

RADx-UP: Return To School Diagnostic Testing Approaches

OTA-21-007



Webinar Overview

Topic	Presenter	Time
Welcome & Housekeeping	Alison Cernich	12:00-12:05
Overview of RADx and RADx-UP	Alison Cernich	12:05-12:15
Return To School Diagnostic Testing Approaches (OTA-21-007)	Sonia Lee	12:15-12:25
Proposal Components	Sonia Lee	12:25-12:40
Other Transactions Award (OTA) Mechanism	Dede Rutberg	12:40-12:50
Question & Answer	All	12:50-1:00

Welcome and Housekeeping

ROA Webinar

- All phones will be muted
- If you have questions today, please place them in the Questions and Answers module; the moderator will facilitate a discussion of them at the conclusion of the presentation or in the chat box
- All questions and answers will be captured in an FAQ that will be distributed after the webinar to all parties who received the solicitation.
- This meeting will be recorded and will be made available via a link that will be distributed after the webinar to all parties who received the solicitation.
- All discussions that occur during this webinar and all official communications must remain confidential and should not be shared with anyone outside of your team.
- This call is for informational purposes only and in no way obligates the NIH to make an Award.

Rapid Acceleration of Diagnostics (RADx)

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

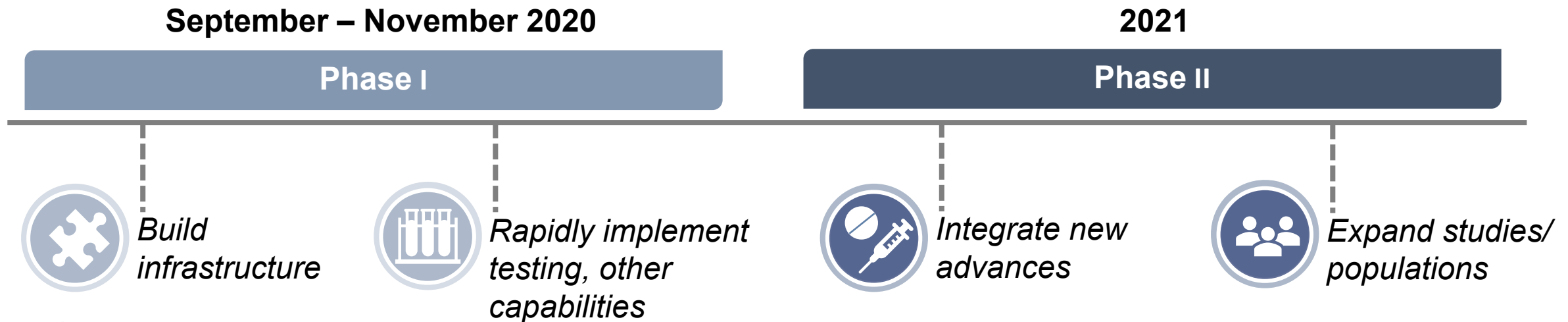
Project	Description
RADx Tech	Highly competitive, rapid three-phase challenge to identify the best candidates for at-home or point-of-care tests for COVID-19.
RADx-Advanced Technology Platforms (RADx-ATP)	Rapid scale-up of advanced POC technologies and laboratories to accelerate, enhance and validate utility of ultra-high throughput machines and facilities.
RADx-Radical (RADx-rad)	Develop and advance novel, non-traditional approaches or new applications of existing approaches for testing.
RADx-Underserved Populations (RADx-UP)	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 Phase I

Funded September 2020

- Focused on communities with established research infrastructures and partnerships to understand COVID-19 testing patterns and implement strategies or interventions with the potential to rapidly increase reach, access, acceptance, uptake, and sustainment of FDA-authorized/approved diagnostics among vulnerable populations in geographic locations that are underserved.
- Provided funding for a **Coordination and Data Collection Center** to work with project teams includes a wide range of education, training, implementation guidance, and coordination. They connect project leadership with experts who provide guidance in:
 - Establishing testing strategies
 - Conducting community education and outreach
 - Maximizing community engagement and testing participation
 - Handling data collection and integration
 - Learning with and from other projects and communities



