Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

National Institutes of Health (NIH (http://www.nih.gov))

Components of Participating Organizations

Office of The Director, National Institutes of Health (OD (https://www.nih.gov/institutes-nih/nih-office-director))

National Eye Institute (NEI (https://www.nei.nih.gov/))

National Heart, Lung, and Blood Institute (NHLBI (https://www.nhlbi.nih.gov/))

National Human Genome Research Institute (NHGRI (https://www.genome.gov/))

National Institute on Aging (NIA (https://www.nia.nih.gov/))

National Institute on Alcohol Abuse and Alcoholism (NIAAA (https://www.niaaa.nih.gov/))

National Institute of Allergy and Infectious Diseases (NIAID (https://www.niaid.nih.gov/))

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS (https://www.niams.nih.gov/))

National Institute of Biomedical Imaging and Bioengineering (NIBIB (https://www.nibib.nih.gov/))

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD (https://www.nichd.nih.gov/))

National Institute on Deafness and Other Communication Disorders (NIDCD (https://www.nidcd.nih.gov/))

National Institute of Dental and Craniofacial Research (NIDCR (https://www.nidcr.nih.gov/))

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK (https://www.niddk.nih.gov/))

National Institute on Drug Abuse (NIDA (https://www.drugabuse.gov/))

National Institute of Environmental Health Sciences (NIEHS (https://www.niehs.nih.gov/))

National Institute of General Medical Sciences (NIGMS (https://www.nigms.nih.gov/))

National Institute of Mental Health (NIMH (https://www.nimh.nih.gov/index.shtml))

National Institute of Neurological Disorders and Stroke (NINDS (https://www.ninds.nih.gov/))

National Institute of Nursing Research (NINR (https://www.ninr.nih.gov/))

National Institute on Minority Health and Health Disparities (NIMHD (https://www.nimhd.nih.gov/))

National Library of Medicine (NLM (https://www.nlm.nih.gov/))

National Center for Complementary and Integrative Health (NCCIH (https://nccih.nih.gov/))

National Center for Advancing Translational Sciences (NCATS (https://ncats.nih.gov/))

National Cancer Institute (NCI (https://www.cancer.gov/))

Tribal Health Research Office (THRO (https://dpcpsi.nih.gov/thro))

All applications to this funding opportunity announcement should fall within the mission of the Institutes/Centers. The following NIH Offices may co-fund applications assigned to those Institutes/Centers.

Division of Program Coordination, Planning and Strategic Initiatives, Office of Disease Prevention (ODP (https://prevention.nih.gov/))

Office of Behavioral and Social Sciences Research (OBSSR (https://obssr.od.nih.gov/))

Sexual and Gender Minority Research Office (SGMRO (https://dpcpsi.nih.gov/sgmro))

Office of Research on Women's Health (ORWH (https://orwh.od.nih.gov/))

Environmental Influences on Child Health Outcomes (ECHO (https://www.nih.gov/research-training/environmental-influences-child-health-outcomes-echo-program))

Funding Opportunity Title

Emergency Award: RADx-UP - Social, Ethical, and Behavioral Implications (SEBI) Research on Disparities in COVID-19 Testing among Underserved and Vulnerable Populations (U01 Clinical Trials Optional)

Activity Code

U01 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=u01&Search.x=0&Search.y=0&Search_Type=Activity) Research Project – Cooperative Agreements

Announcement Type

New

Related Notices

- **April 22, 2021** - Notice of Pre-Application Webinar for Phase II of the RADxSM-UP Initiative. See Notice NOT-OD-21-115 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-115.html).

Funding Opportunity Announcement (FOA) Number

RFA-OD-21-009

Companion Funding Opportunity

RFA-OD-21-008 (https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-21-008.html), U01 (https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=U01&&Search.x=0&&Search.y=0&&Search_Type=Activity) Research Project (Cooperative Agreements)
NOT-OD-21-103 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-103.html)
NOT-OD-21-101 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-101.html)

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)

93.310, 93.865, 93.838, 93.839, 93.840, 93.233, 93.837, 93.393, 93.394, 93.395, 93.396, 93.399, 93.350, 93.213, 93.867, 93.172, 93.846, 93.121, 93.847, 93.113, 93.143, 93.859, 93.242, 93.853, 93.361, 93.866, 93.273, 93.173, 93.279, 93.307, 93.313, 93.286, 93.879, 93.855

Funding Opportunity Purpose

High rates and disparities of COVID-19 infection, morbidity, and mortality continue among underserved and vulnerable populations across the United States. The overarching goal of the Rapid Acceleration of Diagnostics for Underserved Populations (https://www.nih.gov/research-training/medical-research-initiatives/radx/radx-programs#radx-up) (RADx-UP) initiative is to understand and ameliorate factors that have placed a disproportionate burden of the pandemic on underserved and/or vulnerable populations, specifically by implementing programs that expand the scope and reach of COVID-19 testing interventions to reduce these disparities. To address barriers to testing and vaccination, social, ethical, and behavioral research is urgently needed to inform related mitigation efforts. This Phase II RADx-UP Funding Opportunity Announcement (FOA) is designed to expand research to understand and address the social, ethical, and behavioral implications (SEBI) of COVID-19 testing interventions among underserved and vulnerable populations. Desirable studies for Phase II will move beyond descriptive health disparities research to focus on developing interventions and other actionable solutions in collaboration with community partners and stakeholders. The funding for this initiative is provided from the American Rescue Plan Act of 2021.

Key Dates

Posted Date

April 13, 2021

Open Date (Earliest Submission Date)

June 07, 2021

Letter of Intent Due Date(s)

Not Applicable

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS	Scientific Merit Review	Advisory Council Review	Earliest Start Date
July 07, 2021	Not Applicable	Not Applicable	July 2021	Not Applicable	December 2021

All applications are due by 5:00 PM local time of applicant organization. All types of non-AIDS applications allowed for this funding opportunity announcement are due on the listed date(s).

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

Late applications will not be accepted for this Funding Opportunity Announcement.

Expiration Date

July 08, 2021

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the Research (R) Instructions in the SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url_redirect.htm?id=12000), except where instructed to do otherwise (in this FOA or in a Notice from NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/)).

Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

Applications that do not comply with these instructions may be delayed or not accepted for review.

There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners. You **must** use one of these submission options to access the application forms for this opportunity.

1. Use the NIH ASSIST (https://public.era.nih.gov/assist) system to prepare, submit and track your application online.

   Apply Online Using ASSIST

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons (http://public.era.nih.gov/commons/) to track your application. Check with your institutional officials regarding availability.

3. Use Grants.gov (https://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=RFA-OD-21-009) Workspace to prepare and submit your application and eRA Commons (http://public.era.nih.gov/commons/) to track your application.

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

The National Institutes of Health (NIH) is issuing this funding opportunity announcement (FOA) in response to the declared public health emergency issued by the Secretary, HHS, for 2019 Novel Coronavirus (COVID-19).This FOA uses an emergency U01 mechanism to support the Rapid Acceleration of Diagnostics-Radical (RADx[SM]-UP) initiative.

The Office of the Director (OD) is issuing this FOA to address the objectives described below. This FOA is one of four related RADx[SM]-UP funding opportunities. This SEBI research FOA will support research teams with established community engaged partnerships to address the scientific objectives described herein.

