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.
Review of Agenda and Overview of RADx Program
# Webinar Agenda

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

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

<table>
<thead>
<tr>
<th>Rate ratios compared to White, Non-hispanic persons</th>
<th>American Indian or Alaska Native, Non-Hispanic persons</th>
<th>Asian, Non-Hispanic persons</th>
<th>Black or African American, Non-Hispanic persons</th>
<th>Hispanic or Latino persons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cases</td>
<td>1.6x</td>
<td>0.8x</td>
<td>1.1x</td>
<td>1.5x</td>
</tr>
<tr>
<td>Hospitalization</td>
<td>2.5x</td>
<td>0.7x</td>
<td>2.1x</td>
<td>1.8x</td>
</tr>
<tr>
<td>Deaths</td>
<td>2.0x</td>
<td>0.7x</td>
<td>1.6x</td>
<td>1.7x</td>
</tr>
</tbody>
</table>

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

• **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

**Sept – Nov 2020**
- **Phase I**: Build infrastructure

**Jan – Nov 2021**
- **Phase II**: Rapidly implement testing, other capabilities
- Integrate new advances
- Expand studies/populations
- School based studies

**2022**
- **Phase III**: Emphasis on Rapid Testing and Testing in Schools
- Investigate social, ethical, & behavioral barriers to testing

**2023**
- **Phase IV**: Cross-site analysis of existing data
- D&I Research

(NIH National Institutes of Health)
RADx-UP At-A-Glance

137
COVID-19 Testing and SEBI projects

>368,000
Enrolled participants (prospectively)

49
Community Collaboration Grants

1
Coordination & Data Collection Center

>492,000
COVID-19 tests conducted (prospectively)

13
Rapid Research Pilot Awards

56
States, Territories* and D.C.

109
Projects submitting data to CDCC

199
Journal articles (acknowledged RADx-UP project grant #)

Data as of April 2023

* Territories include sites in: Guam, American Samoa, US Virgin Islands, Northern Mariana Islands and Puerto Rico
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

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

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

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

<table>
<thead>
<tr>
<th>Potential research topics include but are not limited to:</th>
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<tr>
<td><strong>Testing Interventions</strong></td>
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<tr>
<td><strong>COVID-19 Testing Options</strong></td>
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<td><strong>Common Data Elements</strong></td>
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<tr>
<td><strong>Social Determinants of Health (SDOH):</strong></td>
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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 an evaluation plan demonstrating how proposed analyses will be assessed for integrity, usefulness, and impact.

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

Must include milestones towards progress and timeline for completion.

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

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 in-equitable, 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:

<table>
<thead>
<tr>
<th>Topic</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Culturally &amp; Community Specific D&amp;I Strategies</td>
<td>Strategies that enhance reach, adoption, effectiveness, integration and maintenance of COVID-19 testing interventions that are culturally and community specific.</td>
</tr>
<tr>
<td>D&amp;I Strategies to Overcome Structural Racism/Discrimination</td>
<td>Strategies for implementing evidence-based COVID-19 testing interventions to optimally overcome structural racism and discrimination barriers.</td>
</tr>
<tr>
<td>Testing Strategies in Community/Clinical Settings</td>
<td>Strategies for multiple evidence-based COVID-19 testing interventions within community and clinical settings caring for underserved and vulnerable patients.</td>
</tr>
<tr>
<td>Facilitators/Barriers to Testing Interventions</td>
<td>Understanding facilitators and barriers to adoption and sustainability of evidence-based COVID-19 testing interventions in multiple settings with evolving COVID-19 landscape.</td>
</tr>
</tbody>
</table>
## Potential research topics include but are not limited to:

<table>
<thead>
<tr>
<th>Research Topic Examples for RFA-OD-23-051</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Circumstances for De-Implementation of Practices</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Optimal Strategies for Disseminating De-Implementation Evidence</strong></td>
<td>Understanding context-specific strategies and considerations for successfully disseminating evidence related to de-implementation practices to of ineffective COVID-19 testing</td>
</tr>
<tr>
<td><strong>Multilevel Change in Testing Behavior</strong></td>
<td>Understanding effective efforts to change behavior at multiple levels related to COVID-19 testing, prevention of health disparities, and improved quality of care</td>
</tr>
</tbody>
</table>
Key Research and Data Requirements

- Align with all requirements of new NIH Data Management and Sharing (DMS) policy to promote sharing of scientific data
- Use of FDA EUA/approved/cleared rapid diagnostic tests and supplies
- Occur in settings with high potential risk of COVID-19 transmission
- Provide project sustainability descriptions, milestones and timelines
- Support early-stage investigators and diverse teams
- Collect NIH RADx-UP common data elements
- Comply with federal, state, local, and/or Tribal requirements on testing, reporting, and surveillance policies in study protocols
- Include community-engaged/community-driven partnerships
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 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.
- The administrative and funding instrument used for this program will be an R01 grant. A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.
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Question & Answer

Moderated By:
• Jenna Norton, Ph.D., M.P.H.
• Sonia Lee, Ph.D.

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