Rapid Acceleration of Diagnostics (RADx) – Underserved Populations (UP)
Funding Opportunity Announcements (FOAs)
Webinar

Monica Webb Hooper, Ph.D.
National Institute on Minority Health and Health Disparities (NIMHD) – RADx-UP co-chair

Ming Lei, Ph.D.
National Institute of General Medical Sciences (NIGMS) – RADx-UP co-chair

RADxInfo@nih.gov  
July 1, 2020
Session Objectives

1. Provide an overview of the RADx-UP initiative
2. Overview of RADx-UP FOAs
3. Answer questions
## Agenda

<table>
<thead>
<tr>
<th>Topic</th>
<th>Content</th>
<th>Person responsible</th>
<th>Timing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Welcome</td>
<td>• Purpose of webinar</td>
<td>Ming Lei, Ph.D.</td>
<td>3:00 p.m. – 3:05 p.m.</td>
</tr>
<tr>
<td></td>
<td>• Administrative Items</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overview of RADx-UP</td>
<td>• Background on RADx-UP</td>
<td>Monica Webb Hooper, Ph.D.</td>
<td>3:05 p.m. – 3:15 p.m.</td>
</tr>
<tr>
<td></td>
<td>• Four FOAs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overview of NOT-OD-20-121 and</td>
<td>• Update on opportunity</td>
<td>Wilson Compton, M.D., M.P.E</td>
<td>3:15 p.m. – 3:25 p.m.</td>
</tr>
<tr>
<td>NOT-OD-20-120</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overview of NOT-OD-20-119</td>
<td>• Update on opportunity</td>
<td>Dave Kaufman, Ph.D.</td>
<td>3:25 p.m. – 3:35 p.m.</td>
</tr>
<tr>
<td>Overview of RFA-OD-20-013</td>
<td>• Update on opportunity</td>
<td>Dorothy Castille, Ph.D. Gwen Collman, Ph.D.</td>
<td>3:35 p.m. – 4:20 p.m.</td>
</tr>
<tr>
<td>Q&amp;A</td>
<td>• Attendees submit questions through Feedback option on videocast</td>
<td>Presenters / attendees</td>
<td>4:20 p.m. – 5:00 p.m.</td>
</tr>
</tbody>
</table>

[https://www.nih.gov/research-training/medical-research-initiatives/radx](https://www.nih.gov/research-training/medical-research-initiatives/radx)
RADxInfo@nih.gov
RADx-UP Overview

Monica Webb Hooper, Ph.D.

monica.hooper@nih.gov
COVID-19

• Novel severe acute respiratory syndrome coronavirus 2
• Global pandemic
• U.S. cases: 2,581,229
• U.S. deaths: 126,739

As of June 30, 2020
For Native Americans, COVID-19 is ‘the worst of both worlds at the same time’

The Striking Racial Divide in How Covid-19 Has Hit Nursing Homes

Homes with a significant number of black and Latino residents have been twice as likely to be hit by the coronavirus as those where the population is overwhelmingly white.

Rural America Could Be the Region Hardest Hit by the COVID-19 Outbreak

Black Americans Face Alarming Rates of Coronavirus Infection in Some States

Data on race and the coronavirus is too limited to draw sweeping conclusions, experts say, but disparate rates of sickness — and death — have emerged in some places.

Many Who Need Testing For COVID-19 Fail To Get Access

COVID-19 in Prisons and Jails in the United States

Laura Hawks, MD1,2; Steffie Woolhandler, MD, MPH2,3; Danny McCormick, MD, MPH1,2

Author Affiliations | Article Information

Rapid Acceleration of Diagnostics (RADx) Initiative

Signed into law, April 24, 2020

Supplemental Appropriations Language:

…not less than $1,000,000,000 shall be transferred to the “National Institutes of Health—Office of the Director” to develop, validate, improve, and implement testing and associated technologies; to accelerate research, development, and implementation of point of care and other rapid testing; and for partnerships with governmental and non-governmental entities to research, develop, and implement the activities outlined in this proviso…

Rapid Acceleration of Diagnostics (RADx): Testing

- Identify
- Treat
- Isolate
- Contact trace

USA
35,475,589
TESTS REPORTED
CDC | Updated: June 30 2020 6:03 PM

USA
3,324,331
POSITIVE TESTS
CDC | Updated: June 30 2020 6:03 PM

USA
9%
OVERALL % POSITIVE
CDC | Updated: June 30 2020 6:03 PM

United States Laboratory Testing
Commercial and Reference, Public Health, and Hospital Laboratories
Preliminary data: Reported by U.S. Laboratories including Commercial and Reference, Public Health, and Hospital Laboratories
Totals may include antibody data from some states

