

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

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National Institute on Minority Health and Health Disparities (NIMHD) – RADx-UP co-chair

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RADxInfo@nih.gov

June 26, 2020



Session Objectives

1 | Provide an overview of the RADx-UP initiative

2 | Overview of RADx-UP FOAs

3 | Answer questions

Agenda

Topic	Content	Person responsible	Timing
Welcome	<ul style="list-style-type: none">• Purpose of webinar• Administrative Items	Ming Lei, Ph.D.	2:00 p.m. – 2:05 p.m.
Overview of RADx-UP	<ul style="list-style-type: none">• Background on RADx-UP• Four FOAs	Monica Webb Hooper, Ph.D.	2:05 p.m. – 2:15 p.m.
Overview of NOT-OD-20-121 and NOT-OD-20-120	<ul style="list-style-type: none">• Update on opportunity• Q&A	Wilson Compton, M.D., M.P.E	2:15 p.m. – 2:25 p.m. 2:25 p.m. – 2:40 p.m.
Overview of NOT-OD-20-119	<ul style="list-style-type: none">• Update on opportunity• Q&A	Dave Kaufman, Ph.D.	2:40 p.m. – 2:50 p.m. 2:50 p.m. – 3:00 p.m.
Overview of RFA-OD-20-013	<ul style="list-style-type: none">• Update on opportunity• Q&A	Dorothy Castille, Ph.D.	3:00 p.m. – 3:10 p.m. 3:10 p.m. – 3:25 p.m.
Q&A	<ul style="list-style-type: none">• Attendees type questions in Feedback form link	Presenters / attendees	3:25 p.m. – 4:00 p.m.

RADxInfo@nih.gov

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

RADx-UP – Upcoming Event

Wednesday, July 1

- **Public webinar to review RADx-UP FOAs**
 - **Register at**
<https://www.nih.gov/research-training/medical-research-initiatives/radx/events>
-

