

# RADx UP: Return To School Diagnostic Testing Approaches

NOT-OD-21-097



# Rapid Acceleration of Diagnostics (RADx)

**Goal:** Rapidly scale-up testing across the country and enhance access to those most in need

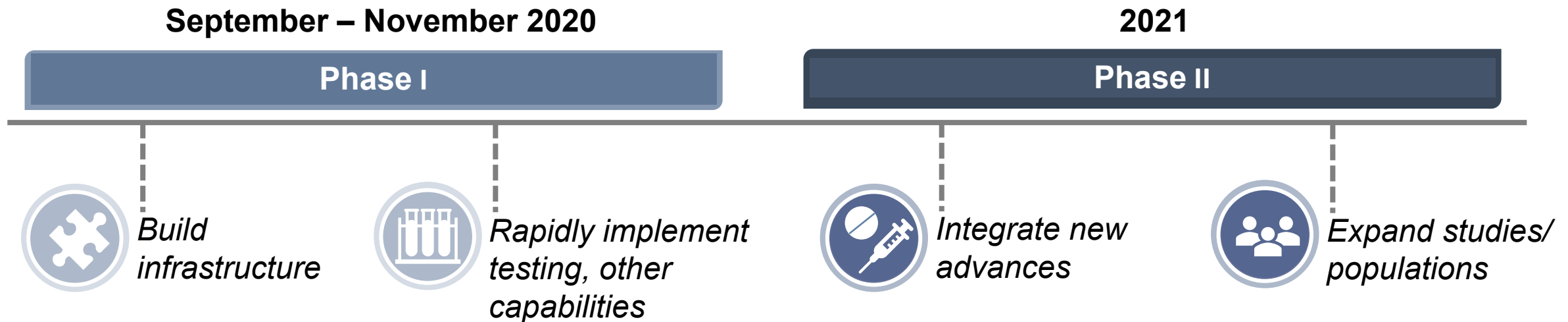
<b>Project</b>	<b>Description</b>
<b>RADx Tech</b>	Highly competitive, rapid three-phase challenge to identify the best candidates for at-home or point-of-care tests for COVID-19.
<b>RADx-Advanced Technology Platforms (RADx-ATP)</b>	Rapid scale-up of advanced POC technologies and laboratories to accelerate, enhance and validate utility of ultra-high throughput machines and facilities.
<b>RADx-Radical (RADx-rad)</b>	Develop and advance novel, non-traditional approaches or new applications of existing approaches for testing.
<b>RADx-Underserved Populations (RADx-UP)</b>	Interlinked community-engaged projects focused on implementation strategies to enable and enhance testing of COVID-19 in underserved and/or vulnerable populations.

<https://www.nih.gov/research-training/medical-research-initiatives/radx>

# RADx-Underserved Populations (RADx-UP)

## Overarching Goals

- Enhance COVID-19 testing among **underserved and vulnerable populations** across the US.
- Develop/create a **consortium of community-engaged research projects** designed to rapidly implement testing interventions.
- **Strengthen the available data** on disparities in infection rates, disease progression and outcomes, and **identify strategies to reduce these disparities** in COVID-19 diagnostics.





# RADx-UP: Return To School Diagnostic Testing Approaches

## Goal

Solicit research on COVID-19 diagnostic testing approaches to safely return children and staff to the in-person school setting in underserved and vulnerable communities.

## Approach

- Focus on children and adolescents below the age eligible for vaccination via Emergency Use Authorization (age 16) and all school personnel
- Advance methods to integrate testing in return to or maintenance of in-person instruction
- Identify effective, scalable, and sustainable testing implementation strategies, including in-school testing, in community pediatric primary care clinics, childcare centers, preschool, and school settings serving primarily underserved or disadvantaged children and their families.
- Applications proposing work with early education programs or in densely populated urban settings are encouraged.

# Research Opportunity



## Phases

- **Phase I:** Targeted solicitation to rapidly accelerate research already ongoing in the school setting (provide data from spring 2021) - ongoing; in negotiations
- **Phase II:** Open solicitation to start new cohorts or approaches to gain data related to safe return to the in-person school setting (current opportunity)

## Mechanism

- Uses the Other Transaction Agreements (OT2) which are not grants, contracts or cooperative agreements. These awards are flexible and provide NIH the ability to design unique collaborations with entities that may not have experience with grants or cooperative agreements.

# Requirements



## All Submissions Should Include:

- Access to FDA-authorized/approved COVID-19 test kits or Clinical Laboratory Improvement Amendments (CLIA)-certified laboratories
- Commitment to share data through the RADx-UP Coordination and Data Collection Center ([CDCC](#); RFA-OD-20-013; except where limited by Tribal sovereignty)
- Commitment 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
- Commitment to utilize specific language in the Informed Consent Form (ICF; English and Spanish) as provided on the RADx-UP website

# Letters of Interest



**Due April 16, 2021**

- Submissions should be no more than 5 pages in length
- Letter of Interest (3 pages)
  - Organizational details and confirmation of terms of participation
  - Summary of 3 to 4 compelling research questions
  - Description of rationale and study plan
- Budget (2 pages)
  - Budget plan with cost and justification
  - Budgets in excess of \$3 million direct costs must receive prior approval and include a partnership with institutions that serve historically under-represented groups that includes allocation of 40% of project budget to that partnering institution
  - These institutions also must not have received more than an average of \$6 million in [NIH research project grant funding](#) (Total Costs) per year over the fiscal years 2018 through 2020

# Submission

**Submit applications and all questions to: [RADx-UPR2Sinfo@nih.gov](mailto:RADx-UPR2Sinfo@nih.gov)**

- Due April 16, 2021 by 5 PM local time of applicant organization
- Authorized organizational representative must submit the document
- Letters of interest will be reviewed by internal NIH staff and invitations for submission of full application will be sent by email on April 23, 2021
- No feedback or written review will be provided to organizations submitting Letters of interest



# Questions?



# RADx-UP Announcements

[NOT-OD-21-064](#) - Notice of Intent to Publish Funding Opportunity Announcements for the RADx-UP Initiative (Phase II)

[NOT-OD-20-119](#) - Notice of Special Interest (NOSI): Emergency Competitive Revisions for Social, Ethical, and Behavioral Implications (SEBI) Research on COVID-19 Testing among Underserved and/or Vulnerable Populations

[NOT-OD-20-120](#) - Notice of Special Interest (NOSI): Emergency Competitive Revisions for Community-Engaged Research on COVID-19 Testing among Underserved and/or Vulnerable Populations

[NOT-OD-20-121](#) - Notice of Special Interest (NOSI): Limited Competition for Emergency Competitive Revisions for Community-Engaged Research on COVID-19 Testing among Underserved and/or Vulnerable Populations

[RFA-OD-20-013](#) - Emergency Awards: RADx-UP Coordination and Data Collection Center (CDCC) (U24 Clinical Trial Optional)