acceptable?**

    Yes. Depending on the study design, these can be acceptable research aims. Please note that even if you choose to conduct qualitative research, NIH requires that the project collect the required common data elements.

14. **Which opportunity is more appropriate to apply to if the PI plans to both implement rapid testing in the community AND address the social, ethical, and behavioral implications related to that implementation process?**

Please reach out to one of the scientific contacts listed on RFA-OD-22-005 and RFA-OD-22-006 to discuss your proposal. The most appropriate opportunity depends on the primary aims of the study.

15. **Can a proposal target more than one underserved populations, such as Latino/as and sexual minority?**

    Yes. NIH welcomes proposals to study intersecting risk groups. The proposal will need to show that the project has the appropriate infrastructure and expertise to address both populations and the complexity of the study that is proposed.

16. **Are the ethical and behavioral implications related to the ethics of testing research an appropriate research aim for RFA-OD-22-005?**

    No. An appropriate study aim would focus on the ethics of the test being conducted rather than the ethics of the testing research itself. For further information, please speak with the scientific contacts listed on the RFA.

17. **Is the collection of RADx-UP Tier 1 and Tier 2 Common Data Elements (CDEs) required?**

    Yes. RADx and RADx-UP Tier 1 CDEs are required to be collected for all projects, including qualitative SEBI projects, and submitted to the RADx-UP Coordination and Data Collection Center (CDCC) on a weekly basis. If appropriate for the study design, all Tier 2 CDEs that are collected are required to be submitted quarterly. All other project data should also be submitted to the CDCC on a quarterly basis. Data should be deidentified before transmission to the CDCC. These requirements should be reflected in the proposal's data sharing plan. Please reference the CDCC data webpage for more information about CDE requirements.

18. **Are projects required to have staff dedicated to coordination with the RADx-UP Coordination and Data Collection Center (CDCC)? What does this entail?**

    Yes. One person on each project team should be designated as the representative to the CDCC. The project must meet milestones and checkpoints before entering the field, participate in weekly meetings and data reporting exercises with the CDCC, and ensure that all RADx-UP consortium requirements are being met. The proposal should provide detailed plans for interaction with the CDCC. For more information about the CDCC, please see the CDCC RADx-UP website.

19. **Does the entire CDE tool have be administered at one time? Can it be divided and collected at different times during a project?**

    If appropriate to the study design, the CDE questionnaires can be divided and collected at different times, but data submission to the CDCC needs to include full sets of responses for each participant. Therefore, careful consideration about how the data will be compiled is needed.

20. **Are consent forms required to be submitted with the proposal by the submission due date of 5/2/2022?**

    No. Consent forms are not required as part of the submission.

21. **Are purchasing COVID-19 tests and testing supplies eligible project budget expenses?**

Yes. If based on the study design, tests and testing supplies are necessary and directly tied to the research, they are an allowable direct cost. However, NIH funds cannot be used to set up a testing lab itself. All tests, procedures, and supplies must be FDA-approved or emergency use authorized and used on label for SARS-CoV-2 testing. Please discuss the planned purchase of tests and testing supplies and how they will be used with your grants management official to determine if this is an eligible expense for your proposed project. NIH and the CDCC may also be able to help projects with procurement of affordable tests and testing supplies.

22. Can partners request capital expenditures such as vans to reach scattered populations?

Yes. However, the capital expenditure must be scientifically justified. Please reach out to one of the grants management contacts for RFA-OD-22-005 and RFA-OD-22-006 as appropriate to discuss your proposal if you are uncertain about these issues.

23. If a PI is unsure of the personnel that will be needed, should they overbudget for personnel?

No. The budget needs to reflect the work that the project proposes, and all personnel need to be justified in the budget, whether those individuals are existing personnel or need to be recruited. The PI should work with a scientific contact and grants management official to determine appropriate cost levels if they are unsure of the budget needed.

24. Can the proposed study budget include patient payments?

Yes. Depending on the proposed study, respondent payments are typically an allowable expense, if scientifically justified and at a reasonable and customary level. The PI should discuss the costs with a grants management official in advance of submitting a proposal to determine if the cost is appropriate within the context of their study.

25. Can the proposed study budget include cultural activities and practices that are needed for project success?

Yes, depending on the circumstance(s). There are instances on NIH grants where specific costs are allowable, if it is the way to obtain participation for the research intended. Please discuss your proposed study and associated costs with a grants management contact on the RFA of interest to determine if the costs are appropriate for your study.