The related program initiatives include:

- RFA-OD-21-008 (https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-21-008.html)- Emergency Awards: Community-engaged COVID-19 Testing Interventions among Underserved and Vulnerable Populations-RADx[SM]-UP Phase II (U01, Clinical Trial Optional)
- NOT-O (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-103.html)D-21-103 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-103.html) – Notice of Special Interest (NOSI): Emergency Competitive Revisions for NIH Grants to Add or Expand Community-engaged COVID-19 Testing Interventions among Underserved and Vulnerable Populations – RADx[SM]-UP Phase II (Emergency Supplement- Clinical Trial Optional)
- NOT-OD-21-101 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-101.html)- Notice of Special Interest (NOSI): Administrative Supplements for Rapid Acceleration of Diagnostics-Underserved Populations (RADx[SM]-UP) Phase I Projects to Address Vaccine Hesitancy and Uptake
- NOT-OD-21-097 (//grants.nih.gov/grants/guide/notice-files/NOT-OD-21-097.html) - Notice of Intent to Publish a Research Opportunity Announcement for RADx[SM]-UP Return to School Diagnostic Testing Approaches (OT2 Clinical Trial Optional

Collectively, projects funded under these FOAs will join the RADx-UP (https://www.nih.gov/research-training/medical-research-initiatives/radx/radx-programs#radx-up) consortium of community engaged research projects across the United States to understand COVID-19 health disparities, and to test interventions that improve the reach, uptake, and sustainability of COVID-19 testing in various settings.

NIH expects that all projects funded under this FOA will actively collaborate with other SEBI projects, the Testing Research Projects, collect common data elements (CDEs) and share data (as allowed and with considerations under tribal IRB and data sovereignty processes) with the Coordination and Data Collection Center (https://radx-up.org/) (CDCC (https://radx-up.org/)). Researchers applying to this FOA are strongly encouraged to read all interrelated funding opportunities.

Research proposed in response to this FOA should address social, ethical, behavioral, structural, environmental, historical and policy factors, including structural racism within public health and health care delivery systems, that lead to disparities in access to and uptake of COVID-19 testing in underserved and/or vulnerable populations. Even with the availability of vaccines, testing for the SARS CoV-2 virus will remain a critical aspect of pandemic control. It is also important to understand whether and how the availability of COVID-19 vaccines affects the need for, and propensity to seek testing in both symptomatic and asymptomatic testing programs. Phase II projects should focus on SARS CoV-2 testing and consider the roles testing may play in the dynamic environment of the pandemic, where vaccine availability, distribution, and uptake, and the need to monitor and document COVID-19 status continue to evolve. The influences of cultural beliefs, expectations, mistrust, and communication norms and preferences on underserved, medically and/or socially vulnerable populations willingness to get tested, get vaccinated, and participate in follow-up evaluations are of interest. Multi-level barriers to testing and vaccination should be addressed in these applications, including barriers at the interpersonal, institutional (e.g., health care system), community, and policy levels.

Key Definitions

This FOA is applicable to underserved and vulnerable populations that are COVID-19 vulnerable due to medical, geographic, and social factors, as defined below (referred to as "underserved and vulnerable" elsewhere in this FOA):

Underserved: NIH-designated health disparity populations and/or other groups known to experience barriers to needed health care services, or to have inadequate health care coverage. A full description can be found at https://www.nimhd.nih.gov/about/overview/ (https://www.nimhd.nih.gov/about/overview/).

COVID-19 medically and/or socially vulnerable populations: Homeless populations; individuals involved with the criminal or juvenile justice systems (incarcerated or under community supervision); pregnant and post-partum women; children and adolescents; individuals living in congregate housing such as shelters or residential treatment facilities; individuals in overcrowded housing; individuals with substance use disorders or serious mental illness; migrant and immigrant populations; residents of tribal lands or reservations; communities exposed to high rates of air pollution or other toxic exposures; communities with high levels of social vulnerability; residents of nursing homes and assisted living facilities; community-dwelling older adults; individuals with intellectual, developmental, sensory, or physical disabilities, cognitive impairment or dementia, or communication disorders; individuals with medical comorbidities known to increase risk of severe COVID-19, including heart failure and related cardiovascular conditions, diabetes mellitus, chronic lung disease, obesity, HIV/AIDS; and rural and remote communities.

Discrimination: A socially structured action that is unfair or unjustified and harms individuals and groups. Discrimination can be attributed to social interactions that occur to protect more powerful and privileged groups or institutions at the detriment of other groups. Racism refers to discrimination based on race or ethnicity.

Structural discrimination refers to macro-level conditions (e.g., residential segregation) that limit opportunities, resources, and well-being of less privileged groups (Healthy People 2020, https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-health/interventions-resources/discrimination (https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-health/interventions-resources/discrimination)).

Structural racism and discrimination (SRD): For the purposes of this FOA, SRD refers to structural discrimination on the basis of race/ethnicity and/or other statuses, including but not limited to gender, sexual orientation, gender identity, disability status, social class or socioeconomic status, religion, national origin, immigration status, limited English proficiency, or physical characteristics or health conditions.

Background

SARS-CoV-2 is the novel coronavirus and causative agent of COVID-19, a respiratory disease that exhibits a wide range of clinical outcomes from asymptomatic and mild disease to severe complications and death. COVID-19 diagnostic testing with emergency use authorization (EUA) or (eventually) approval from the United States (U.S.) Food and Drug Administration (FDA) remains critical for tracking and slowing the spread of the virus and preventing future outbreaks. NIH is committed to applying scientific methods to ensure that all populations have optimal access to and uptake of COVID-19 diagnostic and seroprevalence testing —with the goal of reducing health disparities— and to build enhanced point-of-care infrastructures that can be sustained beyond the current pandemic.

Phase I of the Rapid Acceleration of Diagnostics – Underserved Populations (RADx-UP) initiative established a consortium of community engaged research projects focused on increasing access and uptake of COVID-19 testing among U.S. underserved and vulnerable populations as well as understanding the social, ethical, and behavioral implications on testing and testing related outcomes. Phase I includes 69 funded projects and a Coordination and Data Collection Center (CDCC).

Phase II of the RADx-UP initiative will maintain the focus on COVID-19 testing while responding to the dynamics of case, hospitalization, morbidity and mortality rates across the U.S. Projects should work to understand, inform, and improve SARS CoV-2 testing interventions and other mitigation strategies (e.g., contact tracing, testing combined with behavioral mitigation strategies, education programs, self-isolation after exposure).

Projects should build on knowledge and experience gained to date both by the research team and other relevant studies, and address actionable social, ethical, behavioral, structural, environmental, historical and policy factors that are sources of COVID-19 disparities, including inequities in testing access resulting from multiple levels of influence.

Projects should focus on the factors above while considering vaccine availability, distribution, and uptake across populations.

Research Objectives

Incidence, hospitalization, and mortality rates from COVID-19 remain higher in underserved and vulnerable populations. Availability and uptake of high-quality, affordable, accurate, and rapid SARS CoV-2 testing is important to ensure that new cases are identified, tracked, and supported in a timely way. Where data are reported, disparities for racial/ethnic populations in accessibility and uptake of vaccinations are observed. Access and uptake of testing are also critical in communities demonstrating inadequate vaccination uptake. If these shortfalls continue, they are likely to exacerbate the spread of COVID-19, worsen outcomes, and perpetuate the current, well-recognized disparities.

Many SEBI grants in the initial phase of RADx-UP focus on how individual, person-level beliefs and behaviors contribute to disparate access to, and uptake of COVID-19 testing. Phase II encourages applications that address multiple levels of influence (e.g., individual, interpersonal, institutional, community, and policy levels) and lead to actionable solutions to address COVID-19 disparities. Applications should inform the distribution, accessibility, acceptability and use of COVID-19 testing resources in underserved and vulnerable populations. This FOA solicits applications aimed at understanding the social, ethical, behavioral, structural, environmental, historical and policy factors surrounding COVID-19 testing. Addressing the roles of structural racism and discrimination and other ideologies that may contribute to observed disparities is also important. Research is needed to examine institutional decisions, practices, and biases that can be modified to recognize and better meet communities' preferences and goals related to COVID-19 testing. Studies can inform policymakers, providers, and communities about strategies to ensure equitable access to the resources and data necessary to prevent COVID-19.

