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

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July 1, 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	• Purpose of webinar • Administrative Items	Ming Lei, Ph.D.	3:00 p.m. – 3:05 p.m.
Overview of RADx-UP	• Background on RADx-UP • Four FOAs	Monica Webb Hooper, Ph.D.	3:05 p.m. – 3:15 p.m.
Overview of NOT-OD-20-121 and NOT-OD-20-120	• Update on opportunity	Wilson Compton, M.D., M.P.E	3:15 p.m. – 3:25 p.m.
Overview of NOT-OD-20-119	• Update on opportunity	Dave Kaufman, Ph.D.	3:25 p.m. – 3:35 p.m.
Overview of RFA-OD-20-013	• Update on opportunity	Dorothy Castille, Ph.D. Gwen Collman, Ph.D.	3:35 p.m. – 4:20 p.m.
Q&A	• Attendees submit questions through Feedback option on videocast	Presenters / attendees	4:20 p.m. – 5:00 p.m.

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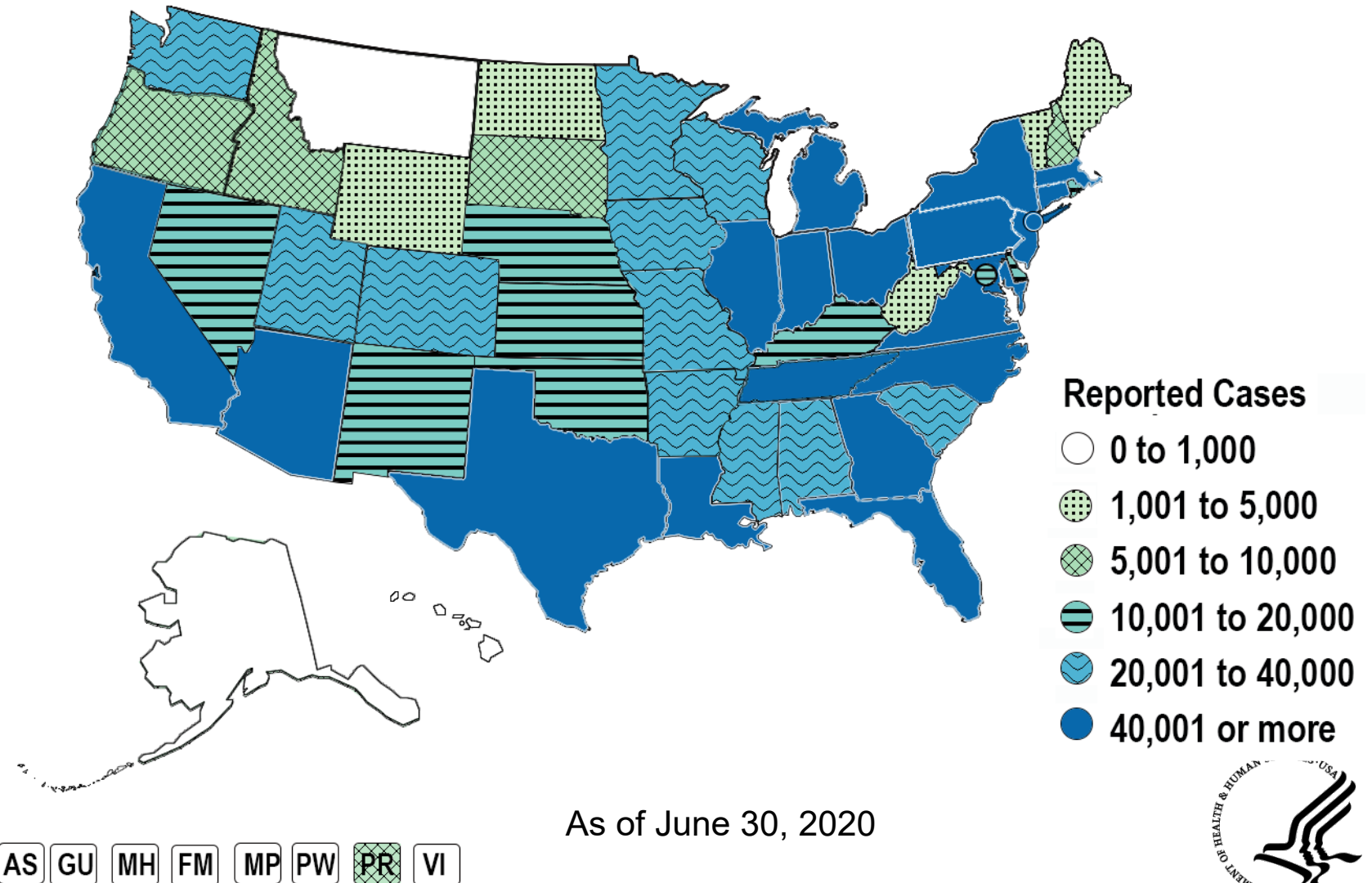RADxInfo@nih.gov