As of June 30, 2020

RADx-UP: Major Component of the NIH COVID-19 Response

- $500 million commitment, 50% of NIH OD congressional appropriation
- All NIH Institutes and Centers
- **Overarching goal**: Understand factors influencing the disproportionate burden of the pandemic on underserved and/or vulnerable populations so that interventions can be implemented to decrease these disparities
- Emergency mechanisms utilized to encourage rapid scientific response and impact this year
RADx-UP: Phase I

• Four FOAs:
  1. 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 (NOT-OD-20-121)
  4. Emergency Awards: RADx-UP Coordination and Data Collection Center (CDCC) (U24 Clinical Trial Optional; RFA-OD-20-013)
Populations

- **Underserved**: NIH-designated U.S. health disparity populations
- **COVID-19 medically and/or socially vulnerable populations**
  - Known medical comorbidities; older adults; nursing home residents; homeless populations; pregnant women; children; persons with disabilities; individuals with substance use disorders or serious mental illness; migrant communities; residents of tribal lands or reservations, communities exposed to high rates of air pollution, and others
RADx-UP: Coordination & Data Collection Center (CDCC; U24)

- Administration
- Testing technology
- Community engagement
- Data integration
RADx-UP: Community Engagement

- Leverage existing partnerships
  - Tribal governments & agencies
  - Medical centers and clinics
  - Social services
  - Grassroots organizations
  - Public health departments
  - Faith-based organizations
  - Schools, childcare settings

- Evidence of collaboration
RADx-UP: Phase II

- Phase I – four released FOAs
- Phase II – anticipated within one year
- Goals (tentative):
  - Infrastructure enhancement
  - Expand multisector partnerships
  - New scientific questions
  - Resource for vaccine trials
RADx-UP: Diversity & Inclusion

• To address the expected impacts of COVID-19 on the scientific workforce, projects are also strongly encouraged to support early stage investigators, specifically targeting the ability to enhance diversity in their research workforce.
RADx-UP Review Overview

**Limited Competition Testing Research Projects – administrative review**
- **Timing**: August 7, 2020 – single receipt
- **Reviewers**: IC of parent application provides initial assessment; Trans-NIH team completes review

**CDCC – hybrid review**
- **Timing**: August 7, 2020 – single receipt
- **Reviewers**: NIMHD will convene review group with experienced staff from across NIH and outside expertise

**Testing Research Projects – administrative review**
- **Timing**: Two submission dates August 7, 2020 and September 8, 2020; award mid-September
- **Reviewers**: IC of parent application provides initial assessment; Trans-NIH team completes review

**SEBI – administrative review**
- **Timing**: Two submission dates August 7, 2020 and September 8, 2020; award mid-September
- **Reviewers**: IC of parent application provides initial assessment; Trans-NIH team completes review

Governance Committee will receive the following for each application:

1) Feasibility based on knowledge and progress of the parent grant(s),
2) Scientific strengths (based on the review criteria specified in the NOSIs),
3) Overall recommendation
RADx-UP: Community-Engaged COVID-19 Testing Research

• Remember:
  • Carefully read the FOA requirements
  • Ensure programmatic responsiveness
  • Community engagement is at the core
  • Potential to establish scientific knowledge, implement impactful interventions

“Science that partners with, serves, & benefits communities.”

- M. Webb Hooper
Thank you!
Overview of Research Testing
Project FOAs:

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

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

Wilson Compton, M.D., M.P.E. – National Institute of Drug Abuse (NIDA)

wcompton@nida.nih.gov
Overall Purpose: Understand factors that have led to disproportionate COVID-19 burden so that interventions can be implemented to decrease these disparities

Research Topic Examples (see NOSIs for details):

- Increasing reach, access, uptake, and impact of COVID-19 testing in underserved and/or vulnerable populations
  - Determine baseline rates of testing
- Create strategies to widely disseminate up-to-date FDA-authorized/approved testing
  - Consider viral detection point-of-care tests (including antigen and antibody tests that emerge from NIH-supported technology development programs)
- Test community engagement strategies to reduce barriers and increase access
  - Leverage community relationships to test strategies for adoption
- Comparisons across datasets/studies and data integration are essential
  - Studies with human participants should incorporate social determinants of health (SDOH) measures
  - Collaboration with other RADx-UP studies and possibly with other federal agencies
Additional Requirements (see NOSIs for full list)

