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RADx-UP Funding Opportunities Frequently Asked Questions

RADx-UP Program Questions

What is the RADx Program? Why was it created?

Congress provided supplemental appropriations of no less than \$1,000,000,000 to the NIH

Yes. Competitive revision applications can be submitted for any current and eligible NIH parent award. If an investigator has multiple NIH awards that are current and eligible, they may submit competitive revision applications through multiple parent awards.

**Can an investigator apply to more than one COVID-19 NOSI using a single parent grant?
For example, a COVID-19 NOSI issued by an IC and a RADx-UP NOSI.**

Yes, in general, you may apply to multiple supplement or competitive revision NOSIs using a single parent award unless other specific NOSI(s)

Yes. If the tribal organization has an active, eligible NIH award, then they may apply for a competitive revision. If the tribal organization is not a current recipient, they can apply for a new award via RFA-OD-21-008 or RFA-OD-21-009. Information regarding the May 28th tribal consultation can be found [here](#).

If the parent grant has an international focus (non-US target population), is it still eligible for the competitive revision NOSI for which the eligible target population is only US residents?

Yes. An award with existing foreign subaward or foreign component is eligible to apply for a competitive revision. The NOSIs/FOAs are focused on the US population. However, as stated in NOT-OD-21-103, competitive revision applications to these NOSIs may not propose new foreign components or subawards and may not request additional funding for existing foreign components or subawards. Foreign institutions, non-domestic components of US institutions, and foreign components are not eligible for new awards in response to RFA-OD-21-008 and RFA-OD-21-009.

Regarding investigator/institutional eligibility within a network: Do all members of the designated network need to apply jointly for a competitive revision?

No. A competitive revision is a revision to a parent NIH award. Therefore, the contact PI indicated on your competitive revision application will be the contact PI indicated on the parent award. Recipients may add members to the leadership team outside of the named PD/PIs, to provide expertise needed for the supplemental activities. The contact PD/PI and Multi-PD/PIs may not differ from the parent award. Any changes to the PD/PIs must be submitted as a prior approval request, along with an updated leadership plan for the award.

If a group of awardees (e.g., network, consortium, center) is intending to apply “together” for competitive revisions, then there are a couple options.

Each interested awardee in the eligible network could apply for a separate competitive revision for their specific parent award.

A single parent award could submit a competitive revision on behalf of the network. If a group of sub-awardees (e.g., network, consortium, center) is intending to apply “together” for competitive revisions, then there are a couple options.

What is the application due date for NOT-OD-21-103?

The application due date for this NOSI is May 28, 2021. The original application due date of May 24 was extended to May 28. The expiration date for the NOSI will/has been pushed back to May 29, to accommodate the new date.

When applying to the competitive revision NOSI (NOT-OD-21-103), do I also need to specify the IC? Is there any advantage to applying to one IC over another?

No. When you apply to a competitive revision NOSI, you are doing this through a parent award

Do the funding announcements require applicants to use FDA-authorized tests or obtain FDA authorization for their tests prior to submission?

Yes. Applicants should demonstrate in their application that they have the capacity to acquire, disseminate, and utilize diagnostic tests that have already been FDA-authorized/approved. Because the specific tests that have been FDA-authorized/approved may change over time, applicants are encouraged to check with the FDA for updates.

For NOT-OD-21-103 and RFA-OD-21-008

Is there a required minimum number for the project sample size?

No. There is no required project sample size; however, the purpose of these FOAs/Notices is “to understand factors that have led to the disproportionate burden of the pandemic on underserved populations so that interventions can be implemented to decrease these disparities”. Projects will be evaluated for scope and potential breadth of impact.

Can a subpopulation (e.g., cancer patients) be used for RFA-OD-21-008 or NOT-OD-21-103?

Yes. There is no prohibition on the analysis of sub-populations if it is justified based on power calculations and impact.

Can you use a non-FDA authorized test as a comparison?

Yes. You must use an FDA-authorized test for the primary purpose of the testing research. However, if a researcher wants to use another test as a comparison (that may not be FDA authorized), this would be permitted.

Can you include SEBI components for NOT-OD-21-103, NOT-OD-21-101, and RFA-OD-21-008?

Yes. You may ask SEBI-related research questions in applications to the three FOAs/Notices, but the primary focus of applications needs to align with the parameters outlined in each respective FOA/Notice.

Is follow-up of participants to observe infection expected?

Follow up requirements will depend on the study design. If necessary, to achieve the goals of the proposed study, follow up will be expected.

Is the expectation that research projects should be doing their own testing or linking to other available testing in the area?

Where feasible to link to local resources for testing, certain cost-efficiencies may be found and longer-term sustainability may be seen. But for areas where such testing is not available, incorporating testing into the research study is acceptable.

For the competitive revision NOSI (NOT-OD-21-103) if the original/parent grant does not have a community outreach focus, can we still submit to the NOSI with an added community outreach/partners focus?

Yes. You may add an outreach focus through a competitive revision, which expands the scope of the parent award.

For the SEBI RFA (RFA-OD-21-009), can testing be done as part of the approach to, for instance, test hypothesis related to mechanisms and mediators of testing dissemination/implementation?

No. No applicants who submit in response to NOT-OD-21-103, RFA-OD-21-008, and RFA-OD-21-009 will receive a summary statement.

Who selects and pays for these awards?

Following the review process, the RADx-UP Governance Committee will make funding recommendations to the NIH Director based on review results as well as consideration of program balance and program priorities.

Though all awards will be by the NIH Institutes and Centers (ICs), decisions on which applications to fund will be made centrally, and only the NIH Office of the Director will be funding these awards. ICs may not fund the applications received through the three funding opportunities.

Especially given the COVID-19 pandemic, most tribal communities have been totally shut down, meaning that we have not been able to determine our data-sharing approach. Will the reviewers be properly prepared to understand tribal data sovereignty-related issues?

Yes. Multiple participants on the review panels are familiar with working with Tribal Nations and the considerations that need to be given to this community.

Expectations of Recipients

For NOT-OD-21-103 (competitive revision NOSI) am I expected to collaborate or share data with other recipients, even if my parent award is not a cooperative agreement?

Yes. NIH expects that all competitive revisions funded under this NOSI will actively coordinate, collaborate, and share data with other Testing Research P4 BD (b)5.1CghMC /PP0.6 (ev) (ing appr1 (.153 Td3

What are the expectations of reporting test results to local Tribal and/or community partners?

Recipients are expected to demonstrate knowledge of and to comply with federal, state, local, and/or Tribal requirements on testing, reporting and surveillance policies in study protocols.

Have Native American nations, (e.g. Navajo Nation) need to DCC collection and handling of their data?

