FREQUENTLY ASKED QUESTIONS

RADx-UP Return to School Diagnostic Testing Approaches (NOT-OD-21-097)

SUBMISSION INFORMATION

Q: Is this a targeted solicitation (for those who received a specific invitation) or is this an open solicitation?

A: NOT-OD-21-097 is an open solicitation for letters of interest. The full application will be requested by invitation and the OT number will be issued at that time.

Q: Are applicants who were not successful during the targeted solicitation phase able to resubmit during the open phase?

A: Yes.

A: In addition, RADx-UP is beginning a second phase of funding that will have two requests for applications (RFAs) and two notices of special interest (NOSIs). These are forthcoming and a notice was recently issued.

Q: Does this application need to be under a parent grant (e.g., as administrative supplements or competitive revisions)?

A: No, the application would not be submitted under a parent grant as these are not administrative supplements or competing revisions.

Q: This does not have to be under a parent grant but could it include the same sites?

A: Yes.

Q: Can projects incorporate existing sites from other grants/projects?

A: Correct. This mechanism allows NIH the flexibility to link awards/projects.

Q: Can current RADx-UP sites apply?

A: Yes.

Q: Can large networks apply or is this really meant for single site applications?

A: Large networks can apply.

Q: Can there be more than one application per institution?

A: Yes, but the applications need to be distinct from one another. There should be minimal overlap of personnel or clear justification of the roles of personnel on distinct applications.

Q: Can for-profit small businesses apply? In that case can the Principal Investigator also be the authorized business official for the purpose of submission?

A: For-profit small businesses and large businesses are eligible under this mechanism. If the Principal Investigator is also the Authorized Signing Official (AOR) for the organization (e.g., the investigator is the business owner), then the individual can be specified in both roles for the purpose of this application.

Q: This submission process and the application seems non-traditional. Is this correct or should we use NIH forms?

A: This is correct, this is not a traditional application for NIH. The LOI submission will be a PDF submitted by email to RADx-UPR2Sinfo@nih.gov . The Letter of interest is 5 pages maximum in length and follows the specified format.

Q: Can Principal Investigators submit Letters of interest directly or does this need to be submitted through our sponsoring organization?

A: The Letter of interest must be submitted by an authorized business official for the organization to the email address specified.

Q: Is there a way to see a successful OT application?

A: There are no successful applications for this OT announcement as this is the first phase. Examples of other funded OTs can be found in Federal Reporter or NIH Reporter by searching under the OT mechanism.

Q: Do citations need to be included in the Letter of interest?

A: No, these are not required.

Q: How many awards will be given?

A: The current budget available for this phase is $20 million. Given the range of budgets that could be proposed and the availability of funds, the number of awards for this phase is difficult to specify.

Q: When will the full Research Opportunity Announcement (ROA) come out and when will application applications be due?

A: On Friday, April 23, 2021 the program (and business) official will send the ROA to those invited to apply (e.g., the Principal Investigator and the Authorized Organizational Representative). If your organization is invited to a full application phase, applications will be due May 14, 2021 by 5 pm local time, and awards should be issued in June.

Q: What is the Earliest Start Date allowed in the application?

A: This will be negotiated with NIH staff. It will be no later than June 30th if possible.

Q: What is the difference between NOT-OD-21-097 and NOT-OD-21-064?

A: NOT-OD-21-097 is a specific initiative within RADx-UP that will rapidly implement research focused on the use of diagnostic testing to enable the return of children and school personnel to the in-person school setting. It uses the Other Transaction Authority of the NIH to negotiate awards to best fit the purpose and intent of the initiative. NOT-OD-21-064 details the NIH's plan to publish two Requests for Applications (RFAs) and two Notices of Special Interest (NOSIs) to conduct community-engaged research to understand COVID-19 disparities and implement testing interventions to mitigate these disparities in the context of vaccine implementation and uptake among underserved and vulnerable populations. The details of each can be found at the links above.

PROJECT SCOPE

Q: What is the overarching premise for this initiative?

A: RADx-UP is focused on testing strategies and underserved and vulnerable communities. We are prioritizing projects that address the scientific questions to inform the safe return of children, faculty, and staff to the school setting.

A: While children were considered to be a vulnerable population in the overall RADx-UP program, this initiative is requiring other specific criteria to be met, including inclusion of a high proportion of disadvantaged school settings and/or inclusion of those populations who experience significant health disparities.

A: Criteria were specified in the guidance for the Letter of interest (include link here) as to the criteria that define disadvantaged schools. If other metrics are suggested, such as CDC's social vulnerability index or other research indicators of disadvantage, these should be justified in the letter.

Q: Can you speak to scope or scale of the projects?

A: Research applications need to be appropriately targeted for the populations in the Letter of interest. The intent is to study a broad range of school ages: the scope should be impactful to the underserved/vulnerable and geographic locations and reach as many as students as possible relative to your access. The budget should reflect the scope and scale of the application. Applications should be limited to what can be realistically accomplished and include a specific focus on collecting data in the fall. If feasible, data collection in summer will be supported.

