



March 29, 2021

## Request for Letter of Interest

**Research Opportunity Title:** RADx<sup>SM</sup>-UP Return to School Diagnostic Testing Approaches (OT2 Clinical Trial Optional)

**Participating Organization(s):** National Institutes of Health

### Overview

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## Overview of the RADx-UP Return to School Diagnostic Testing Approaches Initiative

### Purpose

In 2020, the NIH launched the RADx<sup>SM</sup> Underserved Populations initiative ([RADx-UP](#)). The goal of RADx-UP is to understand the factors associated with disparities in COVID-19 morbidity and mortality and to lay the foundation to reduce disparities for those underserved and vulnerable populations who are disproportionately affected by, have the highest infection rates, and/or are most at risk for complications or poor outcomes from the COVID-19 pandemic.

The NIH recognized that there is a significant need to expand the evidence base of scalable and sustainable approaches to safely return children to school, especially those within [underserved](#) and vulnerable communities. The RADx-UP Return to School Diagnostic Testing Approaches initiative recognizes the need to support scalable and sustainable strategies that build an evidence base to inform safe return to in-person schooling with an emphasis on COVID-19 testing in combination with other [mitigation strategies](#) in disadvantaged school settings (e.g., programs with greater than 50% of students eligible free/reduced price meals, Head Start programs, schools who serve communities that are predominantly ethnic minorities). The initiative focuses on children under 16 years of age and school faculty and staff who are underserved and COVID-19 vulnerable due to medical, geographic and social factors. In addition, there are significant and unique social, ethical, and behavioral implications that must be examined among underserved and vulnerable children and school personnel in disadvantaged school settings. This initiative intends to solicit letters of interest to meet this challenge.

### Specific Objectives

This request for Letters of Interest encourages investigators to propose approaches to promote the development of scientific evidence for the use of COVID-19 safety measures, testing, and follow-up with children, families, and staff in the school setting. There is a need



for coordination between applicants to identify evidence that will ease implementation, ensure the development of scalable solutions, and determine the best approaches for acceptability of protocols in the community. Clinical trials can be proposed if the investigator can provide a plan for protection of human subjects including plans to monitor ethical and social implications and human subject concerns in testing implementation.

Projects will be required to share data through the RADx-UP Coordination and Data Collection Center ([CDCC](#); RFA-OD-20-013) and are required to collect NIH [RADx-UP Tier 1 Common Data Elements](#) or provide a proposal for a modification of the Tier 1 Common Data Elements to accommodate pediatric populations that will require approval (except where limited by Tribal sovereignty). Permission to collect and share these CDEs will be given through specific language in the Informed Consent Form (ICF; [English](#) and [Spanish](#)).

The RADx-UP program encourages studies that move away from an exclusively "top-down" approach to one that is community centric, emphasizing collaboration with community partners, leaders and knowledge holders, leveraging community resources and local service delivery settings to address the needs of multiple stakeholders to enhance COVID-19 testing and safety measures. Evidence of partnership with the community and with school districts and relevant stakeholder groups are encouraged; collaboration with projects funded by other federal agencies will be eligible for inclusion. NIH encourages partnerships with institutions or groups that serve historically under-represented groups (see Developing Letters of Interest section). In this solicitation, applications proposing work with early education programs or in densely populated urban settings are encouraged.

## Eligibility

This Research Opportunity will continue the RADx-UP Return to School Diagnostic Testing Approaches initiative. Applicants are strongly encouraged to work with community and scientific partners to identify opportunities to pursue this work. Letters of Interest are encouraged from groups with: 1) a strong track record with and established connection to school communities, especially those in disadvantaged settings; 2) expertise in community engaged research or large-scale implementation research efforts; 3) demonstrated access to FDA-authorized/approved COVID-19 test kits or Clinical Laboratory Improvement Amendments (CLIA)-certified laboratories; and 4) the ability to accommodate data harmonization and sharing with the RADx CDCC. NIH encourages applications from institutions that serve historically under-represented groups.

Letters of Interest will be considered nonresponsive if they: 1) do not involve a school or early childhood education setting; 2) do not include underserved or COVID-19 vulnerable populations; 3) do not include FDA-authorized/approved tests; and 4) do not have the infrastructure to report study data and outcomes to the CDCC. Letters of Interest which propose studies in vertebrate animals will be considered non-responsive to this funding opportunity and will be withdrawn without review.

## Organizations

Non-domestic (non-U.S.) Entities (Foreign applicants) **are not** eligible to apply. Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply. Foreign components **are not** allowed. Foreign consultants are allowed if approved by the NIH official in advance of the full application submission. Applicant organizations may submit more than one application, provided that each application is scientifically distinct. Individuals not



affiliated with an organization, or who want to submit an application independently of their current organization, **may not** apply.

The following entities are eligible to apply under this ROA:

#### Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

#### Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Faith-based or Community-based Organizations
- Regional Organizations

#### For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

#### Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- Eligible Agencies of the Federal Government
- U.S. Territory or Possession Other
- Independent School Districts
- Native American Tribal Organizations (other than Federally recognized tribal governments)

Investigators whose Letters of Interest are evaluated to be innovative and responsive to the RADx-UP program will be invited to submit an application to a Research Opportunity Announcement that will be offered in May of 2021. The funding instrument for this announcement is the Other Transaction (OT) Award mechanism. OT awards are not grants, cooperative agreements, or contracts, and uses Other Transaction Authority, provided by Congress. Policies and terms for individual OT awards may vary between awards. Each award is therefore issued with a specific Agreement, which is negotiated with the recipient and details specific terms and conditions for that award. Support will be provided for two years to conduct studies that will build the evidence base for the COVID-19 testing and mitigation strategies that facilitate return to in-person learning for school communities. These



awards will be milestone driven, and timelines and deliverables will be negotiated with the NIH.

