

# RADx Underserved Populations (RADx-UP)

## Phase IV Pre-application Webinar

May 24, 2023 1:30-3:00PM



# Housekeeping

- This webinar will be recorded.
- All participants except speakers will be muted.
- Please place questions in the Questions and Answers module; they will be answered either in the chat box or during the Q&A session.
- An extended Q&A session at the end will cover questions received during both presentations.
- All questions and answers will be captured in an FAQ.
- The FAQ, recorded video, and the slide presentation for today's webinar will be posted on the NIH RADx website and emailed to registrants.

**Speaker**



**Wilson Compton, M.D., M.P.E.**

# **Review of Agenda and Overview of RADx Program**

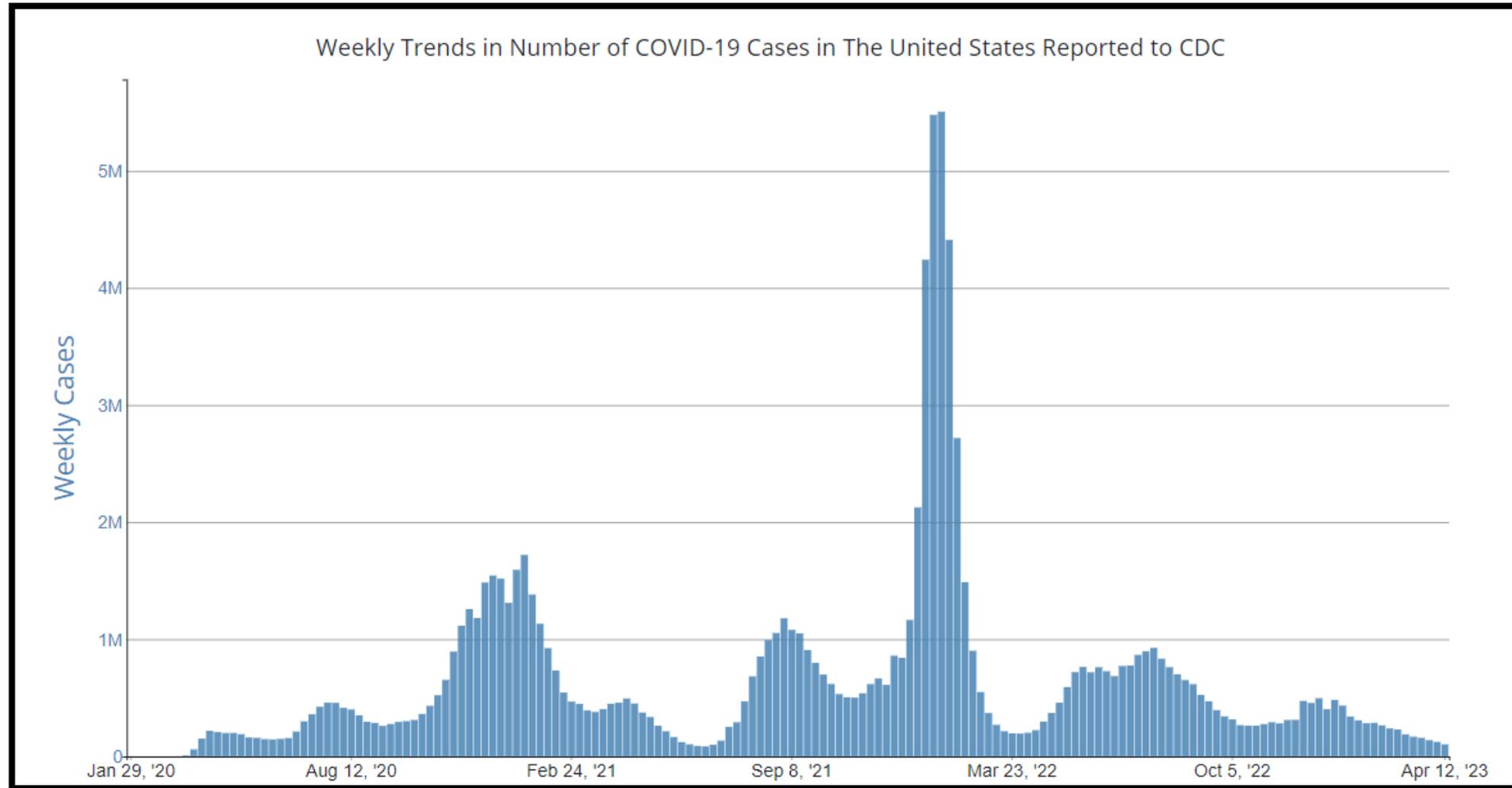
# Webinar Agenda

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Topic	Presenter	Time
<b>Review of Agenda and Overview of RADx-UP</b>	Wilson Compton M.D., M.P.E. <i>RADx-UP Working Group Co-Chair Deputy Director, NIDA</i>	1:30 - 1:45PM
<b>Novel Insights through Cross-Site Analysis</b> RFA-OD-23-050	Sonia Lee, Ph.D. <i>RADx-UP Working Group Member Chief, Maternal and Pediatric Infectious Disease Branch, NICHD</i>	1:45 - 2:00PM
<b>Dissemination &amp; Implementation Research</b> RFA-OD-23-051	Jenna Norton, Ph.D., M.P.H. <i>RADx-UP Working Group Member Program Director, Division of Kidney, Urologic, and Hematologic Diseases, NIDDK</i>	2:00 - 2:15PM
<b>Question &amp; Answer</b>	Moderated by: Jenna Norton, Ph.D., M.P.H. Sonia Lee, Ph.D.	2:15 - 3:00PM

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# Daily Trends in COVID-19 Cases in the United States Reported to CDC



**April 12, 2023**

**7-day average: 14,491**

**Total Cases Reported: 104,348,746**

Source: <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html>