A: This mechanism allows for linking of awards. We can find ways to link awards during negotiations. The OT mechanism allows NIH the flexibility to meet the needs of the program. Collaborations are encouraged.

A: There is no minimum number of children or tests required. The project should be proposed for the scope and scale needed to answer the scientific questions proposed. Optimally, the projects should be proposed in such a way to be generalizable and informative to the overall strategy for returning children to school in the United States.

Q: Should applications be hypothesis driven or can they be program evaluations? Is one of the goals of this initiative to develop "proof of principle" practices that can be expanded or extended?

A: These are research awards and the intent is to have specific research questions or hypotheses that will be answered by the project. Implementation science approaches would be acceptable.

A: The goal of the initiative is to address scientific questions that will inform the safe return of children and personnel to the school setting. Projects should help to build the evidence base for that goal in ways that are scalable if possible.

Q: Regarding flexibility, what are we talking about in terms of length of project and size?

A: The Letter of interest guidance outlines specifics about budget, scope, and scale. The OT mechanism allows the flexibility to evolve (expand or contract) projects given new information, changing environment and funding.

A: Letters of interest will be evaluated based upon feasibility, scientific merit, and addressing the criteria of interventions related to testing in schools that serve underserved and vulnerable children.

A: All extensions of invitation to submit a full application will be approved by the Governance Committee of RADx-UP.

Q: Is the intent to cover the 2021-2022 school year?

A: Yes, it is the intent to obtain data for the 2021-2022 school year, and possibly summer programs.

A: We are using a flexible mechanism because the strategies, scope and budget may change. Any investigator coming in will have the expectation to work with us to respond to the dynamic situation in this area. You will work with us to establish milestones and adjust as needed. Currently existing relationships and established trusted partnerships are beneficial.

Q: Can projects test mitigation strategies that are not consistent with the CDC recommendations for return to school?

A: CDC guidance for the school setting is based on best available evidence at present. If a project proposes an intervention or trial that tests new strategies, clinical trial guidance that follows NIH policy would need to be in place. This includes appropriate consent, data safety monitoring, and other human subjects protections consistent with the clinical trials policy.

Q: Can observational studies be proposed?

A: We are looking for interventions in these areas to the extent possible. With an eye toward generalizability, we encourage applications to detail cohort and observation data that will be collected.

Q: To what extent do we need to use actual testing technology vs., for example, examining different messaging scenarios in the schools?

A: Investigating engagement approaches, messaging, behavior modification, etc. are acceptable, in conjunction with the other goals of the program (e.g., involve testing, include underserved and vulnerable populations). Testing data, if available in the community and accessible to the investigator, does not need to be collected directly by the project.

Q: The Letter of interest discusses follow-up care as a potential focus of study, can you provide more detail?

A: After a positive test for COVID-19 a number of activities need to occur to care for the individual with the positive test (e.g., health care referral if required), efforts contain the infection and prevent an outbreak (e.g., quarantine and contact tracing), and efforts to ensure that the person is safely returned to the school setting when asymptomatic (e.g., testing before re-entry).

Q: Can this mechanism be used to study novel biomarkers for infection if the specimen collection used in the study is leveraged?

A: The intent of this initiative is to support the evidence base for return of students and personnel to the in-person school setting. If consent allows, the specimens could be used to support other applications for funding to support the identification of novel biomarkers.

Q: Can the project plan include a reasonable planning period?

A: Given the emergency nature of the awards, a planning period can be included but the intent is for work to begin at the beginning of the 2021-22 school year.

SCHOOL SETTINGS

Q: Is this program flexible when changes arise in school opening status or guidance from local county departments of health or state education mandates change?

A: Yes, the program can be flexible, and projects can be modified if the situation in the area changes.

Q: Is this targeted to public schools or are tribal, charter, and private schools eligible?

A: All schools are eligible as long as there is representation of underserved and vulnerable communities. We understand if a school district is involved that it may not include only underserved and vulnerable communities and that studying the sociodemographic and cultural differences within a school district or multiple school district could advance the goal of this program.

Q: Can the project serve all schools in a county versus just a select group of schools?

A: A project could serve all schools in a county and not just a select group of schools if the county includes a significant number and proportion of disadvantaged school settings.

Q: Are schools in rural areas considered underserved or would they need to meet other criteria (e.g., free & reduced lunch proportion)?

A: Schools in rural and remote areas can be considered underserved.

Q: Are these COVID-19 tests for teachers as well? And in our local school districts we are still restricted by spacing requirements – is that a consideration?

A: Yes, projects may include testing for teachers. We acknowledge the back-to-school environment is evolving and we need data and testing strategies that reflect the current state of this environment. Schools operating at various levels less than full capacity will be considered.

Q: Can we include summer learning programs?