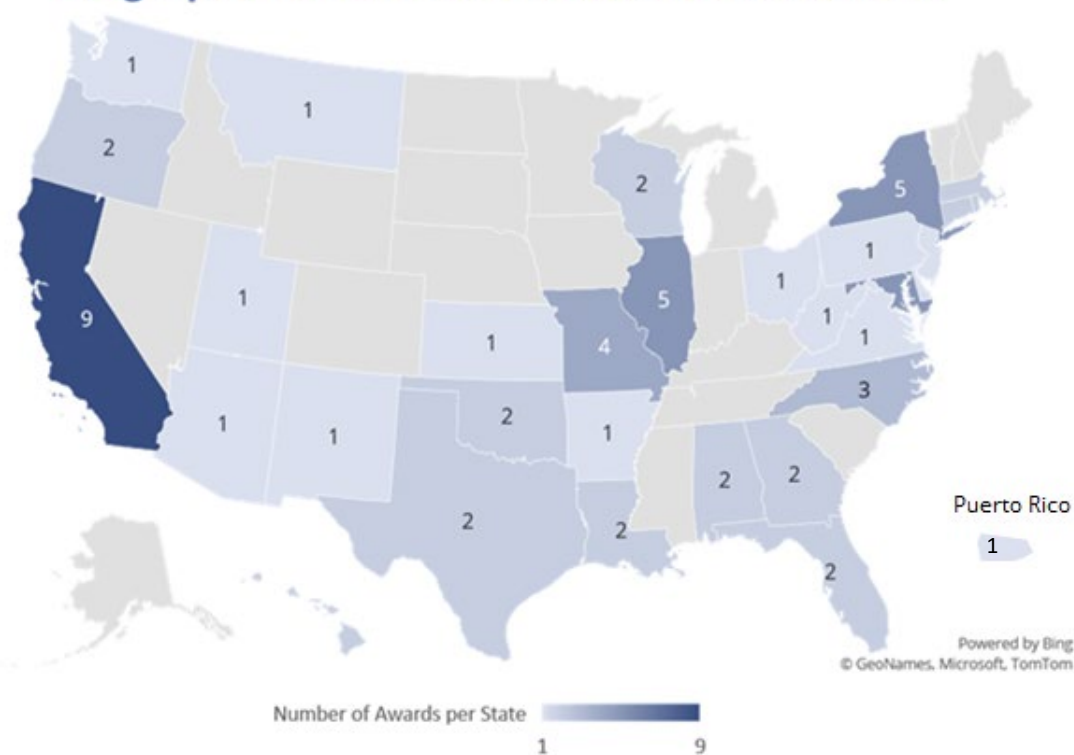
RADx-UP Phase I Snapshot: 69 Funded Sites and Research Projects

NOT-OD-20-121, NOT-OD-20-120, NOT-OD-20-119

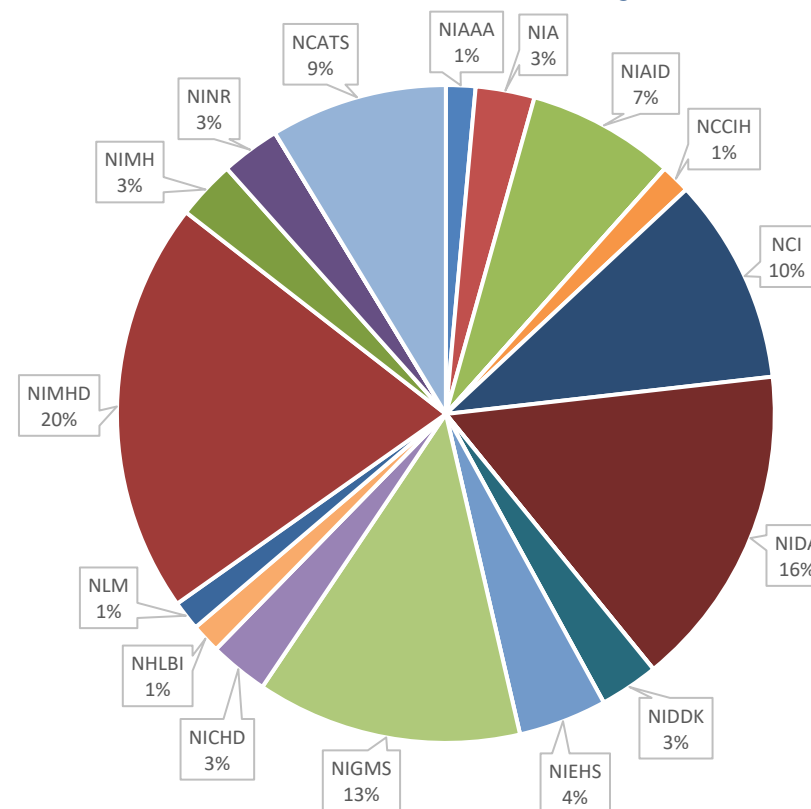
Funded sites and research projects span a total of **31 states** in addition to DC and Puerto Rico and include **55 institutions**.