- **Data sharing for all COVID-19 projects** where not prohibited (e.g. possible restrictions due to Tribal data sovereignty)

- Submit **common evaluation metrics** to the RADx-UP Coordinating and Data Collection Center (CDCC)

- Applicants **must include:**
  - Progress milestones
  - Measure of reporting relevant testing information
  - Description of sustainability, including obtaining and retaining personal identifiers (where not prohibited)
  - Partnership that may be leveraged for future public health pandemic mitigation efforts

- Provide **letters of support** from community partners
Inappropriate and Possibly Non-Responsive Factors (see NOSIs for full list)

- Population not underserved or COVID-19 vulnerable
- Lack of demonstrated engagement with populations of interest
- Non-U.S. testing population
- Lack of consideration of social, ethical and behavioral issues
- Exclusively qualitative research (mixed quantitative/qualitative acceptable)
- Lack of infrastructure to coordinate with CDCC
- Lack of ability to conduct diagnostics
- Ineligible grants for supplementation
Review Process (see NOSIs for details)

- Internal NIH staff review panel using standard criteria, with additional details related to:
  - Urgency and significance of research
  - Research and evaluation design
  - Investigators
  - Community partnerships
  - Data sharing plans
  - Coordination plans
  - Specification of outcomes
  - Sustainability
  - Testing feasibility and appropriateness
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 - NOT-OD-20-121

Purpose

- Understand and address COVID-19 morbidity and mortality disparities among underserved and vulnerable populations across the United States
- Examine SARS-CoV-2 infection patterns
- Increase access and effectiveness of diagnostics
- Understand factors that have led to disparities

- Large scale networks, consortia, centers that support large scale testing
- 12 page research strategy
- Administrative review
- **Amount of funding:** $3,500,000 maximum direct costs for 2-year budget; 75% allocated year 1
- **Application Due Date:** August 7, 2020
- **Award Date:** By September 30, 2020
- **Estimated Number of Awards:** 25
Notice of Special Interest (NOSI): Emergency Competitive Revisions for Community-Engaged Research on COVID-19 Testing among Underserved and/or Vulnerable Populations - NOT-OD-20-120

Purpose

- Understand and address COVID-19 morbidity and mortality disparities among underserved and vulnerable populations across the United States
- Examine SARS-CoV-2 infection patterns
- Increase access and effectiveness of diagnostics
- Understand factors that have led to disparities

- Collaborative and Individual research awards
- 6 page research strategy
- Administrative review
- Application Due Dates: August 7, 2020 and September 8, 2020
- Amount of funding: $1,300,000 maximum in direct costs for 2-year budget; 75% allocated year 1
- Award Dates: September (for some August 7 submissions; November for others)
- Estimated Number of Awards: 30
## NOT-OD-20-121 (LIMITED COMPETITION) VS. NOT-OD-20-120

<table>
<thead>
<tr>
<th></th>
<th>NOT-OD-20-121 (limited competition)</th>
<th>NOT-OD-20-120</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eligible grants</td>
<td>Large centers and networks</td>
<td>Collaborative and Individual research awards</td>
</tr>
<tr>
<td>Size of award</td>
<td>$3,500,000 maximum direct costs for 2-year budget; 75% allocated year 1</td>
<td>$1,300,000 maximum direct costs for 2-year budget; 75% allocated year 1</td>
</tr>
<tr>
<td>Expected number of awards</td>
<td>25 awards</td>
<td>30 awards</td>
</tr>
<tr>
<td>Application</td>
<td>12 pages</td>
<td>6 pages</td>
</tr>
<tr>
<td>Submission Date</td>
<td>August 7, 2020</td>
<td>August 7 and September 8, 2020</td>
</tr>
</tbody>
</table>
Overview of Social, Ethical, and Behavioral Implications (SEBI) Research FOA:

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

Dave Kaufman, PhD – National Human Genome Research Institute (NHGRI)
dave.kaufman@nih.gov
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-20-119

Purpose

- Identify, analyze, and address the social, ethical, and behavioral factors influencing access to and uptake of COVID-19 testing in underserved and/or vulnerable populations
- Identify high priorities for community partners. In response, develop interventions, strategies or products to improve access to and acceptability of COVID-19 diagnostics
- Address factors at multiple levels (e.g., individual, interpersonal, institutional, community, policy)