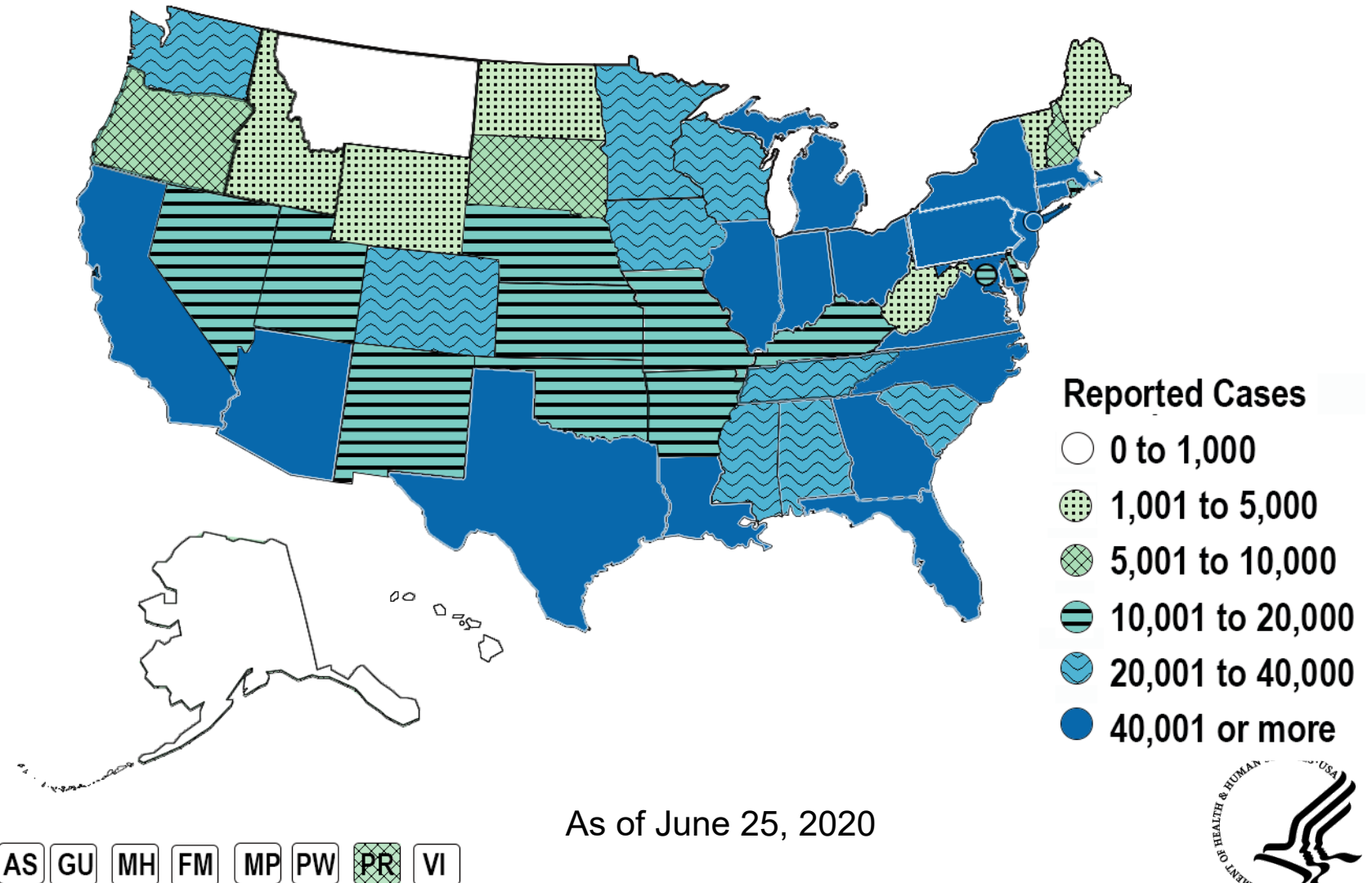
RADx-UP Overview

Monica Webb Hooper, Ph.D.

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COVID-19

- Novel severe acute respiratory syndrome coronavirus 2
- Global pandemic
- U.S. cases: 2,374,282
- U.S. deaths: 121,809



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

The Skywalk over the Grand Canyon was closed by the Hualapai tribe to increase social distancing measures during the pandemic.

Stan Lawrimore/Unsplash



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

April 3, 2020 · 5:00 AM ET

COVID-19 in Prisons and Jails in the United States

Laura Hawks, MD^{1,2}; Steffie Woolhandler, MD, MPH^{2,3}; Danny McCormick, MD, MPH^{1,2}

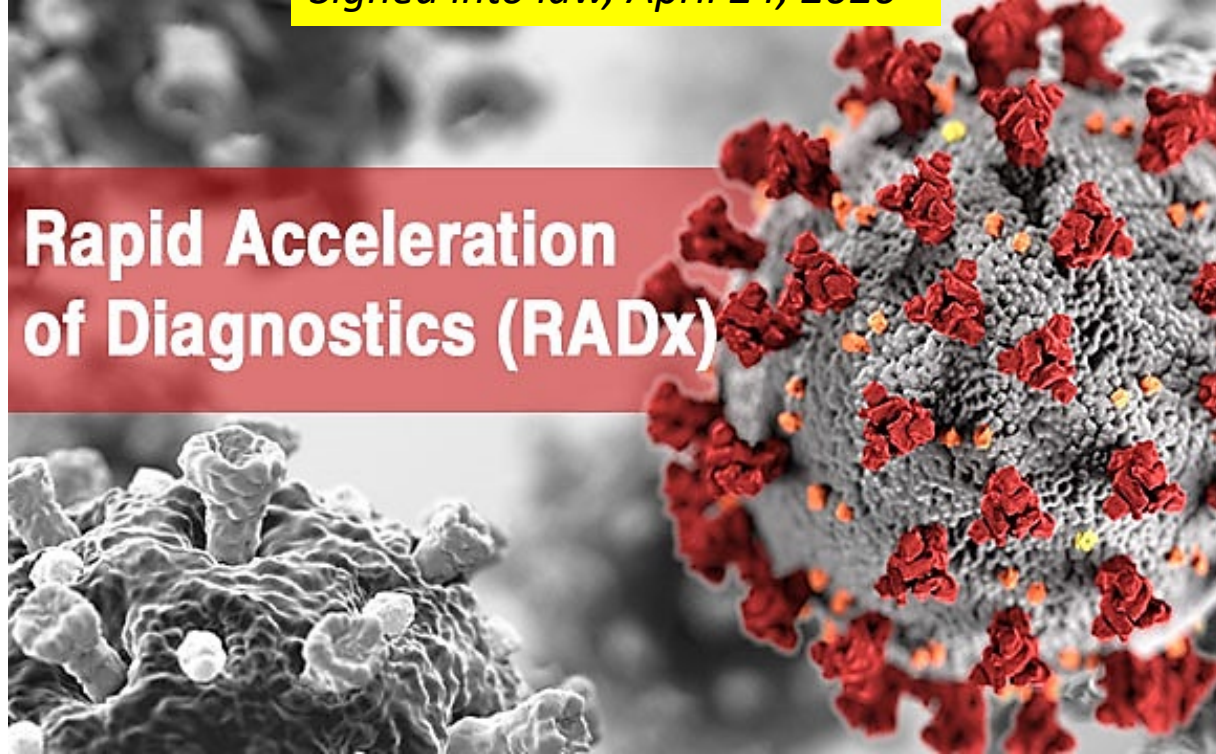
» Author Affiliations | Article Information