Awards were distributed among **16 Institutes** across the NIH.

Geographic Distribution of Award Institutions



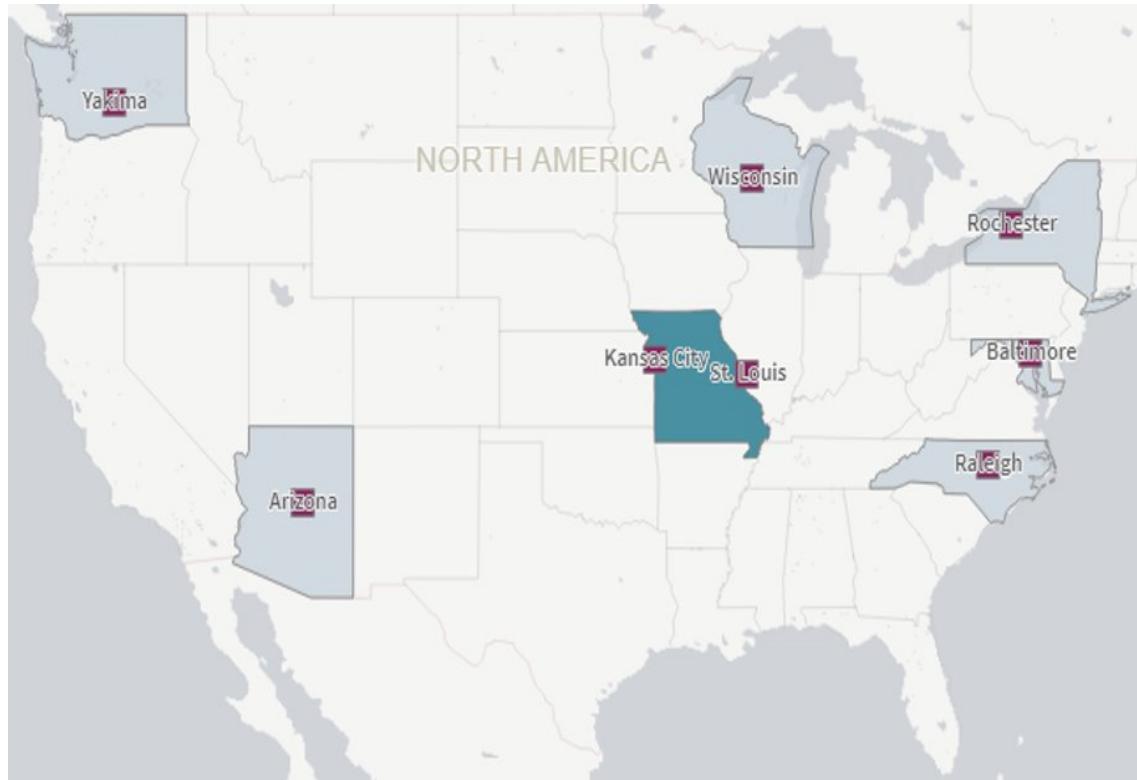
Award Distribution by IC



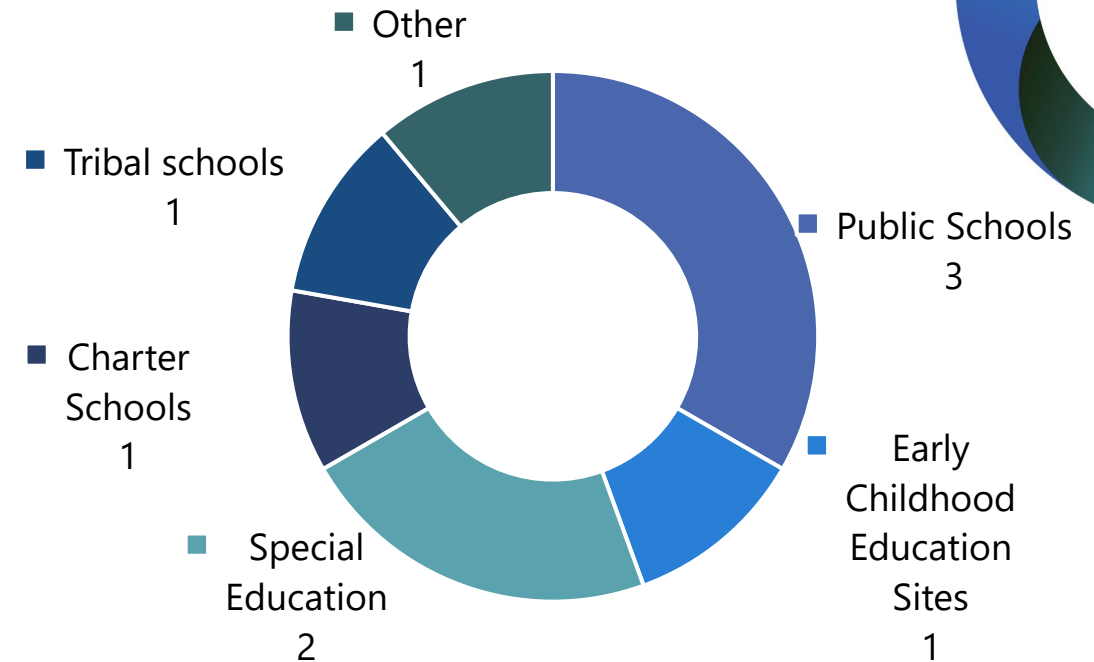
RADx-UP Return to School Phase I Snapshot: Project Settings