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

Reported Cases
- ○ 0 to 1,000
- ⊙ 1,001 to 5,000
- ⊗ 5,001 to 10,000
- ⊜ 10,001 to 20,000
- ⬤ 20,001 to 40,000
- ⬤ 40,001 or more

As of June 30, 2020

AS GU MH FM MP PW PR VI

The Harvard Gazette

NATIONAL & WORLD AFFAIRS

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

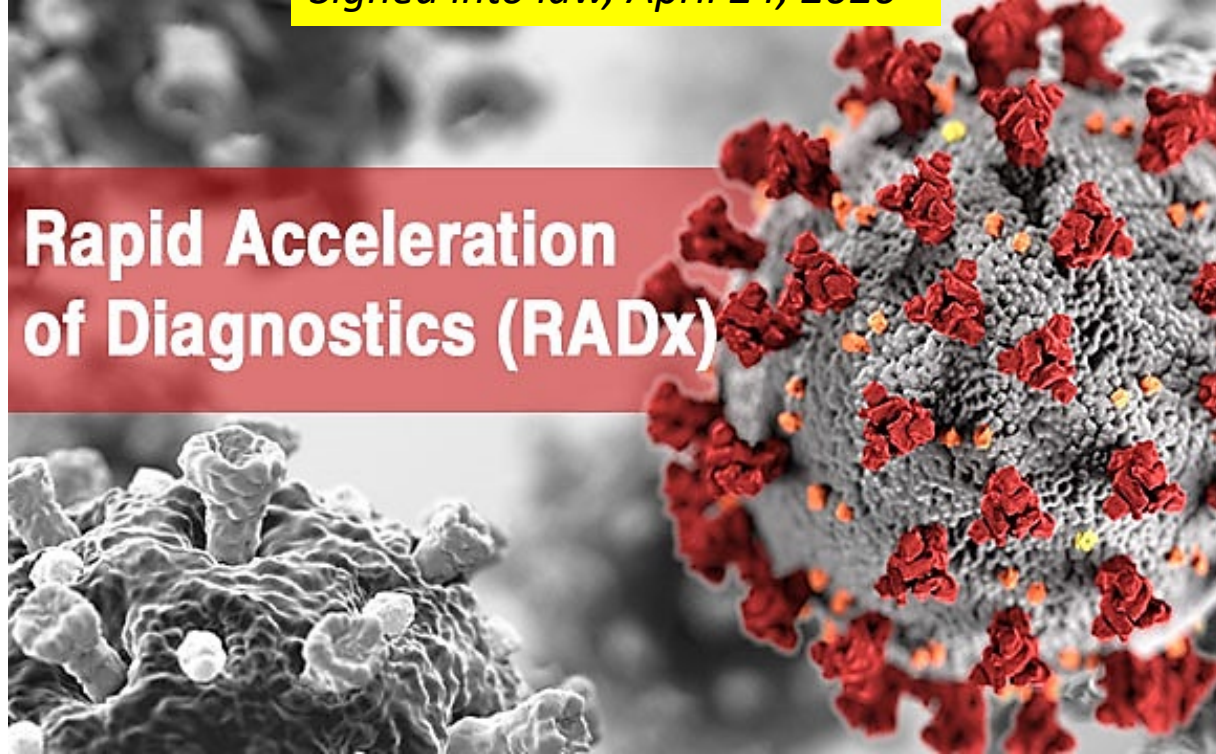Laura Hawks, MD[1,2]; Steffie Woolhandler, MD, MPH[2,3]; Danny McCormick, MD, MPH[1,2]