# Racial and Ethnic Minority Groups are Disproportionately Affected by COVID-19\*

## Risk for COVID-19 Infection, Hospitalization, & Death by Race/Ethnicity

Rate ratios compared to White, Non-hispanic persons	American Indian or Alaska Native, Non-Hispanic persons	Asian, Non-Hispanic persons	Black or African American, Non-Hispanic persons	Hispanic or Latino persons
Cases	1.6x	0.8x	1.1x	1.5x
Hospitalization	2.5x	0.7x	2.1x	1.8x
Deaths	2.0x	0.7x	1.6x	1.7x

Race and ethnicity are risk markers for other underlying conditions that affect health, including socioeconomic status, access to health care, and exposure to the virus related to occupation, e.g. frontline, essential and critical infrastructure workers.

Note: adjusting by age is important because risk of infection, hospitalization, and death is different by age, and age distribution differs by racial and ethnic group. If the effect of age is not accounted for, racial and ethnic disparities can be underestimated or overestimated.

Table Source CDC as of April 24, 2023: [Risk for COVID-19 Infection by Race/Ethnicity \(CDC\)](#)

\*Note that the CDC data shown does not include Pacific Islander populations which is another population disproportionately affected by COVID-19

# RADx-UP Strategies

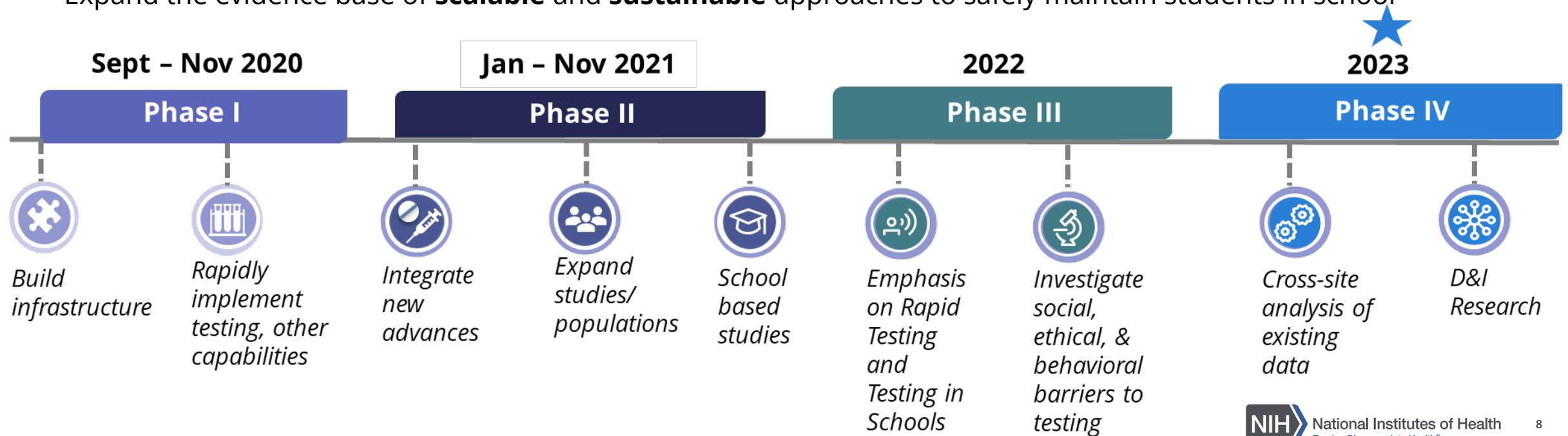
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- **Expand capacity to test broadly** for SARS-CoV-2 in highly affected populations, including asymptomatic persons.
- **Deploy validated point of care tests** as available, including self-test and saliva-based methods.
- **Inform implementation of mitigation strategies** based on isolation and contact tracing to limit community transmission.
- **Understand factors** that contribute to COVID-19 disparities and **implement interventions** to reduce these disparities.
- **Establish infrastructure** that could facilitate evaluation and distribution of vaccines and therapeutics.
- **Explore the effectiveness of interventions** used to tackle COVID-19 in underserved and vulnerable populations.