OTA-21-004

Study Locations: Awarded Projects



Funded Projects at Each Site



Note: other refers to a Pediatric Complex Care Program (1)

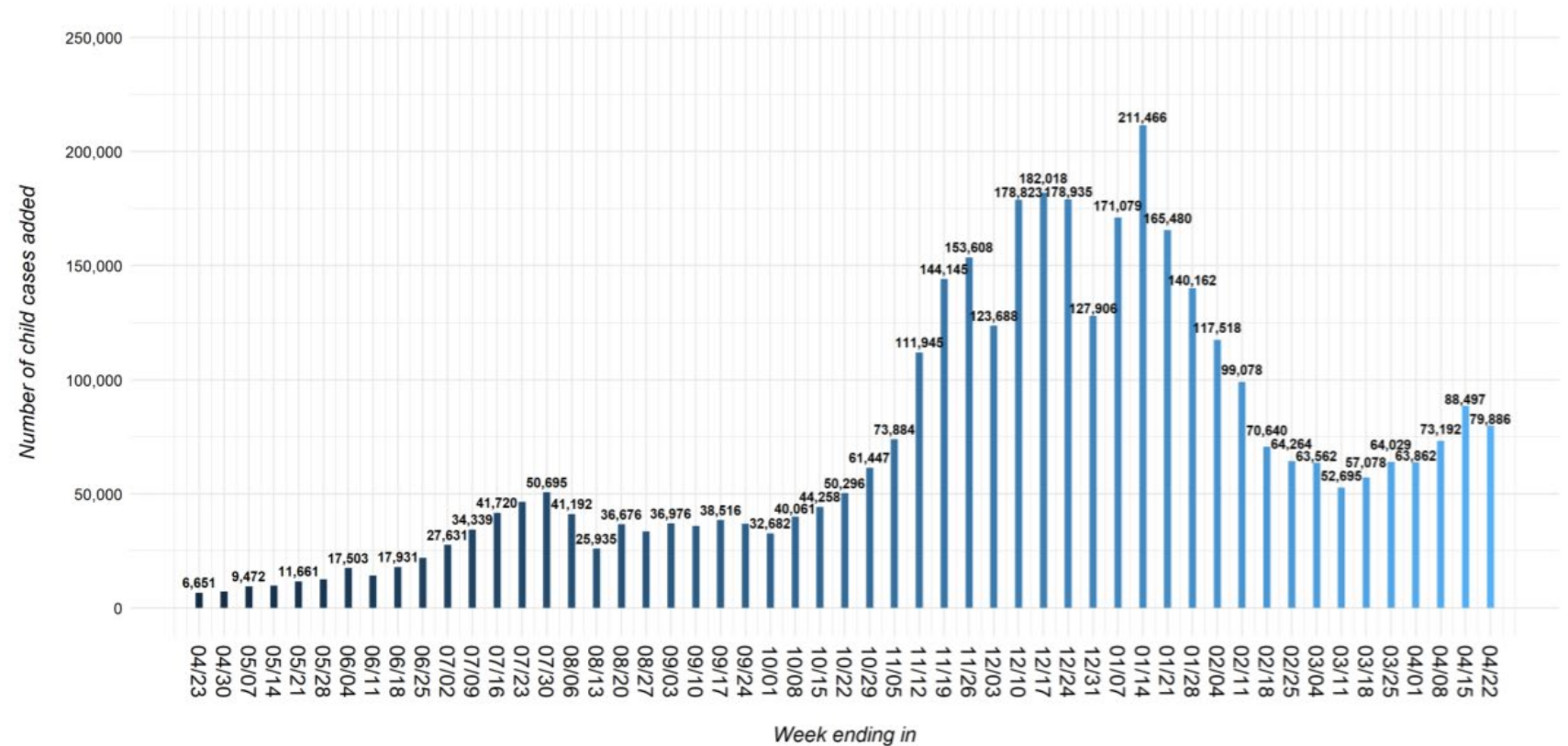
Note: The breakdown of sites is not additive; some projects work in multiple settings