» 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

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

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

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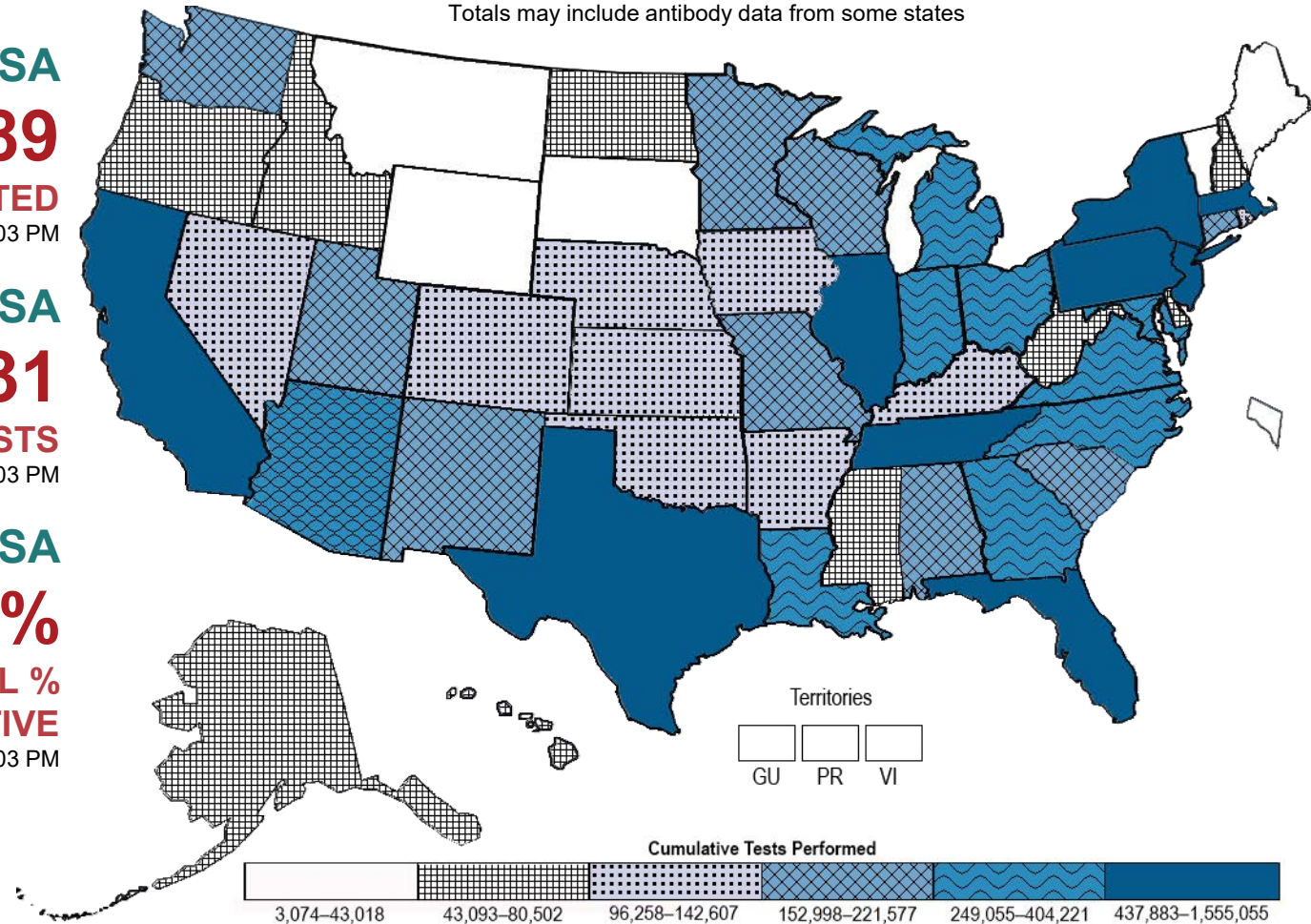**POSITIVE TESTS**
CDC | Updated: June 30 2020 6:03 PM