SEBI applications should be developed to inform distribution, implementation, uptake, and evaluation of COVID-19 testing and vaccination programs. The development of pragmatic, ethically congruent guidance for COVID-19 testing and vaccine resource sharing and allocation is encouraged. Research may assess tailored testing programs and develop and examine communication strategies to mitigate barriers to testing and vaccination. Studies may develop consent materials, referral resources, and processes to deliver tests and return COVID-19 testing results that reflect community needs or practices. Studies focused on unintended positive and negative consequences of COVID-19 testing, including factors that contribute to vaccine uptake and reinforce protective behaviors, are also of interest. Studies may also examine and address the effects that mistrust of medical and public health research associated with COVID-19 testing and vaccination programs is having on the uptake of COVID-19 related public health services.

RADx^{SM}-UP Phase II projects must demonstrate relevance of the scientific questions to underserved and vulnerable populations. Projects should utilize rigorous research designs and describe research strategies that reflect the evolving landscape and availability of COVID-19 tests and vaccines. Applications should articulate clear research goals, but also demonstrate the ability and flexibility to address new questions that may arise as the pandemic, access to testing and vaccination, and behavioral norms and recommendations continue to change. Applications should delineate concrete outcomes that can be rapidly shared with communities and other stakeholders.

Studies supported under this FOA should work closely with community leaders, community-based organizations, and other relevant stakeholders to support in-depth examination of social, ethical, behavioral, structural, environmental, historical and policy factors related to COVID-19 testing and vaccination. Use of existing resources and expansion of extant community partnerships (e.g., tribal leadership, academic, private, safety-net health systems, community organizations, public health departments, state and local governments, test and vaccination providers, faith-based organizations, and school or child care settings) is strongly encouraged. Applicants should document existing collaboration with community organizations and must describe the roles of all community partners. Study budgets should provide appropriate levels of funding for community partners commensurate with the level of effort of the community partners in research design and implementation. Applicants are encouraged to collaborate where appropriate with RADx-UP studies funded through Phase I.

Applications to this SEBI FOA are not required to administer COVID-19 testing. However, in all cases where a SEBI project proposes to provide COVID-19 testing as part of the project, or to partner with a COVID-19 testing program (e.g. to study its participants), the COVID-19 testing being offered must use FDA-authorized/approved test kits,

supplies, and data collection materials, and assays must be conducted in Clinical Laboratory Improvement Amendments (CLIA) certified laboratories (e.g., hospital, public health, or commercial). Please note that applications to this FOA whose primary aim is to conduct or administer COVID-19 testing and return results will be deemed non-responsive. Applicants interested in a project focused primarily on COVID-19 test implementation rather than SEBI barriers should consider applying to RFA-OD-21-008 (https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-21-008.html)).

To address expected impacts of COVID-19 on the scientific workforce applications are also strongly encouraged to involve early stage investigators, including those from diverse backgrounds (NOT-OD-20-031 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html)).

Areas of Research Interest

Proposed studies should examine social, ethical, behavioral, structural, environmental, historical and policy implications of testing in underserved and vulnerable populations with disparities in COVID-19 testing. Applications are encouraged to address more than one level of analysis (e.g., individual interpersonal, institutional, community, and policy levels). Topics may include, but are not limited to:

- Assess and address SEBI factors and barriers that result in disparities in COVID-19 testing, vaccination, and outcomes. Factors could include but are not limited to
    - Systemic and policy factors (e.g., current and historical structural racism and discrimination; variations in testing and vaccination policy; community mistrust; inequitable resource distribution)
    - Geographic (place-based) factors (e.g., residential segregation, concentrated social stressors, inadequate transportation)
    - Communication challenges (e.g., health literacy levels, language access, exposure to misinformation, digital access)
    - Social and community-level influences (e.g., state and local policies in healthcare, and social services; workplace and school policies; cultural beliefs, community and family norms)
    - Test characteristics and processes - differences in quality (accuracy, mode, burden, time to results); cost and availability; dependence on digital tools; and experiences related to the tests and vaccination processes (e.g., appointment registration, proof of residency)
    - Motivations and barriers that affect salient behaviors including the use of testing and mitigation strategies.
- Understand and incorporate the perceptions, attitudes, beliefs, and intentions of community leaders, community-based organizations, religious faith-based institutions, city council/local government/state level agencies, grassroot organizations' and other stakeholders towards COVID-19 testing and vaccination strategies and programs
- Address individual, family, and household impact and sequelae of COVID-19 diagnostic tests and results (e.g., mental health and psychosocial consequences; stigma; challenges and implications in multigenerational households; occupational testing implications) as well as unique testing needs of multi-generational households, close social networks, etc.
- Assess information needs, as well as the impact of misinformation regarding the COVID-19 pandemic, testing, and vaccines; design messages to mitigate the impact of exposure to misinformation
- Develop and disseminate culturally competent communication about COVID-19 testing and vaccination that addresses safety concerns, fear, and distrust
- Assess state and local testing and vaccination programs' frameworks to prioritize resource allocations and determine characteristics of these programs that perpetuate or mitigate disparities
- Design, assess, and deploy reliable, community-congruent disease surveillance systems and accompanying metrics to improve tracking of testing, vaccination, and outcomes in underserved and vulnerable communities
- Address SEBI concerns (e.g., distrust of medical research, transparency, privacy) regarding the conduct of biomedical and public health research within COVID-19 testing and vaccination programs, to ensure COVID-19 research does not inhibit uptake of COVID-19 related public health services
- Assess how the presence and prevalence of COVID-19 vaccinations will affect societal views, roles, and uptake of SARS CoV-2 testing

- Examine whether and why testing and/or vaccination may, as an unintended and adverse consequence, reduce adherence to other prevention behaviors (e.g., mask-wearing, and physical distancing), and implement interventions to ameliorate these effects
- Understand and address the SEBI issues related to pediatric vaccine trials
- Address unique SEBI issues associated with testing children and results reporting in children/pediatric/school-based contexts
    - Research to assess outcomes and impact of school-based testing programs on root causes of stigma and inequity, and to identify characteristics of effective programs in promoting equity

Applications should focus on well-defined problems and actionable strategies and develop outcomes or products that could be used by communities, COVID-19 service providers, institutions, and public health agencies to improve equity, access, acceptability and uptake of COVID-19 testing and vaccines.

NIH is striving for consistency and high levels of rigor and reproducibility in all research, particularly in programs related to COVID-19 pandemic. All RADx-UP researchers engaging human participants in their projects are required to use a set of Common Data Elements (CDEs) to standardize the collection of data and ensure that data can be aggregated and compared across study populations and research topics (where not otherwise prohibited such as by Tribal authority). This data standardization will permit evaluation of the overall RADx^{SM}-UP consortium and impacts on COVID-19 disparities in specific populations, facilitate analysis of research questions and may inform policy at the local, community, and/or Tribal levels. Details for researchers about the RADx-UP Common Data Elements including FAQs can be found at https://radx-up.org/learning-resources/cdes/ (https://radx-up.org/learning-resources/cdes/). Where it is appropriate, projects responding to this funding opportunity are required to collect the NIH RADx-UP Tier 1 Common Data Elements or a modification of the Tier 1 Common Data Elements for pediatric populations (https://radx-up.org/learning-resources/cdes/). Permission from participants to collect and share these CDEs will be given through specific language in the informed consent process.