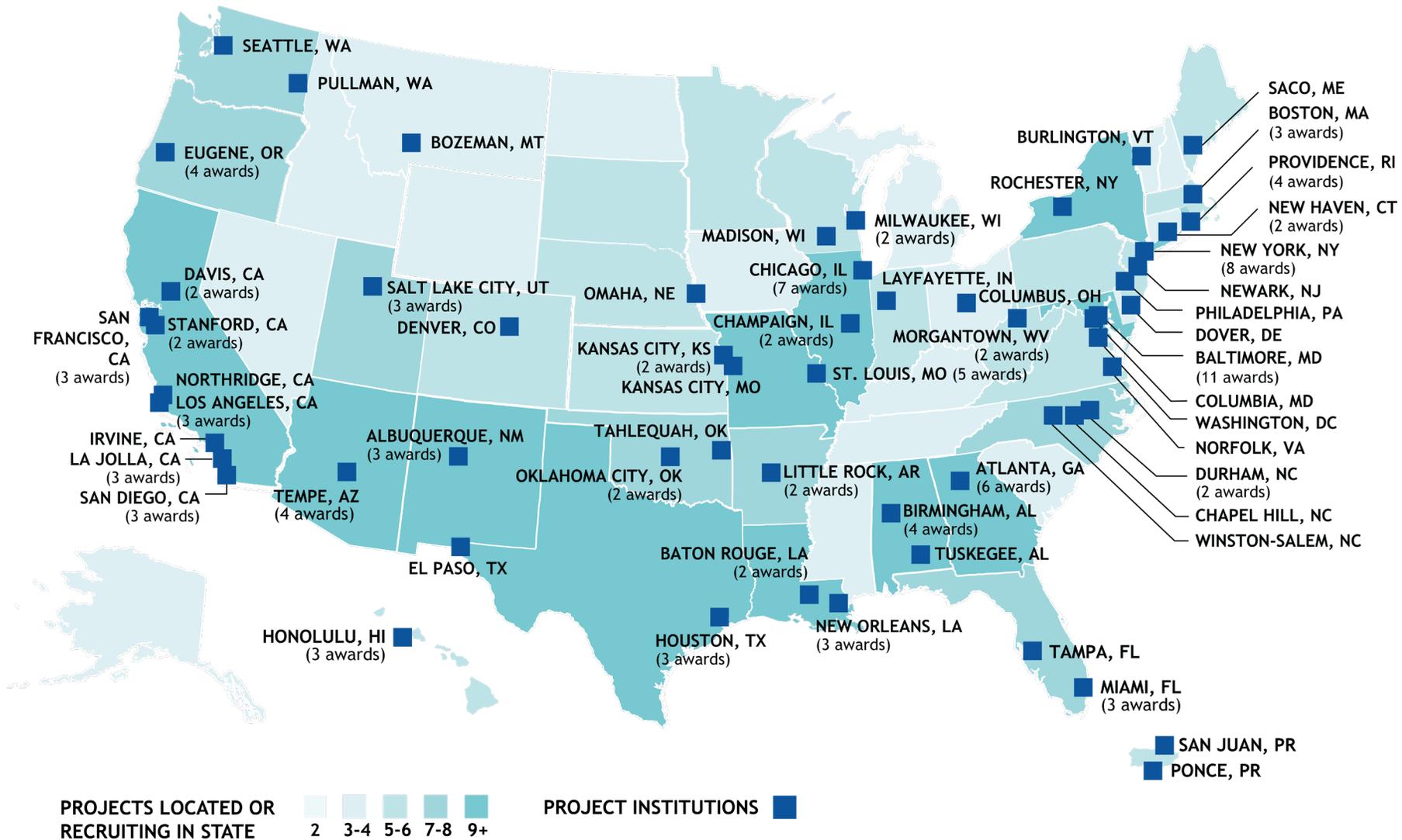
# RADx-UP Phases and Timeline

## Program 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 disparities** in COVID-19 diagnostics
- Reduce barriers and increase access and utilization of COVID-19 tests combined with other mitigation strategies
- Expand the evidence base of **scalable** and **sustainable** approaches to safely maintain students in school



# RADx-UP Locations (Phase I-III)



**Key**

■ Phase I - III Project Institutions

# RADx-UP At-A-Glance

**137**

COVID-19 Testing and SEBI projects

**1**

Coordination & Data Collection  
Center

**56**

States, Territories\* and D.C.