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

Territories

GU   PR   VI

Cumulative Tests Performed

| 3,074–43,018 | 43,093–80,502 | 96,258–142,607 | 152,998–221,577 | 249,055–404,221 | 437,883–1,555,055 |

https://www.cdc.gov/covid-data-tracker/index.html

As of June 30, 2020
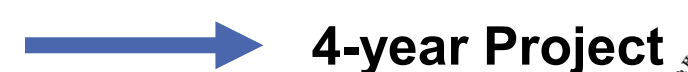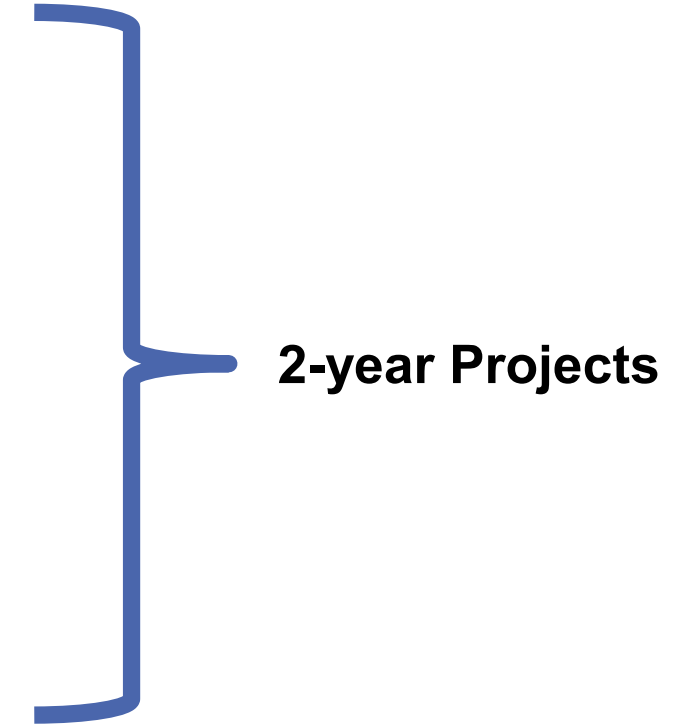
RADx-UP: Major Component of the NIH COVID-19 Response

- $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): <u>Limited Competition</u> 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](#))