Recipients will work closely with the CDCC on data sharing activities as part of the RADx-UP consortium to advance the science of health disparities research in COVID-19 testing across the country. As an initiative that prioritizes community engagement, awardees will work with the CDCC to identify the scope of data sharing agreements that are acceptable to community partners, that allow recruitment and retention of participants, and that build trust, while contributing to consortium activities. The scope of data sharing may include the following : 1)?depositing de-identified data in the CDCC and NIH RADx Data Hub, 2) sharing de-identified data with the CDCC and NIH for future scientific research, 3) sharing identifiable data to?permit re-contact of participants for future follow-up and participation in future research; and/or 4) sharing identifiable data to perform linkages with population and clinical data sets to understand health outcomes of the COVID-19 pandemic among underserved and vulnerable populations.? Applicants are encouraged to discuss acceptability of one or more of these options for data sharing prior to application.

These data to be archived in the NIH RADx Data Hub will enable properly authorized community members, health researchers, and the Federal government to understand the impact of the COVID-19 pandemic on the well-being, risk, resilience and disparities in vulnerable communities across the United States and U.S. Territories. Funded projects will share study instruments and other research products with other RADx^{SM}-UP funded projects through the CDCC.

Projects funded through this FOA are also strongly encouraged to use the following resources as applicable:

- Data Harmonization for Social Determinants of Health (SDOH), COVID-19, and other relevant measures via the PhenX Toolkit: Investigators are strongly encouraged to employ a common set of tools and resources that will promote the collection of comparable data on SDOH across studies. Studies involving human-subjects are encouraged to incorporate SDOH measures from the Core and Specialty collections that are available in the Social Determinants of Health Collection of the PhenX Toolkit (www.phenxtoolkit.org (http://www.phenxtoolkit.org/)).
- Existing COVID-19 survey items and investigator contact information are publicly available through two NIH-supported platforms: the NIH Public Health Emergency and Disaster Research Response (DR2) https://dr2.nlm.nih.gov/ (https://dr2.nlm.nih.gov/) and the PhenX Toolkit https://www.phenxtoolkit.org/index.php (https://www.phenxtoolkit.org/index.php). Researchers addressing COVID-19 questions, whether population-

based or for clinical research, are strongly encouraged to consider these COVID-19 specific survey item repositories and select existing survey items or protocol modules currently being fielded.

Additionally, researchers with funding through this FOA are strongly encouraged to share their survey items to make them public for other researchers to consider by submitting their surveys to NIHCOVID19Measures@nih.gov (mailto:NIHCOVID19Measures@nih.gov).

The NIH also recognizes that other federal agencies who support research or demonstration projects may be strong collaborators for these types of research. NIH encourages collaboration with investigators funded by other agencies, as appropriate, including, but not limited to those funded by the Substance Abuse and Mental Health Services Administration, the Health Resources and Services Administration, the Administration for Children and Families, the Administration on Community Living and its divisions, the Centers for Disease Control and Prevention, the Indian Health Service, the Agency for Health Research and Quality, the Office on Minority Health, the Department of Defense, the Department of Agriculture, the Department of Education, the Department of Justice, the Department of Interior's Bureau of Indian Affairs, and the Department of Veterans Affairs.

Additional Requirements

NIH is requiring data sharing for all COVID-19 projects, where it is not prohibited (i.e., Tribal data sovereignty). The NIH expects and supports the timely release and sharing of final research data from NIH-supported studies for use by other researchers to expedite the translation of research results into knowledge, products, and procedures to improve human health https://grants.nih.gov/grants/policy/data_sharing/ (https://grants.nih.gov/grants/policy/data_sharing/).

- Where projects are collecting data on COVID-19 testing-related outcomes and implementation, the grant recipients are required to work with the RADx^{SM}-UP Coordinating and Data Collection Center (CDCC) to submit common data elements (CDEs) on COVID-19 testing-related outcomes and implementation to the CDCC. Recipients should identify staff responsible for these data coordination and reporting activities.
- Recipients are expected to obtain and retain personal identifiers on all research participants where it is not prohibited (e.g., Tribal data sovereignty) for future longitudinal follow-up and to be leveraged for intervention research. Data collected from this program will be protected by a Certificate of Confidentiality.
- Recipients are expected to use guidance provided by the CDCC for data acquisition, collection, and curation, including consent for data sharing and implementation of methods to enable data collected to be AI (artificial intelligence) ready.
- Recipients are expected to work with the RADx^{SM}-UP consortium members, as appropriate.
- Projects must include a description of sustainability of their infrastructure and partnerships that may be leveraged for future public health pandemic mitigation efforts, including potential vaccine and/or therapeutic implementation efforts.
- Applications must include milestones towards progress and a timeline for completion. The timeline must include plans for regular submission of data and reports of progress to be submitted to the CDCC and meetings with Community Advisory Boards
- As with all NIH supported research, details regarding human subjects research are expected, including, where needed, plans for data safety and monitoring and a Data Safety and Monitoring Board (DSMB). Studies that have a DSMB are expected to coordinate with CDCC (RFA-OD-20-013 (//grants.nih.gov/grants/guide/rfa-files/RFA-OD-20-013.html)) for DSMB activities
- Recipients are expected to participate in CDCC-organized activities, including monthly cross-site meetings, cross-site working groups, and dissemination activities (of effective implementation strategies, tools, and measures, etc.).
- Recipients are expected to demonstrate knowledge of and to comply with federal, state, local, and/or Tribal requirements on testing, reporting and surveillance policies in study protocols.
- Recipients must provide letters of support from the community partners and should include community partners (where possible) as investigators. Budgets should reflect active participation by community partners to the extent possible. When required, Tribal resolutions should be included with the application if possible, but before funds are awarded in all cases. If school or childcare settings are incorporated, recipients must provide letters of support from the school setting, school district or state Department of Education as applicable.

The major focus of these SEBI applications must be to address social, ethical and behavior factors associated with COVID-19 testing disparities. SEBI applications are not required to conduct or administer COVID-19 testing and should not propose the actual administration COVID-19 testing or vaccination as the primary activity or aim.

Applications nonresponsive to terms of this FOA will not be considered. The following types of projects would generally not be appropriate and may be deemed non-responsive:

- Projects that do not have a primary focus on SEBI issues
- Projects where the primary activity or aim is to conduct or administer COVID-19 testing.
- Projects without a focus on one or more underserved and COVID-19 vulnerable populations
- Projects focusing exclusively on vaccination
- Applications offering COVID-19 testing or working with COVID-19 testing or vaccination programs that are not FDA authorized or approved
- Applications offering COVID-19 testing or working with testing or vaccination programs that are not being assayed in CLIA certified laboratories (e.g., hospital, public health, or commercial)
- Projects that do not discuss generalizability and public health impact
- Projects that do not demonstrate a strong equitable relationship or engagement strategy with populations and stakeholders of interest (e.g., community organizations, health care systems, schools, and other institutions)
- Projects that propose to study populations or COVID-19 testing outside the United States
- Projects that do not include a plan to rapidly report study findings and impact to the CDCC

Applications nonresponsive to terms of this FOA will be withdrawn from consideration before review. .

Investigators planning to submit an application in response to this FOA are strongly encouraged to contact and discuss their proposed research/aims with Program staff listed on this FOA well in advance of the application receipt date to better determine appropriateness and interest.

See Section VIII. Other Information for award authorities and regulations.

Section II. Award Information

Funding Instrument

Cooperative Agreement: A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, NIH scientific or program staff will assist, guide, coordinate, or participate in project activities. See Section VI.2 for additional information about the substantial involvement for this FOA.

Application Types Allowed

New

The OER Glossary (//grants.nih.gov/grants/guide/url_redirect.htm?id=11116) and the SF424 (R&R) Application Guide provide details on these application types. Only those application types listed here are allowed for this FOA.

Clinical Trial?

Optional: Accepting applications that either propose or do not propose clinical trial(s).

Need help determining whether you are doing a clinical trial? (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82370)

Funds Available and Anticipated Number of Awards

The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.

NIH intends to commit $24 Million over 2 years to fund approximately 16 awards.