- Active research or resource grants and cooperative agreements
- 12 page research strategy
- Maximum of $400,000 direct costs per year, for up to two years
- Applications Due: August 7, 2020; September 8, 2020
- Award Dates: Mid-September; November
- Estimated Number of Awards: 5-8
Research Topic Examples (see NOSI for details):

In underserved and/or vulnerable groups:

- **Social, ethical, and behavioral influences on decisions** to offer or seek COVID-19 testing
  - Community-defined risks and benefits of COVID-19 testing
  - Implications of getting a COVID-19 diagnostic test and their influence on testing decisions

- **Strategies to mitigate barriers and increase access** to and acceptability of testing

- **Communication** surrounding testing and follow-up

- **Test result** interpretation and use

- Strategies to increase acceptability of vaccine trials and vaccinations
Examples of Products (see NOSI for details):

- **Results templates and toolkits** designed in collaboration with communities
- **Communication strategies and materials** to improve quality, quantity, relevance and consistency of COVID-19 information
- **Strategies to encourage repeat testing and testing of at-risk contacts** when appropriate
- **Community-informed COVID-19 data governance policies**
- Materials and approaches to ameliorate **distrust, fear, stigma and discrimination** surrounding COVID-19
- **Resources for community engagement and collaboration for vaccine trials**

Make products available to, or readily adaptable for **other communities and languages**

Identify high priorities for communities and develop interventions, strategies or products in response, to improve access and acceptability of COVID-19 diagnostics
Additional Requirements (see NOSI for full list)

Research Design
• Consider multiple levels of factors (individual, interpersonal, institutional, community, policy)
• Community partnership required
• Funds for community partners’ participation
• Focus on specific communities, but consider generalizability across populations and contexts

Collaboration
• Letters of support from community partners
• Consider plans to collaborate with and inform RADx-UP field sites
• Data sharing for all COVID-19 projects, except where prohibited (e.g. Tribal data sovereignty)
• Submit common metrics
Inappropriate and Possibly Non-Responsive Factors *(see NOSI for full list)*

- Implementation of a testing program is **not** in scope
- Populations that are neither underserved nor COVID-19 vulnerable
- Lack of demonstrated community engagement with populations of interest
- Non-U.S. study populations
- Exclusively qualitative research (mixed methods are acceptable)
- Lack of structure and planning to coordinate with CC & other RADx-UP sites
- Grants ineligible for supplement
Review Process (see NOSI for details)

- Internal NIH staff review panel using standard criteria, with additional details related to:
  - Urgency and significance of research
  - Research feasibility and design
  - Investigators
  - Community partnerships
  - Data sharing plans
  - Coordination plans
  - Specification of outcomes
  - Sustainability
  - Dynamic and responsive to changes in COVID-19 landscape
<table>
<thead>
<tr>
<th>Eligible grants</th>
<th>Active research or resource grants and cooperative agreements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Size of award</td>
<td>$400,000 direct costs per year maximum, for up to two years</td>
</tr>
<tr>
<td>Expected number of awards</td>
<td>5-8 awards</td>
</tr>
<tr>
<td>Application</td>
<td>12 pages for research strategy</td>
</tr>
<tr>
<td>Submission Dates</td>
<td>August 7 and September 8, 2020</td>
</tr>
</tbody>
</table>

RADxInfo@nih.gov

https://www.nih.gov/research-training/medical-research-initiatives/radx
Overview of Coordination and Data Collection Center (CDCC):

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

Dorothy Castille, Ph.D. – National Institute on Minority Health and Health Disparities
Dorothy.Castille@nih.gov

Gwen Collman, Ph.D. – National Institute of Environmental Health Sciences
Gwen.Collman@nih.gov
Emergency Awards: RADx-UP Coordination and Data Collection Center (CDCC) (U24 Clinical Trial Optional)- RFA-OD-20-013

Purpose

- Coordinate and facilitate research activities for all RADx-UP collaborative research
- Provide de-identified individual data to an NIH-based data center
- Serve as a national resource, with NIH scientific staff and consortium members to coordinate and facilitate research activities

- Fund one CDCC
- $13 M direct costs/year; not more than $80 M total costs for 4 years
- Letter of intent preferred
- 12 page limit
- Hybrid review
- Application Due Dates: August 7, 2020
- Award Dates: Mid-September
RADx-UP: Coordination & Data Collection Center (CDCC; U24)

Administration
Testing technology
Community engagement
Data integration
Administrative and Coordination