**Rapid Acceleration of Diagnostics
Underserved Populations (RADx-UP):**

*Return To School Diagnostic Testing Approaches
(OTA-21-007)*

Background

Fig 6. United States: Number of Child COVID-19 Cases Added in Past Week*



* Note: 4 states changed their definition of child cases: AL as of 8/13/20, HI as of 8/27/20, RI as of 9/10/20, MO as of 10/1/20; TX reported age for only a small proportion of total cases each week (eg. 3-20%)
 See detail in Appendix: Data from 49 states, NYC, DC, PR and GU
 All data reported by state/local health departments are preliminary and subject to change; Analysis by American Academy of Pediatrics and Children's Hospital Association



Cumulative number of child COVID-19 cases since states began reporting: 3,711,075 total child COVID-19 cases reported (13.7% of all cases); Overall rate: 4,931 cases per 100,000 children in population.





Challenges

Developing evidence-based strategies to address challenges related to underserved and vulnerable populations returning to school

- Cost effective implementation strategies that are **scalable and sustainable**
- **Diverse populations and cultures** that may require unique testing and engagement approaches
- Social, ethical, and behavioral challenges that include **mistrust** in health providers and testing programs, unique research and public health concerns related to pediatric and employee-involved research, or **stigma related to testing programs**
- **Resource-related issues** for follow-up care
- **Environmental challenges** related to physical school settings



RADx-UP Return To School Diagnostic Testing Approaches (OTA-21-007)

Goal

Develop and test COVID-19 diagnostic testing approaches to safely return children and staff to the in-person school setting in underserved and vulnerable communities

Mechanism

Other Transaction Authority to provide flexibility for changing circumstances and funding of non-traditional partners

Budget

\$50 million commitment from the OD congressional appropriation

Return to School

OTA-21-004

Program Information: ~\$33M awarded in Phase I; 8 sites

- 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.

Overview

- **Awarded 8 projects** in April FY21
- **Strategies for school-based settings** to combine frequent testing with proven safety measures to reduce the spread of COVID-19
- **Phase II Awards** projected for the summer of FY21



Definitions

- **Underserved**: NIH-designated health disparity populations and other groups known to experience barriers to accessing needed health care services or have inadequate health care coverage.
- **COVID-19 medically and/or socially vulnerable populations**: Specific populations included in this program thought to be specifically vulnerable to the impact of COVID-19 due to specific medical conditions, social determinants, or living situations.
- **Disadvantaged school settings**: School or early education programs who have greater than 50% of students eligible for free and reduced price meals or who serve a large proportion of racial and ethnic minorities.
- **School or child care personnel**: Categories of individuals who provide instruction, support, services, health care, or extracurricular support in the school or early education setting.
- **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.