Award Budget

Application budgets are limited to $400,000 per year in Direct Costs and need to reflect the actual needs of the proposed project.

Award Project Period

The maximum period is 2 years.

NIH grants policies as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120) will apply to the applications submitted and awards made from this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Local Governments

- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)

Other

- Native American Tribal Organizations (other than Federally recognized tribal governments)

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.

Foreign components, as defined in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11118), **are not** allowed.

Required Registrations

Applicant organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The NIH Policy on Late Submission of Grant Applications (//grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html) states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- Dun and Bradstreet Universal Numbering System (DUNS) (http://fedgov.dnb.com/webform) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- System for Award Management (SAM) (https://www.sam.gov/portal/public/SAM/) – Applicants must complete and maintain an active registration, which requires renewal at least annually. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
    - NATO Commercial and Government Entity (NCAGE) Code (//grants.nih.gov/grants/guide/url_redirect.htm?id=11176) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123) - Applicants must have an active DUNS number to register in eRA Commons. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration, but all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov – Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide.

2. Cost Sharing

This FOA does not require cost sharing as defined in the NIH Grants Policy Statement. (//grants.nih.gov/grants/guide/url_redirect.htm?id=11126)

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

The NIH will not accept duplicate or highly overlapping applications under review at the same time. This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see NOT-OD-11-101 (//grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html)).

Section IV. Application and Submission Information

1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace are available in Part 1 of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the Research (R) Instructions in the SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url_redirect.htm?id=12000) except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Page Limitations

All page limitations described in the SF424 Application Guide and the Table of Page Limits (//grants.nih.gov/grants/guide/url_redirect.htm?id=11133) must be followed.

Instructions for Application Submission

The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this FOA.

SF424(R&R) Cover

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Project/Performance Site Locations

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Other Project Information

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Senior/Key Person Profile

All instructions in the SF424 (R&R) Application Guide must be followed.

R&R or Modular Budget

All instructions in the SF424 (R&R) Application Guide must be followed.

R&R Subaward Budget

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Cover Page Supplement

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Research Plan

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Applications are invited from investigators representing a wide range of disciplines, including but not limited to ethics, health disparities research, demography, health policy, health communication and communication science, implementation science, clinical care, home and community-based services, infectious disease, community-based participatory research, policy studies, public health, epidemiology, bioinformatics and health information sciences, behavioral and social sciences (e.g., psychology, sociology, social work, anthropology, nursing, political science, economics, communication science).

Specific Aims

The Specific Aims should be stated concisely and include research to be conducted as well as actionable sources of disparities to be addressed.

This FOA supports collection of multiple types of data including qualitative and quantitative methods, as well as reviews of documents and available data where appropriate. Where possible, primary or alternate methods that are robust or unaffected by shelter-in-place, and other restrictions on research environments, or by existing digital divides is encouraged, although evidence of availability and acceptability for communities and individuals should be provided, along with the capacity to maintain standards of ethical research conduct.

Research Strategy

The Research Strategy should include details on methods, assumptions, research designs, data analysis plans, and any interdependencies of Aims, and justify major choices about populations, goals, outcomes, and methods.

The potential of the proposed approach to yield important contributions applicable to a range of populations and settings, or to inform intervention and prevention strategies, should be addressed. Applications focusing on specific communities should describe how findings and products can be generalized or implemented across other underserved and/or vulnerable populations or to the same populations in other settings (rural/urban and regional differences). Briefly describe the generalizability of study approaches and findings to broader populations and include plans for the development of materials or toolkits to facilitate adaptation, dissemination, and implementation.

Where applicable the Research Strategy should detail community- or stakeholder-engaged methods to assess barriers to COVID-19 test and vaccination access, uptake and follow-up, and develop and evaluate strategies or interventions to address those barriers.

This FOA supports collection of multiple types of data including qualitative and quantitative methods, as well as reviews of documents and available data where appropriate. Where possible, primary or alternate methods that are robust or unaffected by shelter-in-place, and other restrictions on research environments, or by existing digital divides is encouraged, although evidence of availability and acceptability for communities and individuals should be provided, along with the capacity to maintain standards of ethical research conduct.

Applicants should address whether and how ongoing or potential future public health changes or restrictions (e.g., closures, physical distancing, ability to hold large meetings) might affect the research approach and, if so, include a plan to prevent or mitigate any effect on the proposed study.

While preliminary data are not explicitly required the application should clearly outline a solid rationale and conceptual framework to demonstrate the feasibility of the approach.

A description of how the institutional environment will facilitate community or stakeholder engagement and facilitate implementation and dissemination of results should be included where appropriate.

The Research Strategy section should include a project timeline.

NIH reminds applicants that the appropriate consideration of sex and gender as described in NOT-OD-15-102 (https://grants.nih.gov/grants/guide/notice-files/not-od-15-102.html) is NIH policy and a consideration for NIH support.

Applicants should describe in the Research Strategy their ideas for working with other SEBI and RADx^{SM}-UP sites to accomplish project goals, and their willingness to adhere to policies and procedures determined in cooperation with the CDCC (RFA-OD-20-013 (https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-20-013.html)).

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide.

The following modifications also apply:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.
- Feasible and appropriate plans to submit data, data collection instruments, and outcomes/products to the CDCC should be included.
- Additionally, researchers with funding through this FOA will be required to share their survey items, data collection instruments and methods for other researchers to consider by submitting these resources to NIHCOVID19Measures@nih.gov.

Appendix:

Only limited Appendix materials are allowed. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

- No publications or other material, with the exception of blank questionnaires or blank surveys, may be included in the Appendix

PHS Human Subjects and Clinical Trials Information

When involving human subjects research, clinical research, and/or NIH-defined clinical trials (and when applicable, clinical trials research experience) follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions:

If you answered “Yes” to the question “Are Human Subjects Involved?” on the R&R Other Project Information form, you must include at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or **Delayed Onset Study** record.

Study Record: PHS Human Subjects and Clinical Trials Information

All instructions in the SF424 (R&R) Application Guide must be followed.

Delayed Onset Study

Note: Delayed onset does NOT apply to a study that can be described but will not start immediately (i.e., delayed start).All instructions in the SF424 (R&R) Application Guide must be followed.

PHS Assignment Request Form

All instructions in the SF424 (R&R) Application Guide must be followed.

3. Unique Entity Identifier and System for Award Management (SAM)

See Part 1. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov.

4. Submission Dates and Times

Part I. Overview Information contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or Federal holiday

(https://grants.nih.gov/grants/guide/url_redirect.html?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=11128) (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission.

Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review. (//grants.nih.gov/grants/guide/url_redirect.htm?id=11142)

6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

Pre-award costs are allowable only as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11143).

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit How to Apply – Application Guide (https://grants.nih.gov/grants/how-to-apply-application-guide.html). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Dealing with System Issues (https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm) guidance. For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH. See Section III of this FOA for information on registration requirements.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the SF424 (R&R) Application Guide.

See more tips (//grants.nih.gov/grants/guide/url_redirect.htm?id=11146) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review and responsiveness by components of participating organizations, NIH. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in the policy (//grants.nih.gov/grants/guide/url_redirect.htm?id=82299). Any instructions provided here are in addition to the instructions in the policy.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. Applications submitted to the NIH in support of the NIH mission are evaluated for scientific and technical merit through an administrative review.

For this particular announcement, note the following:

•This is an emergency FOA due to the SARS-CoV-2 global pandemic; therefore, preliminary data is not explicitly required in the application.

•Accordingly, reviewers will emphasize the conceptual framework, the level of innovation, and the potential to significantly advance our knowledge or understanding. Appropriate justification for the proposed work can be provided through literature citations, data from other sources, or, when available, from investigator-generated data.