JAMA Intern Med. Published online April 28, 2020. doi:10.1001/jamainternmed.2020.1856

Rapid Acceleration of Diagnostics (RADx) Initiative

Signed into law, April 24, 2020

Rapid Acceleration of Diagnostics (RADx)



<https://www.nih.gov/news-events/news-releases/nih-mobilizes-national-innovation-initiative-covid-19-diagnostics>

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

26,781,666

TESTS REPORTED

CDC | Updated June 25 2020 5:45 PM

USA

2,691,715

POSITIVE TESTS

CDC | Updated June 25 2020 5:45 PM

USA

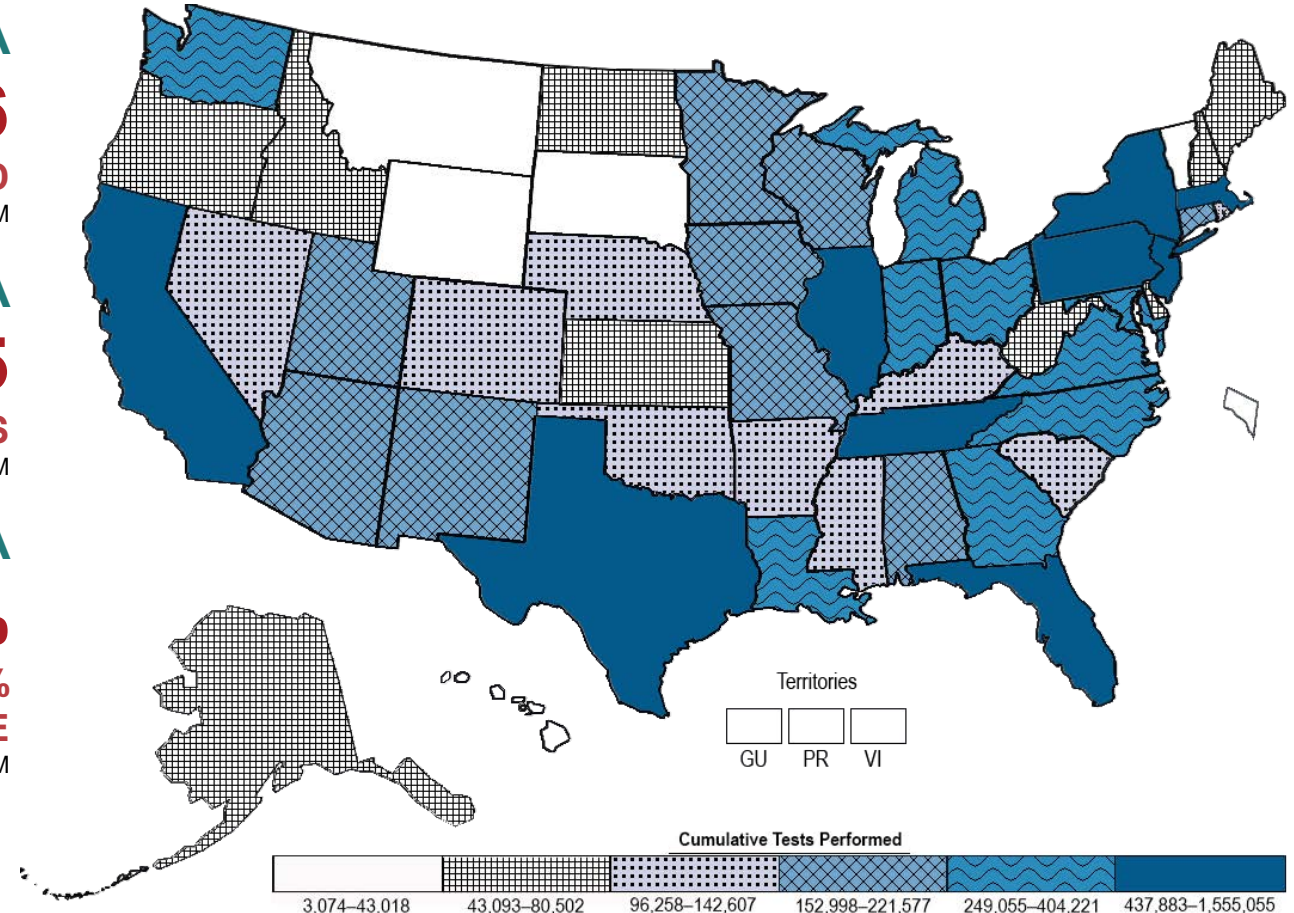
10%

OVERALL %
POSITIVE

CDC | Updated June 25 2020 5:45 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
Totals may include antibody data from some states