**>368,000**

Enrolled participants  
(prospectively)

**>492,000**

COVID-19 tests conducted  
(prospectively)

**109**

Projects submitting data to CDCC

**49**

Community Collaboration Grants

**13**

Rapid Research Pilot Awards

**199**

Journal articles  
(acknowledged RADx-UP project grant #)

# A New Era for RADx-UP: Phase IV

## Moving Out of a State of Emergency to Thoughtful Reflection

*This new phase allows for thoughtful and systematic reflection of lessons learned from Phase I-III of RADx-UP, while maintaining an intentional focus on understanding the unique needs of vulnerable populations.*

### Two New Activities:

- 1. Novel Insights through Cross-Site Analysis of Existing RADx-UP Data**
- 2. Dissemination & Implementation Research**

1

## Continuing to Build the Evidence Base with Secondary Data Analysis

- Utilizing the wealth of data available to gain unique insights by analyzing data from multiple project sites
  - Showcasing the value of the RADx CDEs for continued research use

2

## Evaluating Effective Interventions to Prepare for the Future

- Understanding how successful implementation strategies from RADx-UP can be utilized for future initiatives impacting underserved/vulnerable populations
  - Allowing for effective response to future health emergencies

# RADx-UP Phase IV: New Funding Opportunities

Information	RFA-OD-23-050	RFA-OD-23-051
<b>RFA Focus</b>	Novel Insights through Cross-Site Analyses of Existing RADx-UP Data	Dissemination and Implementation Research
<b>Budget Mechanism</b>	R21 (2 years, with NCE option*)	R01 (3 years, with NCE option*)
<b>Direct costs total</b>	limited to \$275,000	limited to \$1.8M
<b>Application Receipt</b>	July 3 (no late applications accepted)	July 10 (no late applications accepted)
<b>Eligibility</b>	Open	Open
<b>Scientific Focus</b>	<p>COVID-19 testing access and uptake</p> <p>Factors affecting testing and related COVID-19 outcomes</p> <p>Meta-analyses of COVID-19 response and intervention approaches</p>	Increasing access to and uptake of COVID-19 testing interventions to reduce disparities and promote health equity

\*Projects are eligible for standard 12-month NCEs, but project budgets and plans should reflect 2 award years for R21s and 3 award years for R01s

# *Reminder*

Applicants are encouraged to **connect with** the listed **IC contact** (found in each RFA) **prior to submission**.

**Speaker**



**Sonia Lee, Ph.D.**

# **Novel Insights through Cross-Site Analysis**

**RFA-OD-23-050**

# Novel Insights through Cross-Analyses of Existing RADx-UP Data (R21 Clinical Trial Not Allowed)

[RFA-OD-23-050](#) | New R21 awards

## Purposes

1

**To support analyses of existing RADx-UP data** by proposing novel questions related to SARS-CoV-2 testing and health disparities

- COVID-19 testing access and uptake
- Factors affecting testing and related COVID-19 outcomes
- Meta-analyses of specific COVID-19 response and intervention approaches within and across populations

2

**To explore important questions focused on COVID-19 testing access and uptake,** factors affecting testing and related COVID-19 outcomes, and meta-analyses of specific COVID-19 response and intervention approaches within and across populations

- Testing interventions
- COVID-19 testing options
- Common data elements (CDE)
- Social determinants of health (SDOH)
- Community-engaged interventions to address stigma, bias, distrust, and fear
- Psychosocial, behavioral, and ethical factors driving COVID-19 testing and vaccination
- Messaging and policies impact on COVID-19 testing and vaccination



# Novel Insights through Cross-Analyses of Existing RADx-UP Data (R21 Clinical Trial Not Allowed)

[RFA-OD-23-050](#) | New R21 awards

## Eligible Organizations

- ✓ Higher Education Institutions
- ✓ Nonprofits (other than Institutions of Higher Education)
- ✓ For-Profit Organizations
- ✓ Local Governments
- ✓ Federal Government
- ✓ Other Organizations (such as):
  - Independent School Districts
  - Public Housing Authorities/Indian Housing Authorities
  - Native American Tribal Organizations
  - Faith-Based or Community Based Organizations
  - Regional Organizations



# Research Topic *Examples* for RFA-OD-23-050

Potential research topics include but are not limited to:

## Testing Interventions

Analyses to **evaluate the effectiveness of testing interventions** and/or what testing interventions can be implemented to decrease COVID-19 disparities in different regions of the U.S. and across demographic groups.