In addition, for applications involving clinical trials: A proposed Clinical Trial application may include study design, methods, and intervention that are not by themselves innovative but address important questions or unmet needs. Additionally, the results of the clinical trial may indicate that further clinical development of the intervention is unwarranted or lead to new avenues of scientific investigation.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed project rigorous? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

In addition, specific to this FOA

- Does the application focus on social, ethical, and behavioral issues influencing access acceptability and uptake of COVID-19 testing.
- Urgency and significance of research: Will successful completion of the aims contribute to or complement public health efforts to address health equity issues in the control of SARS-CoV-2 (COVID-19) infection and related pathogenic processes?
- Does the proposed research fit within the mission of an emergency response to provide critical expertise, resources or activities?
- Are strategies, communication plans, materials or other outcomes that could be used to improve access, acceptability, and uptake of COVID-19 testing and vaccination in underserved and vulnerable populations likely to result in improved access, acceptability and uptake of COVID-19 testing and vaccination among underserved and vulnerable populations?

- Are the proposed approaches likely to yield important contributions applicable to a range of populations and healthcare settings and/or for similar future public health crises? Does the application provide detail how their findings are portable beyond the (local) populations studied? Have they considered the RADx-UP Consortia or other groups as a possible avenue for dissemination?

In addition, for applications involving clinical trials

Are the scientific rationale and need for a clinical trial to test the proposed hypothesis or intervention well supported by preliminary data, clinical and/or preclinical studies, or information in the literature or knowledge of biological mechanisms? For trials focusing on clinical or public health endpoints, is this clinical trial necessary for testing the safety, efficacy or effectiveness of an intervention that could lead to a change in clinical practice, community behaviors or health care policy? For trials focusing on mechanistic, behavioral, physiological, biochemical, or other biomedical endpoints, is this trial needed to advance scientific understanding?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

In addition, specific to this FOA

Does the composition of the research team have the depth of topical expertise to pose important questions and recognize actionable, meaningful answers, as well, as the methodological experience to carry out the proposed research plan?

Where appropriate does the team include expertise in community engaged research?

When considering experience of community engaged researchers and community partners, nontraditional indices of expertise such as years of work in the index community or successful delivery of health programs to underserved communities can be considered.

In addition, for applications involving clinical trials

With regard to the proposed leadership for the project, do the PD/PI(s) and key personnel have the expertise, experience, and ability to organize, manage and implement the proposed clinical trial and meet milestones and timelines? Do they have appropriate expertise in study coordination, data management and statistics? For a multicenter trial, is the organizational structure appropriate and does the application identify a core of potential center investigators and staffing for a coordinating center?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

In addition, specific to this FOA

- Where vaccination uptake is included as a topic, does the study of vaccination (within the context of COVID-19 testing) clearly add value to the application's aims regarding COVID-19 testing in underserved and minority populations?
- Is the proposed approach dynamic and able to be responsive to evolving changes in COVID-19 diagnostics, vaccination, and treatment?

In addition, for applications involving clinical trials

Does the design/research plan include innovative elements, as appropriate, that enhance its sensitivity, potential for information or potential to advance scientific knowledge or clinical practice?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of individuals of all ages (including children and older adults), justified in terms of the scientific goals and research strategy proposed?

In addition, specific to this FOA

- Communities and community partners: Does the project focus on underserved and vulnerable populations from one or more NIH-designated populations that experience health disparities? Does the project propose approaches that engage the target community/ies? Is there evidence of strong established research collaborations with proposed community partners? How feasible and appropriate are the plans for integrating community partners into the study?
- Does the applicationjustify choices about the level(s) of analysis undertaken (individual, interpersonal, institutional, community, and policy)?
- Is the timeline appropriate, timely and feasible to support the aims and goals of the study?
- Coordination plans: How feasible and appropriate are the plans to submit data, data collection instruments and outcomes/products to the CDCC (FOA RFA-OD-20-013 (https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-20-013.html))? How feasible and appropriate are the plans to collaborate with the existing RADx^{SM}-UP field sites (NOSI NOT-OD-20-121 (https://grants.nih.gov/grants/guide/notice-files/not-od-20-121.html)and NOSI NOT-OD-20-120 (https://grants.nih.gov/grants/guide/notice-files/not-od-20-120.html)) and new RADx^{SM}-UP opportunities?
- Are timely and feasible remediation plans for adverse outcomes included as appropriate?
- Sustainability: How feasible and appropriate are the plans for sustainability of project infrastructure and partnerships that may be leveraged for future public health pandemic mitigation efforts?

In addition, for applications involving clinical trials

Does the application adequately address the following, if applicable

Study Design

Is the study design justified and appropriate to address primary and secondary outcome variable(s)/endpoints that will be clear, informative and relevant to the hypothesis being tested? Is the scientific rationale/premise of the study based on previously well-designed preclinical and/or clinical research? Given the methods used to assign participants and deliver interventions, is the study design adequately powered to answer the research question(s), test the proposed hypothesis/hypotheses, and provide interpretable results? Is the trial appropriately designed to conduct the research efficiently? Are the study populations (size, gender, age, demographic group), proposed intervention arms/dose, and duration of the trial, appropriate and well justified?

Are potential ethical issues adequately addressed? Is the process for obtaining informed consent or assent appropriate? Is the eligible population available? Are the plans for recruitment outreach, enrollment, retention, handling dropouts, missed visits, and losses to follow-up appropriate to ensure robust data collection? Are the planned recruitment timelines feasible and is the plan to monitor accrual adequate? Has the need for

randomization (or not), masking (if appropriate), controls, and inclusion/exclusion criteria been addressed? Are differences addressed, if applicable, in the intervention effect due to sex/gender and race/ethnicity?

Are the plans to standardize, assure quality of, and monitor adherence to, the trial protocol and data collection or distribution guidelines appropriate? Is there a plan to obtain required study agent(s)? Does the application propose to use existing available resources, as applicable?

Data Management and Statistical Analysis

Are planned analyses and statistical approach appropriate for the proposed study design and methods used to assign participants and deliver interventions? Are the procedures for data management and quality control of data adequate at clinical site(s) or at center laboratories, as applicable? Have the methods for standardization of procedures for data management to assess the effect of the intervention and quality control been addressed? Is there a plan to complete data analysis within the proposed period of the award?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

In addition, specific to this FOA

- Where collaborations with community partners are proposed, is there documentation of strong established research collaborations with the proposed community partners?
- How feasible and appropriate are the plans for integrating community partners into the study? Does the budget evidence resources dedicated to the community-based partners?

In addition, for applications involving clinical trials

If proposed, are the administrative, data coordinating, enrollment and laboratory/testing centers, appropriate for the trial proposed?

Does the application adequately address the capability and ability to conduct the trial at the proposed site(s) or centers? Are the plans to add or drop enrollment centers, as needed, appropriate?

If international site(s) is/are proposed, does the application adequately address the complexity of executing the clinical trial?

If multi-sites/centers, is there evidence of the ability of the individual site or center to: (1) enroll the proposed numbers; (2) adhere to the protocol; (3) collect and transmit data in an accurate and timely fashion; and, (4) operate within the proposed organizational structure?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Study Timeline

Specific to applications involving clinical trials

Is the study timeline described in detail, taking into account start-up activities, the anticipated rate of enrollment, and planned follow-up assessment? Is the projected timeline feasible and well justified? Does the project incorporate efficiencies and utilize existing resources (e.g., CTSAs, practice-based research networks, electronic medical records, administrative database, or patient registries) to increase the efficiency of participant enrollment and data collection, as appropriate?

Are potential challenges and corresponding solutions discussed (e.g., strategies that can be implemented in the event of enrollment shortfalls)?

Protections for Human Subjects

For research that involves human subjects but does not involve one of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Guidelines for the Review of Human Subjects (//grants.nih.gov/grants/guide/url_redirect.htm?id=11175).