A: Yes, if these are school based, summer learning programs, staffed by teachers and regular school faculty and staff. Camps staffed by non-school personnel (e.g., community members, college students) or sponsored purely for recreational efforts are not in scope. Sleep-away camps are not in scope.

Q: Can we include students greater than 16 years old since this would include high school and it would be hard to separate schools by age? Can we target specific age ranges?

A: Students older than 16 years could be included, if justified in the application.

A: Specific age ranges can be targeted (e.g., early education enrollees that are 2-4 years of age) if well-justified in the application.

BUDGET AND FUNDING

Q: How many years can the funding cover?

A: The proposed project period is two years.

Q: How do we submit a budget for the project? Will the budget be amended?

A: Applications must provide a realistic budget and cost estimates for performing the work, with the expectation that budgets are tied to milestones achievement and that amendments may be made throughout the course of the project. Budgets will be continuously reviewed, updated, with the possibility for amendment, as needed.

Q: What if everything is okay in the fall and the research is no longer needed? Will these be terminated abruptly?

A: OT awards have a specific close-out process and as mentioned previously, the budget and project timeline and milestones will be negotiated between the NIH and the investigator team. Project deliverables and milestones will be actively monitored and if there is a need for modification or close-out, that will be the subject of active negotiation.

Q: Are there restrictions regarding what the funds can cover (e.g., salary support for staff)?

A: The Letter of interest document provides guidance on the categories of support that can be supported with research funding. This includes personnel, equipment, travel, subawards, and other direct costs and associated f&a (indirect costs). A justification will need to be provided for funds requested.

REVIEW

Q: What is the format for the review process?

A: It will be an internal NIH review process. This will be a rapid review given the emergency nature of this initiative.

COLLABORATION

Q: Does collaboration with NIH occur after the awards are made?

A: Collaboration with NIH will be ongoing before and after agreements are made.

Q: Should we try to convene discussions among investigators up front?

A: Yes. If there are other investigators who you feel would be good partners and who are ready to collect data immediately then feel free to contact them.

Q: Is there a website that discusses the prior work that has been done in case we are interested in partnering?

A: Yes, the RADx-UP website details programs currently funded under the RADx-UP initiative.

Q: For community partners, is there preference and/or necessity for working with community organizations beyond the school administration?

A: If the community organization is relevant, such as a teachers' union or other community group (e.g., community organization, religious organization, or partnering not-for-profit or foundation) linked to the schools with whom you are working, they can be included.

DATA COLLECTION, HARMONIZATION, AND SHARING

Q: Is data sharing required?

A: NIH requires data sharing for all COVID-19 projects, except where prohibited. The RADx-UP CDCC will be part of these projects re: data collection, data harmonization, data sharing. There are also measures, toolkits, and CDEs that these projects may utilize (e.g., PhenX toolkit, D2R).

Q: How will harmonization be facilitated?

A: Except where limited, data acquisition, collection and harmonization strategies will be coordinated with the CDCC guidance for annotation and benchmarking of data, collection of standardized common data elements, and obtaining appropriate consent for data sharing and harmonization.

Q: How much and to what extent is it required to share Protected Health Information (PHI) vs. only sharing de-identified or aggregated data?

A: The requirements for data sharing are noted in the informed consent form and all CDEs are listed on the RADx-UP website.

Q: If we have been capturing data during this school year, can we use those data for this award?

A: A core component of the RADx-UP program is data sharing. If the data are compatible with the RADx-UP Tier 1 Data Elements and were gathered in such a way that they can be shared (e.g., either as an agreement with the school district or school, an exemption from informed consent, or as part of the consent process) then they could be included.

Q: Are the statistical analyses going to be centralized?

A: No, the data collection, storage, and analysis will be the responsibility of the investigators. As noted above, there is the expectation that the data collected by individual projects will be harmonized and shared through the CDCC for integration and use by the broader research community.

Q: Are preliminary data expected or required?

A: Preliminary data are not required. It will be considered if included in the Letter of interest.

TESTING COST AND RESOURCES

Q: Will there be a centralized plan for testing, or should each group plan for testing?

A: Potential resources will be discussed as they become available and during negotiation of the awards. If you need assistance with testing resources, please send us an email.

Q: Will there be commercial rates available for testing?

A: Potential resources for testing will be discussed as they become available and during negotiations of the awards.

Q: Do we have to use a specific type of test?

A: United States Food and Drug Administration (FDA)-authorized/approved COVID-19 testing is critical for slowing the spread of the virus and preventing future outbreaks. Testing includes FDA-authorized/approved test kits and related supplies, as well as access to point-of-care testing (if and when FDA-authorized/approved) or CLIA certified laboratories (e.g., hospital, public health, or commercial) to administer the tests and return of test results as quickly as possible. Testing paradigms can include any of the FDA-authorized/approved modalities, for diagnostic, screening, and surveillance testing, and can include pooled testing if that approach is approved for the test selected. For more information on FDA approved and authorized testing please see FDA's website.

Q: Is wastewater testing considered part of surveillance?

A: Yes.