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

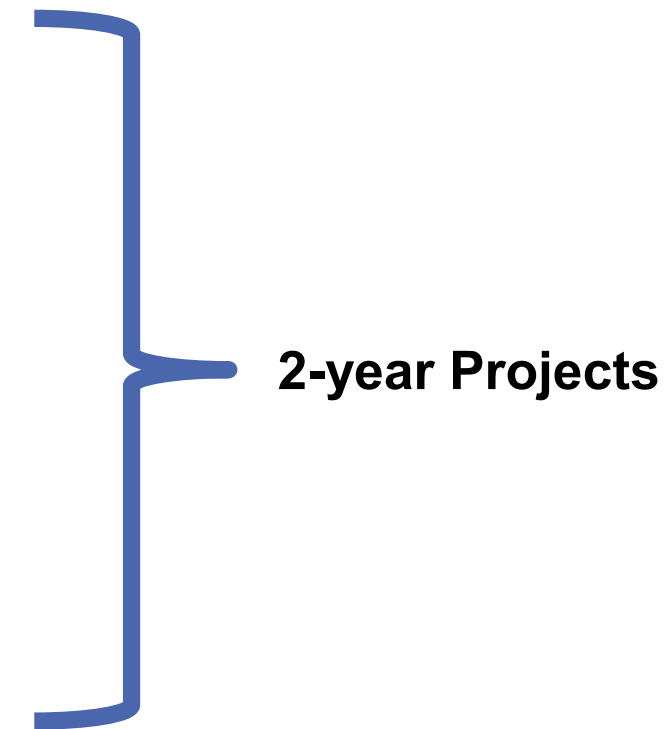
- \$500 million commitment, 50% of NIH OD congressional appropriation
- All NIH Institutes and Centers
- **Overarching goal:** Understand factors influencing the disproportionate burden of the pandemic on underserved and/or vulnerable populations so that interventions can be implemented to decrease these 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](#))
2. 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](#))
3. 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](#))
4. Emergency Awards: RADx-UP Coordination and Data Collection Center (CDCC) (U24 Clinical Trial Optional; [RFA-OD-20-013](#))