Inclusion of Women, Minorities, and Individuals Across the Lifespan

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of individuals of all ages (including children and older adults) to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research (//grants.nih.gov/grants/guide/url_redirect.htm?id=11174).

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (//grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmissions

Not Applicable

Renewals

Not Applicable

Revisions

Not Applicable

Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

Applications from Foreign Organizations

Not Applicable

Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: (1) Data Sharing Plan (//grants.nih.gov/grants/guide/url_redirect.htm?id=11151); (2) Sharing Model Organisms (//grants.nih.gov/grants/guide/url_redirect.htm?id=11152); and (3) Genomic Data Sharing Plan (GDS) (//grants.nih.gov/grants/guide/url_redirect.htm?id=11153).

Is the plan timely and feasible? Does the plan make instruments, products, results, and data findable and accessible to the research and public health community, where not limited by Tribal data sovereignty? In instances involving Tribal data sovereignty, is there documentation of Tribal agreement with adapted data sharing plans? If school data are included, are there considerations of protections such as those included in the Family Educational Rights and Privacy Act (FERPA) (20 U.S.C. § 1232g; 34 CFR Part 99)?

Authentication of Key Biological and/or Chemical Resources:

For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

Budget and Period of Support

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

2. Review and Selection Process

Applications submitted to the NIH in support of the NIH mission are evaluated for scientific and technical merit through an administrative review using the stated review criteria.

Applications may undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.

Appeals (//grants.nih.gov/grants/guide/notice-files/NOT-OD-11-064.html) of initial peer review will not be accepted for applications submitted in response to this FOA.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project
- Availability of funds.
- Relevance of the proposed project to program priorities.

3. Anticipated Announcement and Award Dates

Summary statements will not be generated for the PIs. Written critiques will not be distributed except for internal NIH use.

Information regarding the disposition of applications is available in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11156).

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11157).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the recipient's business official.

Awardees must comply with any funding restrictions described in Section IV.5. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to terms and conditions found on the Award Conditions and Information for NIH Grants (//grants.nih.gov/grants/guide/url_redirect.htm?id=11158) website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

Individual awards are based on the application submitted to, and as approved by, the NIH and are subject to the IC-specific terms and conditions identified in the NoA.

ClinicalTrials.gov: If an award provides for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register and submit results information for certain “applicable clinical trials” on the ClinicalTrials.gov Protocol Registration and Results System Information Website (https://register.clinicaltrials.gov (https://register.clinicaltrials.gov/)). NIH expects registration and results reporting of all trials whether required under the law or not. For more information, see https://grants.nih.gov/policy/clinical-trials/reporting/index.htm (https://grants.nih.gov/policy/clinical-trials/reporting/index.htm)

Institutional Review Board or Independent Ethics Committee Approval: Recipient institutions must ensure that all protocols are reviewed by their IRB or IEC. To help ensure the safety of participants enrolled in NIH-funded studies, the awardee must provide NIH copies of documents related to all major changes in the status of ongoing protocols.

Data and Safety Monitoring Requirements: The NIH policy for data and safety monitoring requires oversight and monitoring of all NIH-conducted or -supported human biomedical and behavioral intervention studies (clinical trials) to ensure the safety of participants and the validity and integrity of the data. Further information concerning these requirements is found at http://grants.nih.gov/grants/policy/hs/data_safety.htm and in the application instructions (SF424 (R&R) and PHS 398).

Investigational New Drug or Investigational Device Exemption Requirements: Consistent with federal regulations, clinical research projects involving the use of investigational therapeutics, vaccines, or other medical interventions (including licensed products and devices for a purpose other than that for which they were licensed) in humans under a research protocol must be performed under a Food and Drug Administration (FDA) investigational new drug (IND) or investigational device exemption (IDE).

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120) as part of the NoA. For these terms of award, see the *NIH Grants Policy Statement* Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (//grants.nih.gov/grants/guide/url_redirect.htm?id=11157) and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities (//grants.nih.gov/grants/guide/url_redirect.htm?id=11159). More information is provided at Award Conditions and Information for NIH Grants (//grants.nih.gov/grants/guide/url_redirect.htm?id=11158).

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex. This includes ensuring programs are accessible to persons with limited

English proficiency. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please see https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html (https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html) and http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html (http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html).

HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research. For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this FOA.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. HHS provides guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html (https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html) and https://www.lep.gov (https://www.lep.gov). For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53 (https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53).
- Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html (http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html).
- HHS funded health and education programs must be administered in an environment free of sexual harassment. Please see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html (https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html); https://www2.ed.gov/about/offices/list/ocr/docs/shguide.html; and https://www.eeoc.gov/eeoc/publications/upload/fs-sex.pdf (https://www.eeoc.gov/eeoc/publications/upload/fs-sex.pdf). For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm (https://grants.nih.gov/grants/policy/harassment.htm).
- Recipients of FFA must also administer their programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws. Collectively, these laws prohibit exclusion, adverse treatment, coercion, or other discrimination against persons or entities on the basis of their consciences, religious beliefs, or moral convictions. Please see https://www.hhs.gov/conscience/conscience-protections/index.html (https://www.hhs.gov/conscience/conscience-protections/index.html) and https://www.hhs.gov/conscience/religious-freedom/index.html (https://www.hhs.gov/conscience/religious-freedom/index.html).

Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at https://www.hhs.gov/ocr/about-us/contact-us/index.html (https://www.hhs.gov/ocr/about-us/contact-us/index.html) or call 1-800-368-1019 or TDD 1-800-537-7697.

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. FAPIIS requires Federal award making officials

to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships.

Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Part 75, and other HHS, PHS, and NIH grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial NIH programmatic involvement with the recipients is anticipated during the performance of the activities. Under the cooperative agreement, the NIH purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the recipients for the project as a whole, although specific tasks and activities may be shared among the recipients and the NIH as defined below.

The Principal Investigator(s) will have the primary responsibility for:

1. Coordinating project activities technically, scientifically, and administratively at the recipient institution and coordinating project activities at other sites that may be supported by the award.
2. Defining objectives and approaches; collecting and analyzing data; and publishing results, interpretations, and conclusions of studies conducted under the terms and conditions of the award.
3. Ensuring that appropriate Institutional Review Board approvals and certifications for research involving human subjects for all participating sites, collaborators or partners are obtained.
4. Consulting with NIH to ensure compliance with relevant grant policies and regulations
5. Provision of information to the NIH Program Official and NIH Project Scientists.
6. Participating in the CDCC-organized activities and with RADx^{SM}-UP consortium members including monthly cross-site meetings, cross-site working groups, and dissemination activities (of effective implementation strategies, tools and measures, etc.).
7. Management of a dedicated unit responsible for data acquisition, collection, curation, and data reporting activities to the CDCC.
8. Implementing collection of data specified by the study protocol. For a multi-center study, each recipient/site is required to ensure that data will be submitted expeditiously to the CDCC. Additionally, individual investigators/sites must demonstrate the ability to implement the strategy specifically designed for their individual study population.
9. Establishing procedures for data quality, completeness, and security. Recipients are responsible for ensuring accurate and timely assessment of the progress of each study, including development of procedures to ensure that data collection and management are: (1) adequate for quality control and analysis; (2) for clinical trials, as simple as appropriate in order to facilitate cooperation/referral of study participants by physicians to avoid unnecessary expense; and (3) sufficiently staffed across the participating institutions. Submitting interim progress reports, when requested or agreed upon by both parties, to the Institute's Program Official including as a minimum, summary data on protocol performance. For coordinated multiple awards or a multi-site single award, the Program Official may require additional information from individual recipients/sites. Such reports are in addition to the required annual noncompeting continuation progress report.
10. Reporting of the study findings. Recipients will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and NIH policies. The recipient must also be adherent to Study Publication and Presentation

Policy. The Institute will have access to and may periodically review all data generated under an award. Institute staff may co-author publications of findings with recipients consistent with NIH and study policies.