Proposal Components

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Potential Impact of the Work

- Scientific question(s) to be answered, approach, and resultant impact
- Group of participants or schools with emphasis on inclusion of underserved and vulnerable populations
- Testing capacity and capability
- Contingency plans for ongoing or potential future public health restrictions
- Human subjects protection plans
- Project management plan



Proposal Components

Plans for partnership and engagement

- Research collaboration with the school/community partner to rapidly implement
 - Includes letter of support in the supplemental materials
 - Include list of collaborators in the cover page
- Involvement of stakeholders in the study implementation
- Communication strategies to inform stakeholders
- Efforts to address social, behavioral and ethical factors that drive disparities
- Plans for confidentiality and privacy of participant data



Proposal Components

Openness to sharing data

- Data sharing plan and coordination with the CDCC
- Intended use, storage and sharing of data from settings proposed
- Informed Consent procedures and collection of Tier 1 CDEs or modifications for pediatric populations



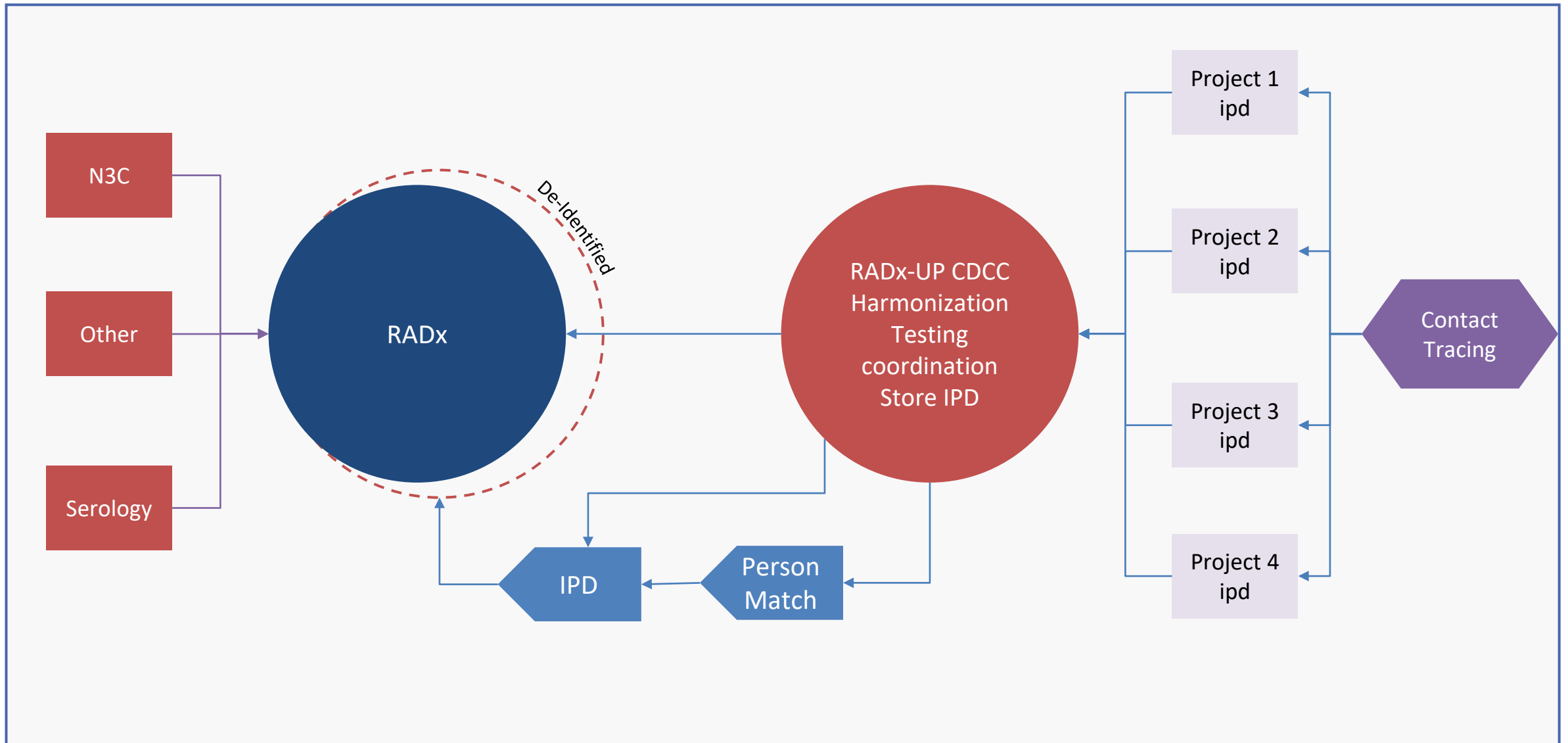
Data

Data Sharing and Standards

- Data acquisition, collection, and curation strategies of Phase II projects shall be coordinated with the CDCC guidance for annotation and benchmarking of data, collection of standardized NIH Tier 1 Common Data Elements (CDEs), and obtaining appropriate consent for data sharing, linkage of data to external data sets, and recontact for future follow-up research
 - Modifications of Tier 1 CDEs for pediatric populations will be negotiated with the CDCC
- Data sharing is required and language for the Informed Consent Form is standardized for use where applicable
 - Includes language to allow for data deposit, sharing of de-identified data, allowance of participant re-contact, and permission to link to external data sources
- If a clinical trial is proposed, data and safety monitoring plans, and, if needed, plans for a Data Safety Monitoring Board (DSMB)