Populations

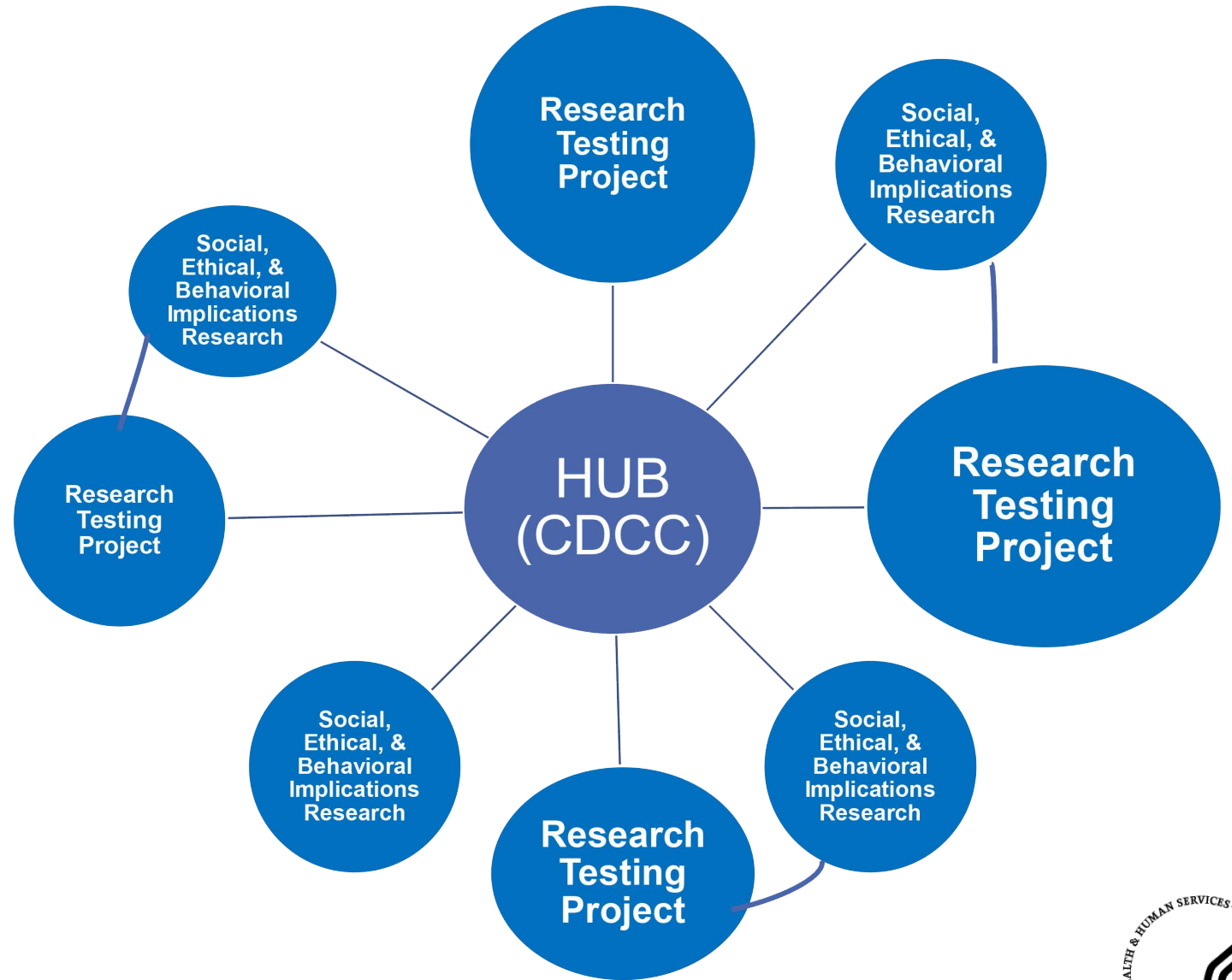


- *Underserved*: NIH-designated U.S. health disparity populations
- *COVID-19 medically and/or socially vulnerable populations*
 - Known medical comorbidities; older adults; nursing home residents; homeless populations; pregnant women; children; persons with disabilities; individuals with substance use 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

60 days
on
street

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

90 days
on
street

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!



A 3D word cloud with the word **ENGAGEMENT** in large, blue, bold letters at the center. Surrounding it are several other words in white, 3D font, including: *encouragement*, **INVOLVEMENT**, **COMMUNITY**, *interaction*, *sharing*, *participation*, *support*, **COMMITMENT**, and **communication**. The words are arranged in a circular pattern around the central word, creating a sense of depth and focus.

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
 - Encouraged to share survey items to make them public for other researchers by submitting to NIHCOVID19Measures@nih.gov
 - Collaboration with other RADx-UP studies and possibly with other federal agencies

Additional Requirements *(see NOS/Is 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

	NOT-OD-20-121 (limited competition)	NOT-OD-20-120
Eligible grants	Large centers and networks	Collaborative and Individual research awards
Size of award	\$3,500,000 maximum direct costs for 2-year budget; 75% allocated year 1	\$1,300,000 maximum direct costs for 2-year budget; 75% allocated year 1
Expected number of awards	25 awards	30 awards
Application	12 pages	6 pages
Submission Date	August 7, 2020	August 7 and September 8, 2020

Questions?

RADxInfo@nih.gov

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

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*

Questions?

RADxInfo@nih.gov

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

NOT-OD-20-119

[HTTPS://GRANTS.NIH.GOV/GRANTS/GUIDE/NOTICE-FILES/NOT-OD-20-119.HTML](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-119.html)

	NOT-OD-20-119
Eligible grants	Active research or resource grants and cooperative agreements
Size of award	\$400,000 direct costs per year maximum, for up to two years
Expected number of awards	5-8 awards
Application	12 pages for research strategy
Submission Dates	August 7 and September 8, 2020

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

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 a single 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

Research Objectives

Administrative and Coordination

- Facilitate the work of the RADx-UP research consortium and NIH scientific staff
- Facilitate overall program management of the initiative

COVID-19 Testing Technology

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

Community Engagement

- Coordinate and support a community of partnership across the RADx-UP Consortium
- Create and implement a mini-grant program to support the inclusion of additional community partners and stakeholder groups

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

PILOT PROJECT PROGRAMS

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

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>