11. Any third-party collaboration (including but not limited to interactions with organizations from industry, academia, and nonprofit institutions) should be governed by a research collaboration agreement (e.g., Clinical Trial Agreement, Research Collaborative Agreement, etc.) or any third-party contract mechanism(s) with terms that ensure the collaboration is conducted in accordance with the Cooperative Agreement, applicable NIH/ Institute policies and procedures, and with written approval from Program staff. Any relevant proposed third-party agreements related to the network studies between recipient and third-party will be provided to the Program staff and Technology Advancement Office for review, comment, and approval to assure compliance with NIH/ Institute policies and network policies. Further, at the request of the Program staff, any other network-relevant third-party agreements must be shared with. Failure to comply with this term may prompt action in accordance with NIH Grants Policy Statement, Section 8.5 titled: “Special Award Conditions and Remedies for Noncompliance (Special Award Conditions and Enforcement Actions”, and Section 8.5.2, titled: “Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding Support”, noncompliance with the terms and conditions of award will be considered by the funding IC for future funding and support decisions and may result in termination of the award.”
12. Any involvement of a third-party (including but not limited to industry, academia, and nonprofit institutions) in the study and network activities that includes access to any network generated resources (i.e., data and biosamples), or study results that are not publicly available, or using the name of the network or study or the name of the NIH or the Institute is permitted only after written permission by the Program staff who will consult with others at NIH and Technology Advancement Office.
13. Study investigators are required to publish and to release publicly and disseminate results and other products of the study, in accordance with study protocols, steering committee policies on publications, and the approved sharing plan.
14. Study investigators are required to comply with NIH Policy on the Dissemination of NIH Funded Clinical Trial Information as stated at https://grants.nih.gov/policy/clinical-trials/reporting/understanding/nih-policy.htm (https://grants.nih.gov/policy/clinical-trials/reporting/understanding/nih-policy.htm). Per policy, the recipient is responsible for meeting the expectations of this policy. Refer to additional information at https://grants.nih.gov/policy/clinical-trials/reporting/index.htm (https://grants.nih.gov/policy/clinical-trials/reporting/index.htm).

NIH staff have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

NIH will assign a Program Official (see below) and Project Scientist(s) to the award. The Project Scientist(s) will have substantial scientific involvement during the conduct of this activity, through technical assistance, advice, and coordination.

The Project Scientists(s) will:

- Review and comment on critical stages in the program implementation;
- Assist in the interaction between the recipient and investigators at other institutions to promote coordination with the CDCC;
- Retain the option of recommending termination of support if technical performance or implementation falls below acceptable standards, or when specific key resources cannot be effectively implemented in a timely manner;

Additionally, the NIH program official will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice.

The Program Official will:

- Assist with the NIH’s monitoring of compliance of award-supported activities;
- Evaluate progress by reviews of technical or fiscal reports or by site visits to determine that performance is consistent with objectives, terms and conditions of the award;

- Help ensure that activities proposed for development or implementation do not overlap or duplicate activities supported by other peer-reviewed funding mechanisms;
- Provide assistance in reviewing and commenting on all major transitional changes of activities prior to implementation to ensure consistency with the goals of this FOA;
- Assist with the NIH's monitoring of financial oversight

Areas of Joint Responsibility include:

- Identifying and facilitating partnerships with other RADx^{SM}UP award recipients or other relevant resources and expertise that could be leveraged to facilitate achievement of the FOA goals and objectives.
- Organizing and participating in the CDCC activities.
- We are mindful of the rapidly changing nature of the COVID-19 pandemic, the likelihood that new key SEBI questions will arise, and that RADx^{SM}UP our responses to it. To ensure continual relevance to the COVID-10 pandemic, at the time of award, and across the lifespan of the project the Program Official and PI(s) will meet to ensuring that the research questions and goals remain in scope while also reflecting the evolving medical, public health and behavioral landscape of COVID-19 disease testing and vaccination

Dispute Resolution:

Any disagreements that may arise in scientific or programmatic matters (within the scope of the award) between award recipients and the NIH may be brought to Dispute Resolution. A Dispute Resolution Panel composed of three members will be convened. It will have three members: a designee of the RADx^{SM}UP consortium member chosen without NIH staff voting, one NIH designee, and a third designee with expertise in the relevant area who is chosen by the other two; in the case of individual disagreement, the first member may be chosen by the individual awardee. This special dispute resolution procedure does not alter the awardee's right to appeal an adverse action that is otherwise appealable in accordance with PHS regulation 42 CFR Part 50, Subpart D and DHHS regulation 45 CFR Part 16.

3. Reporting

When multiple years are involved, awardees will be required to submit the Research Performance Progress Report (RPPR) (//grants.nih.gov/grants/rppr/index.htm) annually and financial statements as required in the NIH Grants Policy Statement. (//grants.nih.gov/grants/guide/url_redirect.htm?id=11161)
The NIH Office of the Director plans to make awards using funds provided in the emergency supplemental appropriations for COVID-19 and coronavirus research: "American Rescue Plan Act of 2021, Public Law 117-2".

Funds awarded using appropriations provided by the "American Rescue Plan Act of 2021, Public Law 117-2" will be issued in unique subaccounts in the HHS Payment Management System and will require separate financial reporting from any other funds awarded.

Interim Reports

In addition to the annual RPPR, recipients are required to submit an interim progress report every six months outlining key milestones that have been met.

- Recipients must upload the interim report using the Additional Materials tool (AM) in eRA. The Authorized Organization Official is required to submit interim reports to the Grants Management Official named on the Notice of Award using AM.
- The interim progress report must outline for each award the following:
    - For each specific aim, a brief summary of major activities, significant results, and key outcomes or other achievements.

A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11161).

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=11170) on all subawards over $25,000. See the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11171) for additional information on this reporting requirement.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than $10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 – Award Term and Conditions for Recipient Integrity and Performance Matters.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, and post-submission issues)

Finding Help Online: http://grants.nih.gov/support/ (//grants.nih.gov/support/) (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

General Grants Information (Questions regarding application instructions, application processes, and NIH grant resources)
Email: GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov) (preferred method of contact)
Telephone: 301-945-7573

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)
Contact Center Telephone: 800-518-4726
Email: support@grants.gov (mailto:support@grants.gov)

Scientific/Research Contact(s)

Nancy Jones, PhD
Phone: 301.594.8945
Email: nancy.jones@nih.gov (mailto:nancy.jones@nih.gov)

Dave Kaufman, PhD
Phone: 301-594-6907
Email: dave.kaufman@nih.gov (mailto:dave.kaufman@nih.gov)

Peer Review Contact(s)

Ramesh Vemuri, PhD
Phone: 301-402-7700

Email: vemuri@nia.nih.gov (mailto:vemuri@nia.nih.gov)

Financial/Grants Management Contact(s)

For Grants Management Questions Specific to RADx[SM]-UP:

Brian Albertini
Phone: 301.594.6869
Email: albertib@mail.nih.gov (mailto:albertib@mail.nih.gov)

Section VIII. Other Information

Recently issued trans-NIH policy notices (//grants.nih.gov/grants/guide/url_redirect.htm?id=11163) may affect your application submission. A full list of policy notices published by NIH is provided in the NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/url_redirect.htm?id=11164). All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75.

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?04-16-21)
NIH Funding Opportunities and Notices (/grants/guide/index.html)

NIH National Institutes of Health (/grants/oer.htm)
Office of Extramural Research

(http://www.hhs.gov/) Department of Health and Human Services (HHS)

USA.gov Government Made Easy (http://www.usa.gov/)

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Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see Help Downloading Files (/grants/edocs.htm).