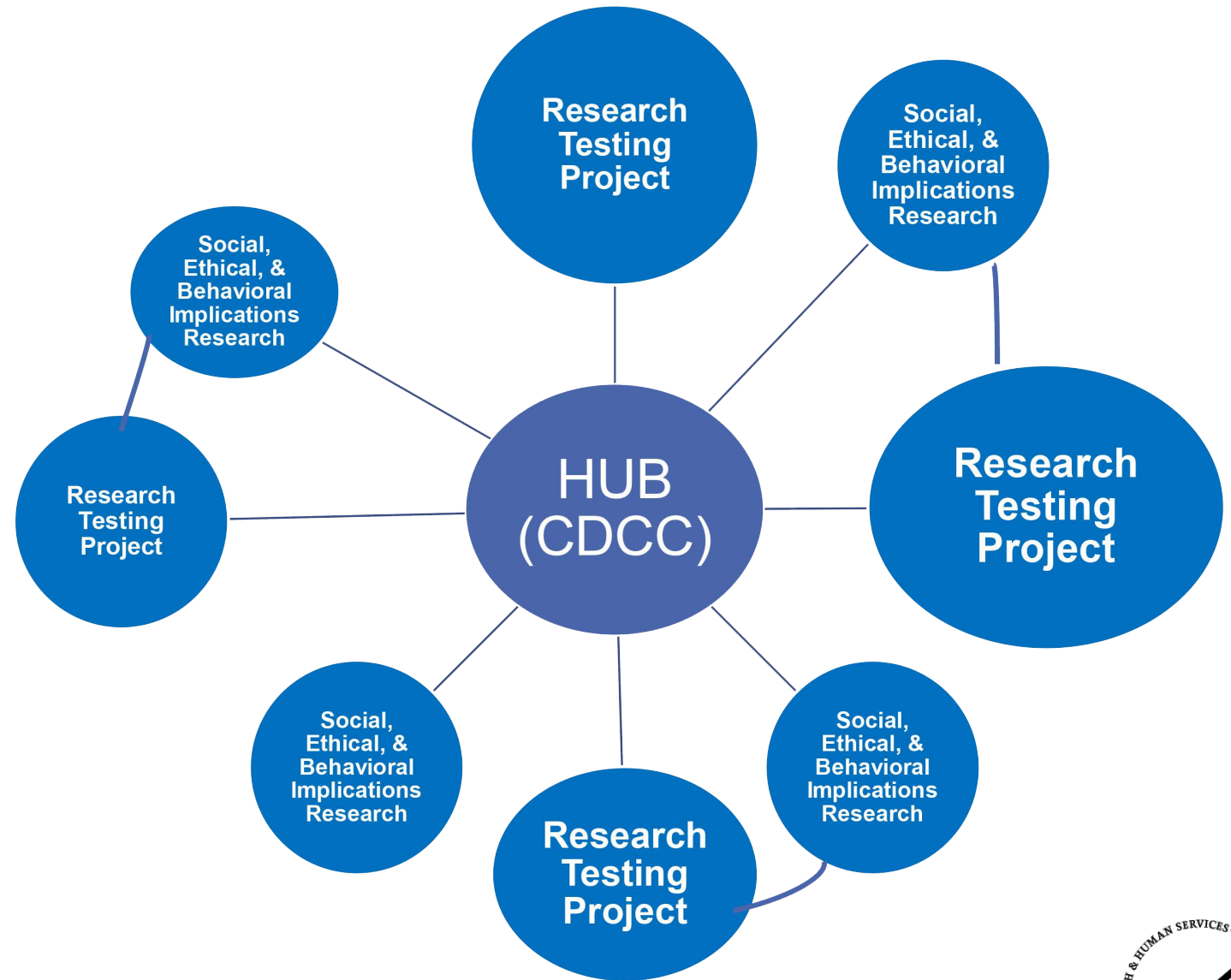**2-year Projects**

4-year Project

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

90 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

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

	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

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**

NOT-OD-20-119

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*

NOT-OD-20-119

NOT-OD-20-119

	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

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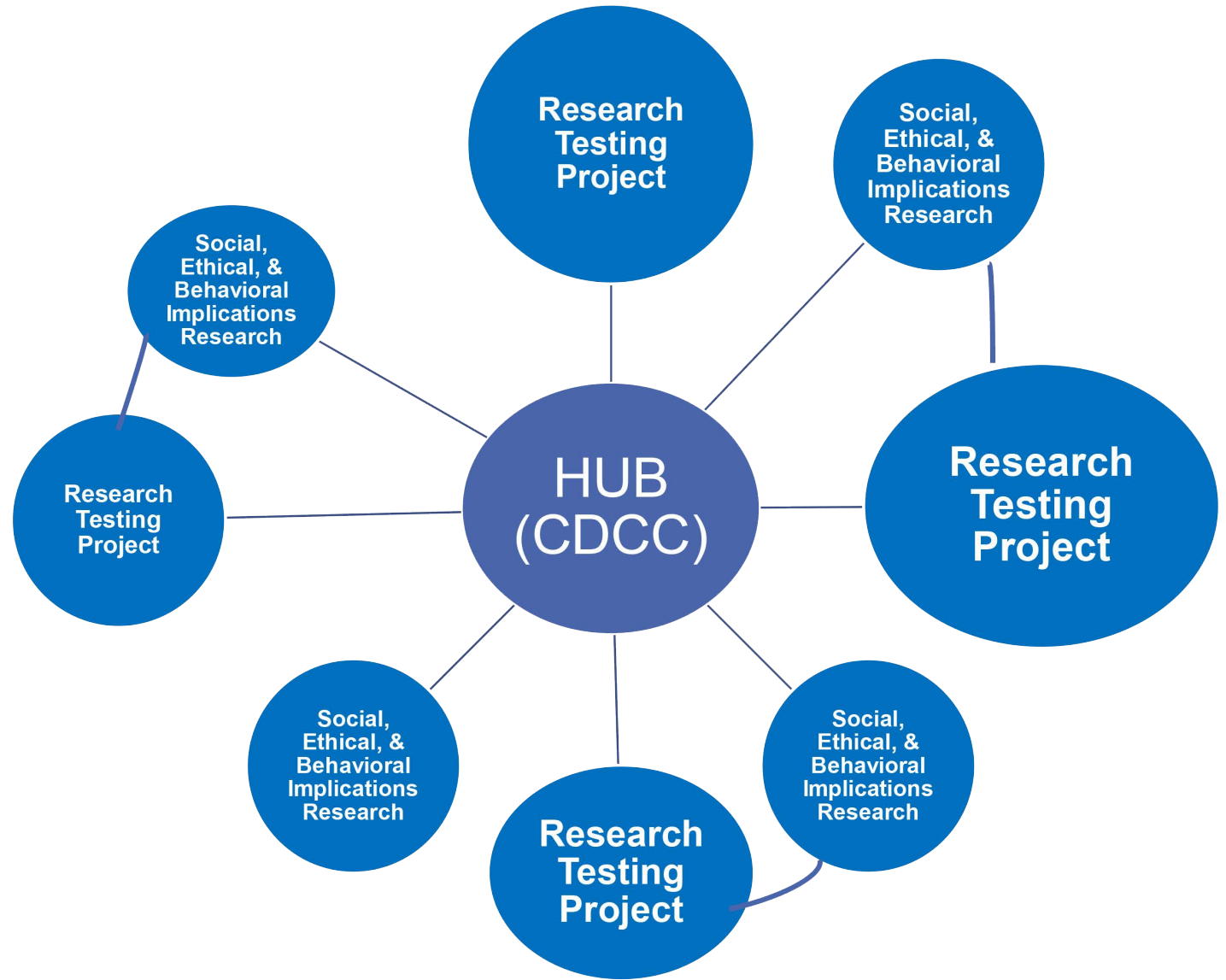
Purpose
- Coordinate and facilitate research activities for all RADx-UP collaborative research
- Provide de-identified individual data to an NIH-based data center
- Serve as a national resource, with NIH scientific staff and consortium members to coordinate and facilitate research activities

- 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

Research Testing Project

Social, Ethical, & Behavioral Implications Research

Social, Ethical, & Behavioral Implications Research

Research Testing Project

HUB (CDCC)

Research Testing Project

Social, Ethical, & Behavioral Implications Research

Research Testing Project

Social, Ethical, & Behavioral Implications Research

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 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 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 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.

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

	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