RADx Program Data Flow



Proposal Components

Past performance and expertise

- Key personnel, project leads, and other personnel
- Effort levels and roles of personnel
- Community partners and roles for the partner
- How the project will leverage the RADx-UP program
- Relevant past collaboration for the team
- Leadership plan for multi-PI proposals



Budget

\$3 million in total costs with any additional funding requiring prior approval



- Budget must be realistic and address costs for the applicant's group and collaborators
- Projects must partner with an underrepresented minority serving institution and 40% of the budget must be allocated to that partner
- Projects that are linked will have combined budgets that may exceed the direct for individual projects if justified and negotiated by the NIH
- Detailed/Categorical budgets: personnel, equipment/testing kits, travel, funds for community partners (if applicable), subawards, other direct costs, and total cost (with indirect costs included); include justification
 - Awardees must have adequate internal controls for project management and cost principles apply
- List of milestones, deliverables, and payment/funding schedule is preferred
- Institutions with an established Facilities and Administrative (F&A) rate should use the approved rate to calculate indirect costs.



Review Criteria



Internal Review by NIH personnel

- The impact and feasibility of each planned activity if it were successfully implemented and the ability to implement rapidly in underserved and vulnerable populations
- Plans for engaging specific community partners and stakeholders, the RADx-UP CDCC, the end-user community (where relevant), and other stakeholders
- Ability to share data, software or algorithms, digital objects, and other resources, as needed, to establish the RADx-UP Return to School Diagnostic Testing Approaches initiative.
- Past performance and expertise of the team members and complementarity with other recipients
- The adequacy and appropriateness of the leadership plan (required for applications with multiple Principal Investigators), budget, resources, data and resource sharing, and collaboration plans



Other Transactions Award Mechanism

Other Transactions (OT2)



- These are funding instruments which do not incorporate the standard terms and conditions of the OMB Circulars, NIH Grants Policy Statement, and FAR based Contract requirements but rather, all terms and conditions are negotiated between the federal sponsor (NIH) on a case-by-case basis with the Awardee.
 - Substantial and active NIH program negotiation and management, before, during and at the end of the project
 - Milestone-driven projects with contingency plans
 - Special award terms
 - Flexibility to alter the course of the project (e.g., expanded, modified, discontinued) and to design unique collaborations with other partners and between awardees



OT Regulatory Requirements



- NIH Salary Cap
- Fly America Act
- Debarment and Suspension 2 CFR 376 and 2 CFR 180
- Federal Information Security Management Act
- USA Patriot Act PL 107-56
- Lobbying Prohibition section 4002 of Public Law 111-148
- Restriction of Pornography on Computer Networks P.L. 113-235
- Giving False or Deliberately Misleading Information under Appropriations Act
- HHS Information Security Program
- Additional requirements to be stated in the terms and conditions



Award Terms



Example of rights with these awards

- Fund projects in increments and/or with options for continued work at the end of one or more phases;
- Fund projects of two or more entities (potentially across different applications) as part of a reorganized collaboration, teaming arrangement, or other means acceptable to the government;
- Reporting requirements;
- Request additional documentation (certifications, etc.); and
- Remove participants from award consideration should the parties fail to reach a finalized, fully executed agreement prior to a date determined by the NIH, or the proposer fails to provide requested additional information in a timely manner.



Negotiation Process



Highly interactive

- You will be asked to submit an electronic application that will include a formal statement of work, detailed budget information, and other certifications
- The applications can be negotiated prior to submission after a formal request for negotiations is issued by the OT official
- Negotiations will be recorded and documented by the NIH; the NIH will likely interact with multiple investigators
- Formal applications need to be submitted no later than **May 14, 2021**
- The recipient of the award will be expected to comply with the regulatory requirements listed in the OTA
- NIH expects to make an award no later than **July 2021**; the scope of work, milestones, and performance requirements will be finalized through negotiation and memorialized on the Notice of Award



Requirements after Award



Interactive Process

- All terms and conditions will be in the agreement; these can be amended during the course of the award
- Generally, payments align with achievement of milestones and a payment schedule will be negotiated prior to issuance of the award
- Financial and progress reports are required
- Organizations will be asked to implement management controls and management roles for staff
- Organizational Conflicts of Interest must be disclosed, and NIH will determine mitigation plans or need for waiver



Questions?