## COVID-19 Testing Options

Analyses to **determine what COVID-19 testing options (e.g., surveillance, symptomatic, etc.)** are most acceptable and in what setting (such as community-based organizations, health clinics, school/academic environments).

## Common Data Elements

Analyses of **Common Data Elements for novel data comparison and synthesis** across project sites and smaller population groups. RADx-UP CDEs collected from the projects are specified at <https://radx-up.org/research/cdes/>.

## Social Determinants of Health (SDOH):

Analyses on **how SDOH help identify, understand, and address testing and vaccine access** and uptake in low-resourced geographic areas or communities with high levels of social vulnerability.

# Research Topic *Examples* for RFA-OD-23-050

Potential research topics include but are not limited to:

## **Community-Engaged Interventions to address Stigma, Bias, Distrust and Fear**

Analyses on **what type of community-driven interventions** effectively ameliorate stigma, bias, distrust, and fear regarding symptomatic and asymptomatic COVID-19 testing and vaccination.

## **Psychosocial, Behavioral, and Ethical Factors Driving COVID-19 Testing and Vaccination**

Analyses on **what specific psychosocial, behavioral, and ethical factors** drive COVID-19 testing and vaccine uptake within and across underserved populations, including the role of healthcare, academic, and social service settings in response to COVID-19 health disparities.

## **Messaging and Policies Impact on COVID-19 Testing and Vaccination**

Analyses on **whether and how messaging and policies at the local, state, and federal** levels in different jurisdictions affect COVID-19 testing and vaccine uptake over time.

# Key Considerations

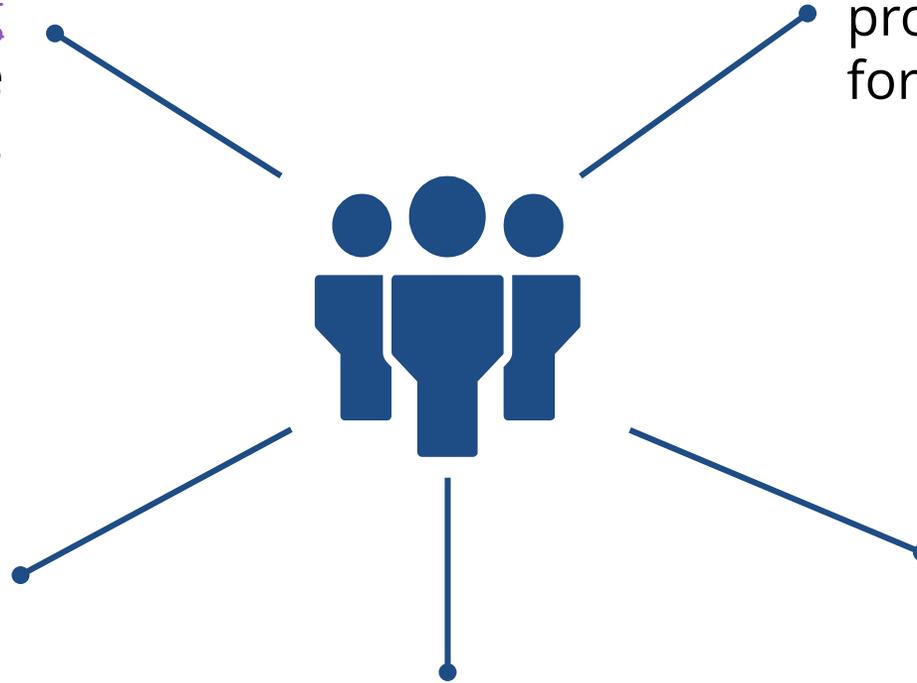
**Below are some key consideration for this NOFO:**

- Projects awarded will be expected to work **collaboratively** with each other and other projects related to COVID-19 testing research
- Projects must demonstrate **relevance** of the scientific questions to COVID-19 testing among underserved and vulnerable populations
- Projects should utilize **rigorous** analyses and methodology
- Results from these **projects must be disseminated rapidly** to increase COVID-19 prevention and control in communities that have been impacted disproportionately.

# Research and Data Requirements: *Examples*

Align with all requirements of new NIH [Data Management and Sharing \(DMS\) policy](#) to promote sharing of scientific data.

Must include milestones towards progress and timeline for completion.