- Facilitate the work of the RADx-UP research consortium and NIH scientific staff
- Facilitate overall program management of the initiative
- Coordination of the research consortium
- Support for the consortium including logistics for frequent meetings of group and working groups
- Steering committee support to develop and implement policies on topics such as publications, return of results to participants, data management and sharing policies
- Compile progress on study milestones and develop reports for many audiences
- Develop a study website that includes public facing information and an internal facing archive of all consortium materials
- Provide coordination with other NIH RADx initiatives
COVID-19 Testing Technology

- Coordination with RADx-tech, RADx-rad, and RADx-ATP

RADx Tech
The RADx Tech initiative aims to speed the development, validation, and commercialization of innovative point-of-care and home-based tests, as well as improve clinical laboratory tests, that can directly detect the virus.

RADx Radical (RADx-rad)
RADx-rad will support new, non-traditional approaches, including rapid detection devices and home-based testing technologies, that address current gaps in COVID-19 testing. The program will also support new or non-traditional applications of existing approaches to make them more usable, accessible, or accurate. These may lead to new ways to identify the current SARS-CoV-2 virus as well as potential future viruses.

RADx Underserved Populations (RADx-UP)
The overarching goal of the RADx-UP initiative 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 of, and/or are most at risk for complications or poor outcomes from the COVID-19 pandemic.

RADx Advanced Technology Platforms (RADx-ATP)
The RADx-ATP program seeks to increase testing capacity and throughput by identifying existing and late stage testing platforms for COVID-19 that are far enough advanced to achieve rapid scale-up or expanded geographical placement in a short amount of time. These efforts will focus on scaling up technologies, including improving existing high-throughput platforms, to increase performance.

RFA-OD-20-013
COVID-19 Testing Technology

- Provide expertise on COVID 19 testing strategies and disseminates information on emerging and new innovations on new diagnostics and test modalities
- Develop, manage, and evaluate a Rapid Pilot Studies program

FDA COVID-19 Testing Resources

- [Emergency Use Authorizations for Medical Devices](#)
- [Medical Devices and the COVID-19 Pandemic](#)
Community Engagement

- Coordinate and support a vibrant community of practice across the RADx-UP Consortium
- Create and implement a Community Collaboration Grant program
- Develop and facilitate working groups on topics of specific interest
- Collaborate with the SEBI program to share best practices and provide technical assistance for community engagement to the entire research consortium
Data Collection, Integration and Sharing

• Manage data collection, integration, and sharing for the RADx-UP consortium
• Facilitate data standardization, harmonization, integration and analysis for RADx-UP projects
• Share survey items by submitting to NIHCOVID19Measures@nih.gov
• Encourage adherence to federal health data standards FHIR and USCDI

Research Methods Resources
Trials that Randomize Groups or Deliver Interventions to Groups
Phenx Toolkit COVID-19
Phenx Toolkit Social Determinants of Health Collection
Disaster Related Research DR2
The Observational Medical Outcomes Partnership (OMOP) CDM
## PILOT PROJECT PROGRAMS

<table>
<thead>
<tr>
<th>Purpose</th>
<th>Rapid Pilot Projects—COVID 19 Testing</th>
<th>Community Collaborations Grants</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Support Pilots coordinated with the NIH-supported RADx initiatives—assess feasibility and utility of new technologies into RADx-UP</td>
<td>Support inclusion of additional community partners and stakeholder groups</td>
</tr>
<tr>
<td>Frequency</td>
<td>4 RFPs/year for each of 4 years</td>
<td>Not specified in the FOA</td>
</tr>
<tr>
<td>Budget</td>
<td>$200,000 max direct costs; $2,000,000 (total costs)</td>
<td>$50,000 max direct costs; $750,000 per year max (total costs)</td>
</tr>
<tr>
<td>Target Investigators</td>
<td>Projects in coordination with other RADx-UP funded projects, other NIH RADx projects, other investigators</td>
<td>Increasing community capacity to participate in research, build infrastructure</td>
</tr>
<tr>
<td>Duration</td>
<td>1 year only, multi-year not encouraged</td>
<td>1 year only, multi-year not encouraged</td>
</tr>
</tbody>
</table>
Eligibility

- Number of Applications:
  - Only one application per institution (normally identified by having a unique DUNS number or NIH IPF number) is allowed

- Will not accept duplicate or highly overlapping applications under review at the same time

- Foreign Institutions are NOT eligible to apply
Questions?

RADxInfo@nih.gov

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