Program Contacts

- Scientific Research Contact: **Sonia Lee, Ph.D.**; sonia.lee@nih.gov
- Financial/Agreements Officer: **Dede Rutberg**; rutbergd@mail.nih.gov

Back-up Slides

Testing Research Projects: Large Networks, Consortia & Research Centers

NOT-OD-20-121

Program Information: \$5M per site over 2 years; 30 projects

- Understand the factors associated with COVID-19 morbidity and mortality disparities and to lay the foundation to reduce disparities for those underserved and vulnerable populations.
- Closely partner with communities to develop and implement interventions to increase access and uptake of testing.
- Provide large-scale testing and collaborate across the consortium of projects to serve as a resource for future studies and outreach.

Overview

- **Awarded 29 projects in FY20, 1 project in FY21.**
 - Approximately 500,000 participants/tests.
- **Testing methods include a range of POC, pooled, & lab-based; PCR, antigen, and Ab:**
 - Abbott ID NOW, Roche cabas, Cepheid GeneXpert, Hologic Aptima/Panther Fusion, Advanta Dx, Quest Diagnostics LDT, ThermoFisher, Infinity BiologiX, LabCorp, and custom tests.
- **Testing at prisons, mental health programs, in public housing & community centers.**
 - Focus on rural and urban, Tribal, and aging communities.



Testing Research Projects: Community Collaborations & Partnerships

NOT-OD-20-120

Program Information: \$2M per site over 2 years; 23 projects

- Strengthen available data on disparities in infection rates and disease progression and outcomes among underserved and vulnerable populations across the US.
- Understand differences in testing access and uptake patterns.
- Partner with communities to build the evidence-base of approaches to identify and address disparities in diagnostic testing uptake and effectiveness.

Overview

- **Awarded 4 projects in FY20, 19 projects in FY21.**
- **Testing methods include a range of POC, pooled, & lab-based; PCR, antigen, and Ab:**
 - Abbott ID NOW, Abbott Architect IgG Assay, Applied BioSystems, Cellex Rapid Test, KorvaLabs Curative SARS-Cov-2 Assay, Cepheid GeneXpert, Cellex Rapid Test, Healgen, Quidel Sofia SARS antigen test, ThermoFisher, TaqPath, LabCorp, Inno Diagnostics, and custom tests.
- **Testing at mobile-sites, community health centers, in public housing & at home.**
 - Focus on individuals with medical comorbidities, substance use disorders or mental illness, and community dwelling older adults.



Social, Ethical and Behavioral Implications

NOT-OD-20-119

Program Information: \$1.2M per project over 2 years; 16 projects

- Assess ethical, historical, healthcare, social, economic, and contextual factors surrounding COVID-19 testing.
- Investigate influence of cultural beliefs and attitudes, perceived expectations, and preferences.
- Inform development of interventions and tools to increase access to and acceptability of testing.

Overview

- **Awarded 5 projects in FY20, 11 projects in FY21.**
- **Research conducted through community health centers, online surveys, public housing developments, and Tribal communities.**
 - Focus on individuals with medical comorbidities, migrant and immigrant populations, Tribal populations, and rural and remote communities.



RADx-UP Coordinating Center (CDCC)

RFA-OD-20-013

Program Information: \$80M over 4 years

- Serve as a national resource to coordinate across the RADx Consortium.
- Provide overarching support and guidance in: (1) Administrative Operations and Logistics, (2) COVID-19 Testing Technology, (3) Community and Health System Engagement and (4) Data Collection, Integration and Sharing.
- Support the pilot project programs: (1) Rapid pilot studies, (2) Community collaboration grants.

Overview

- **Awarded to Duke/UNC.**
- **Innovative ideas for data management, hub and spoke models of networked testing, and outreach to underserved communities.**
- **Experience in developing new SARS-CoV-2 testing technologies.**
 - Provide strong technical assistance to testing protocols and adoption/distribution of new, emerging technologies.