Must include an evaluation plan demonstrating how proposed analyses will be assessed for integrity, usefulness, and impact

Comply with federal, state, local, and/or Tribal requirements on testing, reporting, and surveillance policies in study protocols

Must fully integrate community partners (letters of support and inclusion as investigators)

# Non-Responsive Factors

The following are examples that would be considered non-responsive:

- Projects without a focus on one or more underserved and COVID-19 vulnerable populations
- Projects that do not propose use of data from at least three RADx-UP project sites
- Projects that do not demonstrate relevance of the scientific questions to COVID-19 testing among underserved and COVID-19 vulnerable populations
- Projects that involve COVID-19 testing interventions outside of the United States
- Projects that do not have an infrastructure to rapidly report study findings and impact

# Budget for RFA-OD-23-050

**Respondents can request a budget option limited to \$275K in direct costs.**



**Study budgets should include funds for community partners to participate in research design and implementation**



**Budgets should reflect active participation by community partners to the extent possible**



**Reviewers will consider whether the budget and requested period of support are fully justified and reasonable in relation to the proposed research**



**The administrative and funding instrument used for this program will be an R21 grant.**  
A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

# Review Considerations

RFA-OD-23-050 (R21)

## Overall Impact

- ✓ Likelihood for project to exert a **sustained, powerful influence** on the research field

## Significance

- ✓ **Address an important problem** or critical barrier to progress in the field
- ✓ Prior research that serves as the **key support is rigorous**
- ✓ Achieved **aims will improve** scientific **knowledge**, technical **capability**, and/or **clinical practice**
- ✓ Achieved **aims will change concepts, methods, technologies, treatments, services, or preventative interventions** in the field

## Investigators

- ✓ **PD/PI(s)**, collaborators, and other researchers are **well suited for project**
- ✓ Early-stage investigators have **appropriate experience and training**
- ✓ Established researchers have **ongoing record of accomplishments** that advance their fields
- ✓ Collaborative PD/PI projects have investigators with **complementary expertise** with appropriate leadership, governance, and organizational structure



# Review Considerations

## RFA-OD-23-050 (R21)

### Innovation

- ✓ Application **challenges or seeks to shift current research or clinical practice paradigms** through novel theoretical concepts, approaches, instrumentation, or interventions
- ✓ Concepts, approaches, instrumentation, or interventions are **novel to one field or more broadly**
- ✓ **Refinement, improvement, or new application** of theoretical concepts, approaches, instrumentation, or interventions proposed

### Approach

- ✓ Overall strategy, methodology, and analyses are **appropriate to accomplish aims** of project
- ✓ **Plans to address weaknesses in rigor of key support** for proposed project
- ✓ Strategies to ensure a **robust and unbiased approach**
- ✓ Potential strategies, alternative strategies, and **benchmarks for success presented**

### Environment

- ✓ **Scientific environment** for work will **contribute to probability of success**
- ✓ **Institutional support**, equipment, and other physical resources available to investigators
- ✓ Project benefit from **unique features of scientific environment**, subject populations, or collaborative arrangements.



# Key Dates (RFA-OD-23-050)

See below a timeline with key dates for the application, review, and start period for RFA-OD-23-050.

**MAY 2**  
RFA  
POSTED

**JUNE 2**  
EARLIEST  
SUBMISSION  
DATE

**JUNE 2**  
LETTER OF  
INTENT  
DUE

**JULY 3**  
APPLICATION  
DUE BY 5:00PM  
LOCAL TIME OF  
APPLICANT\*

**JULY-SEPT 2023**  
REVIEW PERIOD

**SEPT 2023**  
EARLIEST  
START  
DATE

**\*NO LATE APPLICATIONS WILL BE ACCEPTED.**

# Speaker



Jenna Norton, Ph.D., M.P.H.

## Dissemination & Implementation Research RFA-OD-23-051

# RADx-®UP Dissemination and Implementation (D&I) Research on COVID-19 Testing Interventions among Underserved and Vulnerable Populations (R01 Clinical Trial Optional)

[RFA-OD-23-051](#) | New R01 awards

## Purpose:

1

To support dissemination and implementation (D&I) research focused on **increasing access to** and **uptake of COVID-19 testing interventions** with the goal of reducing COVID-19 disparities and **promoting health equity** among **underserved** and **vulnerable populations**

- Develop and test D&I strategies for the **equitable and effective adoption, adaptation, integration, scale-up, and sustainability of evidence-based COVID-19 testing interventions** among underserved and vulnerable populations
- Understand circumstances that create a need to **stop, reduce** and/or **replace** (“de-implement”) the **use of COVID-19 testing interventions** that are ineffective, low-value or inequitable, and **identify optimal strategies** to successfully “**de-implement**” such interventions