### Developing Letters of Interest

The Letter of Interest is required to be considered for an invitation to submit to the subsequent Research Opportunity Announcement. The Letter of Interest is not binding and does not represent a commitment to fund any resultant application to the Research Opportunity Announcement. The Letter of Interest will not be considered during the subsequent review of a full application if invited.

NIH will review and determine whether the applicant should be invited to participate in the RADx-UP Return to School Diagnostic Testing Approaches initiative. The NIH may request additional information be provided by the applicant to complete their eligibility. These requests will be sent to the applicant via email. Applicants are strongly encouraged to provide the requested information in a timely manner to prevent any potential delays in the review process. LOIs will be used to select individuals or groups who will be invited to apply by May 14, 2021. Only those who are invited may apply. Applications submitted without an invitation from the NIH will be returned and not reviewed. LOIs that do not meet the initial RADx-UP Return to School Diagnostic Testing Approaches program and eligibility criteria will be considered non-responsive and will not be reviewed.

#### Letter of Interest (up to 3 pages)

1. Proposed Project Title
2. Principal Investigator(s) first and last name, title, institution, mailing address, email address, and phone number. If multiple Principal Investigators are named, the Contact Principal Investigator is clearly identified.
3. Name and address of the submitting organization and department.
4. Authorized Organizational Representative first and last name, title, institution, mailing address, email address and phone number.
5. Other involved personnel names, roles, and organizations (multiple Principal Investigators, co-Investigators, collaborators, contractors, authors of letters of support, etc.)
6. Approximate budget per year (direct and total)
7. Proposed Project Period Dates
8. Confirmation that the work involves human subjects or data from human subjects.
9. Succinct summary of the 3 to 4 most compelling research questions to be addressed with the project
10. Brief description of the rationale for and importance of the research question(s), particularly from the perspective of underserved and/or vulnerable communities, describing what the study will contribute to inform COVID-19 diagnostic testing strategy, in conjunction with mitigation and education strategies, and follow-up care guidance in the school community setting.
11. Confirmation that the project can and will share data through the RADx-UP Coordination and Data Collection Center ([CDCC](#); RFA-OD-20-013)
12. Efforts to standardize and collaborate with other studies, including use of [NIH RADx-UP Tier 1 Common Data Elements or a modification of the Tier 1 Common Data Elements for pediatric populations](#).
13. Willingness to work with other awardees in a collaborative manner, potentially under a shared protocol.



14. Agreement that any and all parts of the Letter of Interest can be shared among other applicants.

#### Budget Section (up to 2 pages)

The budget section of the letter must provide a realistic and justified budget and cost for performing the work over the period of performance needed to achieve the project objectives. Application budgets in general are limited to \$3 million in total costs for a two-year project period.

Applicants requesting greater than \$3 million (up to \$5 million) in total costs must submit a request to the NIH for prior approval. Such requests may be considered for approval if the following conditions are met:

- (1) The applicant(s) will collaborate with one or more investigators from institutions that received no more than an average of \$6 million in [NIH research project grant](#) (RPG) funding (Total Costs) per year over the fiscal years 2018 through 2020 who may serve as either multi-PI(s) or key collaborator(s) of the proposed study.
- (2) The applicant(s) agrees that not less than 40% of the funds of the award will go to the collaborator institution(s), that receive no more than \$6 million NIH RPG funding.

Provide the overall expected cost and justification for each of the following categories:

1. Personnel
2. Equipment
3. Travel
4. Subawards/subcontracts/consultants
5. Other direct costs
6. Total cost (with indirect costs included)
7. Proposed Cost Share contribution (if applicable)

Letters of interest must be submitted by April 16, 2021, 5 PM local time of the applicant organization. Letters of interest must be in text-recognizable PDF (Adobe) format, use Arial 10-point font with 1" margins, be single-spaced, may not exceed 5 pages, and the file size must be no greater than 20 MB.

Letters of interest should be submitted by an Authorized Organizational Representative to the following email address: [RADx-UPR2Sinfo@nih.gov](mailto:RADx-UPR2Sinfo@nih.gov)

### Review of Letters of Interest

Letters of interest will be evaluated by NIH or other federal staff for the following criteria:

- Responsiveness to the RADx-UP Return to School Diagnostic Testing Approaches program priorities and likelihood that the project will address the stated need(s)
- Scientific and technical merit of the project questions and goals
- Past performance and expertise of the team members and complementarity with related RADx-UP program goals awards. This could refer to the applicant's track records of team science, interaction with and inclusion of community and school organizations, previous work with underserved and vulnerable populations, as well as to traditional measures of scientific productivity (e.g. publications, invited presentations, prior funding).



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National Institutes of Health  
Bethesda, Maryland 20892

[www.nih.gov](http://www.nih.gov)

The NIH will use these Letters of Interest to: 1) initiate discussions with the designated project lead(s), the NIH, and the RADx-UP leadership; 2) determine program fit and responsiveness; and, 3) provide a basis for invitation to submit a full application. Letters of Interest will be used to select individuals or groups who will be invited to apply by May 14, 2021. Only those who are invited may apply. If invited to submit a full application by NIH staff, the Authorized Organizational Representative and contact PI will be notified and will be provided with guidance on submission of an application.

Written summaries of the letter of interest review will not be provided to applicants who are not invited to submit an application. Appeals of the review will not be accepted.

Please direct all inquiries to the following email address: [RADx-UPR2Sinfo@nih.gov](mailto:RADx-UPR2Sinfo@nih.gov)