# RADx-®UP Dissemination and Implementation (D&I) Research on COVID-19 Testing Interventions among Underserved and Vulnerable Populations (R01 Clinical Trial Optional)

[RFA-OD-23-051](#) | New R01 awards

## Eligible Organizations

- ✓ Higher Education Institutions
- ✓ Nonprofits (other than Institutions of Higher Education)
- ✓ For-Profit Organizations
- ✓ Local Governments
- ✓ Federal Government
- ✓ Other Organizations (such as):
  - Independent School Districts
  - Public Housing Authorities/Indian Housing Authorities
  - Native American Tribal Organizations
  - Faith-Based or Community Based Organizations
  - Regional Organizations



# Research Topic *Examples* for RFA-OD-23-051

## Potential research topics include but are not limited to:

### **Culturally & Community Specific D&I Strategies**

Strategies that enhance reach, adoption, effectiveness, integration and maintenance of COVID-19 testing interventions that are culturally and community specific.

### **D&I Strategies to Overcome Structural Racism/Discrimination**

Strategies for implementing evidence-based COVID-19 testing interventions to optimally overcome structural racism and discrimination barriers

### **Testing Strategies in Community/Clinical Settings**

Strategies for multiple evidence-based COVID-19 testing interventions within community and clinical settings caring for underserved and vulnerable patients

### **Facilitators/Barriers to Testing Interventions**

Understanding facilitators and barriers to adoption and sustainability of evidence-based COVID-19 testing interventions in multiple settings with evolving COVID-19 landscape.

# Research Topic *Examples* for RFA-OD-23-051

Potential research topics include but are not limited to:

## **Circumstances for De-Implementation of Practices**

Understanding the circumstances that create a need to stop or reduce the use of practices related to COVID-19 testing that are ineffective, low-value, or in-equitable.

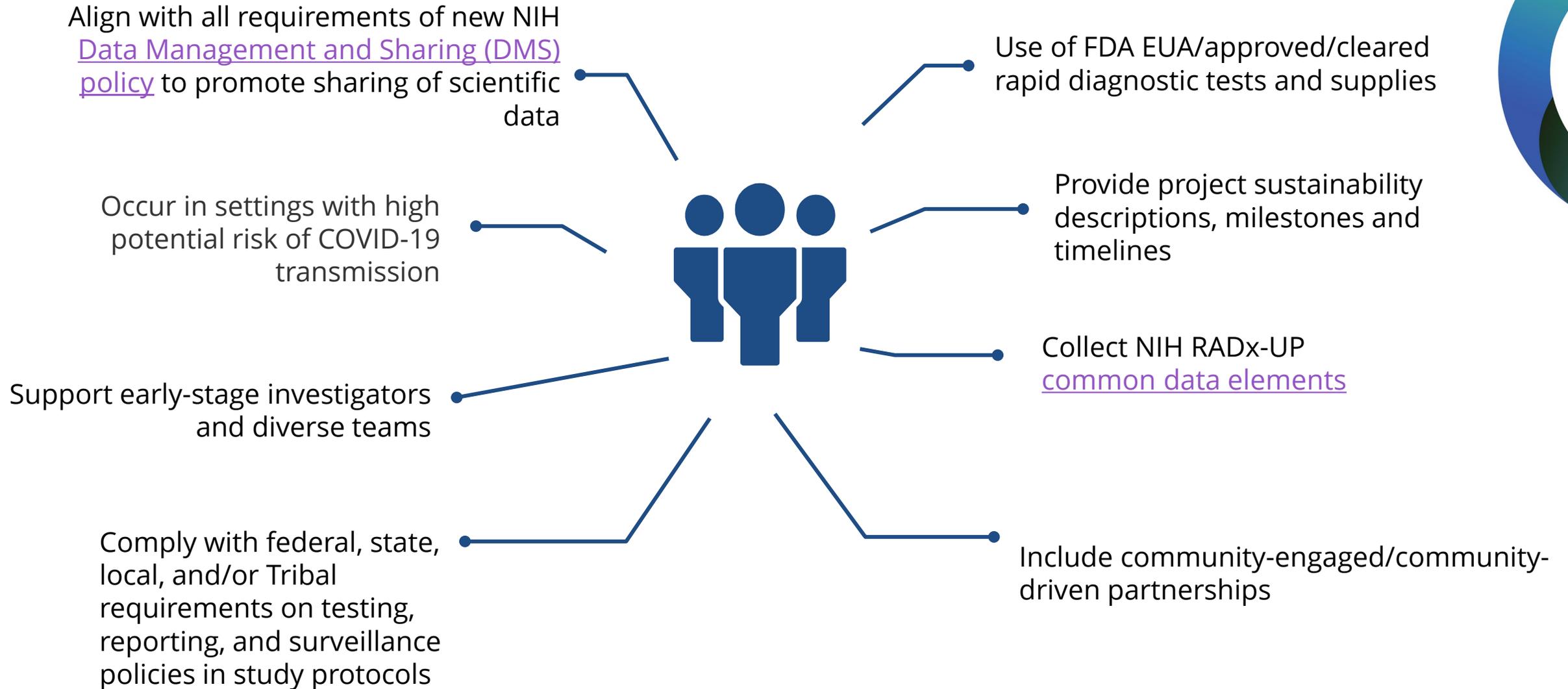
## **Optimal Strategies for Disseminating De-Implementation Evidence**

Understanding context-specific strategies and considerations for successfully disseminating evidence related to de-implementation practices to of ineffective COVID-19 testing

## **Multilevel Change in Testing Behavior**

Understanding effective efforts to change behavior at multiple levels related to COVID-19 testing, prevention of health disparities, and improved quality of care

# Key Research and Data Requirements



# Non-Responsive Factors

The following are examples that would be considered non-responsive:

- Projects without a focus on one or more underserved and COVID-19 vulnerable populations
- Projects that do not focus on dissemination and implementation research
- Projects that have limited population reach
- Projects that do not demonstrate an existing relationship with or engagement strategy with the target community
- Projects that that involve COVID-19 testing interventions outside of the United States
- Projects that do not include the use of FDA EUA/approved/cleared diagnostic tests and supplies that are utilized on-label (that is, in the way they are authorized/approved/cleared.)

# Review Considerations

RFA-OD-23-051 (R01)

## Innovation- Specific Considerations for this RFA:

- ✓ Potential to speed the **translation of research into practice** or produce **novel and robust findings**

## Significance- Specific Considerations for this RFA:

- ✓ **Impact** of results on **science of D&I in underserved communities**
- ✓ **Broad reach** is achieved as well as **equity of reach and outcomes** through knowledge/service delivery contexts selected is likely
- ✓ **Resource requirements** and **cost of implementation/de-implementation strategies** well considered
- ✓ Potential **adopters/organization** able to **determine applicability of results** to setting



# Review Considerations

RFA-OD-23-051 (R01)

## Investigators- *Specific Considerations for this RFA:*

- ✓ Appropriate **expertise of key personnel** to **conduct community-engaged and D&I research**
- ✓ **Well-established and strong engagement and collaboration** between investigators and community
  - Collaborations able to support accomplishment of project aims

## Environment- *Specific Considerations for this RFA:*

- ✓ Applicant is **well-positioned to influence large or influential networks** capable of taking the results of proposed study **to scale to achieve public health impact**
- ✓ Proposed **approaches are able to take advantage of unique features of the intervention delivery environment** or **employ useful collaborative arrangements**
- ✓ Institutional **supports are able to sustain dissemination or implementation strategies** once research funding ends



# Review Considerations

## RFA-OD-23-051 (R01)

### Approach- Specific Considerations for this RFA:

- ✓ Research team is able to **adapt and respond quickly to the changing dynamics of the COVID-19 pandemic**
- ✓ Plans for the **integrating community partners in the study** is feasible and appropriate
- ✓ Applicant justified the **study design** on the **basis of the current state-of-the-art or contextual factors relevant to dissemination and/or implementation** well
- ✓ **Established partnerships and collaboration with the communities of interest** are appropriate
- ✓ **Research methods** proposed are **appropriate, relevant, practical, and rigorous**
- ✓ Proposed **dissemination or implementation approaches** are **relevant and appropriate** to problem and population of interest
- ✓ **Procedures to assess and analyze the dissemination or implementation strategies** are appropriate
- ✓ **Measurements and analysis linked to study aims** are well aligned
- ✓ **Analysis appropriately incorporates the best available data** to track dissemination or implementation process and impact, including cost-effectiveness
- ✓ Proposed plan for **analysis takes into account hierarchical relationships among multiple levels of outcomes** (e.g. patient, provider, system), where applicable



# Budget for RFA-OD-23-051

Respondents can request up to \$1.8M in direct costs for the entire project.



Study budgets should include funds for community partners to participate in research design and implementation



Budgets should reflect active participation by community partners to the extent possible



Reviewers will consider whether the budget and requested period of support are fully justified and reasonable in relation to the proposed research



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# Question & Answer

## **Moderated By:**

- Jenna Norton, Ph.D., M.P.H.
- Sonia Lee, Ph.D.

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