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 Awards: Community-engaged COVID-19 Testing Interventions among Underserved and Vulnerable Populations – RADx-UP Phase II (U01 Clinical Trial 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

See Notices of Special Interest (https://grants.nih.gov/grants/guide/NOSIs_targetingList.cfm?GuideDocID=35086) associated with this funding opportunity

- **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-21-008

Companion Funding Opportunity

RFA-OD-21-009 (https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-21-009.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, 93.837, 93.839, 93.838, 93.840, 93.233, 93.121, 93.859, 93.313, 93.393, 93.865, 93.213, 93.394, 93.395, 93.396, 93.399, 93.350, 93.876, 93.172, 93.855, 93.846, 93.286, 93.847, 93.113, 93.143, 93.242, 93.853, 93.361, 93.866, 93.273, 93.173, 93.279, 93.307, 93.879

Funding Opportunity Purpose

This funding opportunity announcement (FOA) uses an emergency U01 mechanism to support Phase II of the Rapid Acceleration of Diagnostics – Underserved Populations (RADx^{SM}-UP) initiative. These two-year Testing Research Projects will (1) expand the scope and reach of RADx^{SM}-UP testing interventions to reduce COVID-19 disparities among underserved and vulnerable populations and (2) address scientific questions on interventions to increase access and uptake of COVID-19 testing given the increasing availability of SARS-CoV-2 vaccines. 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	October 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-21-008) 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) are issuing this funding FOA in response to the declared public health emergency issued by the Secretary, HHS, for 2019 Novel Coronavirus (COVID-19). This FOA provides an expedited funding mechanism to support Phase II of the Rapid Acceleration of Diagnostics – Underserved Populations (RADx^{SM}-UP) initiative. These two-year Testing Research Projects will (1) expand the scope and reach of RADx^{SM}-UP testing interventions to reduce COVID-19 disparities among underserved and vulnerable populations and (2) address scientific questions on interventions to increase access and uptake of COVID-19 testing given the increasing availability of SARS-CoV-2 vaccines. The funding for this program is provided from the American Rescue Plan Act of 2021.

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 Testing Research Projects FOA will support research teams with established community-engaged partnerships to address the scientific objectives described herein.

The related program initiatives include:

- NOT-OD-21-103 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-103.html)– Notice of Special Interest (NOSI): Emergency Competitive Revisions for 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 (//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
- RFA-OD-21-009 (https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-21-009.html)- Emergency Award:RADx^{SM}-UP -Social, Ethical, and Behavioral Implications (SEBI) Research on Disparities in COVID-19 Testing among Underserved and Vulnerable Populations (U01, Clinical Trial Optional)
- 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 supported under these funding opportunities will join the RADx^{SM}-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 and mitigate 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 RADx^{SM}-UP projects will actively coordinate, collaborate, and share data with other Testing Research Projects, the Coordination and Data Collection Center (https://radx-up.org/) (CDCC (https://radx-up.org/)), and research supported by the social, ethical, and behavioral implications (SEBI) program, as allowed, and with considerations under tribal Institutional Review Board (IRB) and data sovereignty processes. Researchers applying to this FOA are strongly encouraged to read all interrelated funding opportunities.

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 accessing needed health care services or 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, dementia; and rural and remote communities.

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 testing—with the goal of reducing health disparities—and to building enhanced point-of-care infrastructures that can be sustained beyond the current pandemic.

Phase I of the RADx^{SM}-UP initiative established a consortium of community-engaged research projects focused on increasing access to and uptake of COVID-19 testing as well as understanding the social, ethical, and behavioral implications of testing among U.S. underserved and vulnerable populations. The overarching goal is to understand the factors that have led to the disproportionate burden of the pandemic on underserved populations and to implement interventions to decrease these disparities.

Phase II projects will apply scientific knowledge gained in 2020 and 2021 to develop and evaluate interventions with the goal of conducting testing to decrease disparities that contribute to the increased risk of COVID-19 infections, hospitalizations, and mortality. Projects will help to understand and address disparities in testing and the effects of testing combined with other mitigation strategies (e.g., contact tracing, testing combined with behavioral mitigation strategies, education programs, self-isolation after exposure) on infection rates, transmission, and outcomes. Even with the availability of SARS-CoV-2 vaccines, testing will remain an important tool in controlling community spread. Phase II projects are required to include COVID-19 test completion as a primary outcome but should consider that COVID-19 testing interventions will occur in environments with increasing vaccine availability, distribution, and uptake. Accordingly, funding opportunities may include scientific questions within the related topics of testing and vaccine uptake, focusing on interventions that have strong potential to reduce disparities in the real world. Successful Phase II awardees will propose innovative science to fill the gaps and address the new challenges that have arisen in the testing and virus mitigation landscape. Projects must have established research infrastructure and community-engaged partnerships to demonstrate measurable impact within 6 months post-award and across a two-year timeframe. Partnerships with locally relevant public health departments and health care organizations may also be desirable.

Applicants are encouraged to develop research or engagement partnerships with the Community Engagement Alliance (CEAL) Against COVID-19 (https://covid19community.nih.gov/)Disparities initiative, where geographically appropriate (i.e., CEAL study sites are geographically co-located or near the applicant's proposed study site). Phase II projects can be expansions of Phase I projects or new projects.

Research Objectives

Specific research objectives of PhaseII studies will address key questions focused on underserved and vulnerable populations including, but not limited to:

- What testing interventions can be implemented and evaluated rapidly to decrease COVID-19 disparities as COVID-19 vaccines become increasingly available? For example, for those who are unable or unwilling to be vaccinated, how can testing support their health and safety?
- For those who are hesitant about getting vaccinated, would having testing available post-vaccination help reduce hesitancy and foster vaccine confidence?
- What COVID-19 diagnostic options are most acceptable and in what setting?
- What are the effective methods and interventions to incorporate testing and other strategies, such as genetic sequencing, to help identify and mitigate the transmission and population spread of existing or new variants of COVID-19?
- How can research on the social determinants of health (SDOH) help identify, understand, and address testing and vaccine access and uptake in low-resourced geographic areas or communities with high levels of social vulnerability?
- Does COVID-19 testing help address vaccine hesitancy and uptake, and if so, how?

- What community-driven interventions are effective to ameliorate stigma, bias, distrust, and fear regarding symptomatic and asymptomatic COVID-19 testing and vaccination?
- How does COVID-19 vaccine availability affect attitudes, beliefs, and behaviors related to testing intentions in specific communities and how can this information be applied to improve testing uptake?
- What is the role of frequent home testing with point-of-care methods in promotion of behavioral mitigation and vaccine uptake?
- What consent approach, testing method, testing frequency, and contact tracing methodologies are most effective to identify COVID-19 and prevent transmission in school or childcare settings?
- Are there existing prevention and health education programs in the school setting that can be adapted and scaled to promote COVID-19 safety measures, testing participation, testing literacy, and follow-up with health care providers at the child (across early childhood, elementary, middle and high school years), parent, and school staff levels? Could these programs be extended to address vaccine hesitancy and encourage vaccine uptake among adolescents?

Specific Areas of Research Interest

COVID-19 Testing Research Topics focused on underserved and vulnerable populations of interest include, but are not limited to, the following:

- Studies using rapid cycle designs to examine evolving COVID-19 testing technologies to improve uptake of testing, vaccination, and repeat testing of communities and individuals across the lifespan due to changes in the nature of the virus (variant presentation, infection risk, transmission rates)
- Interventions to improve implementation and adherence to Centers for Disease Control and Prevention (CDC) behavioral mitigation (https://www.cdc.gov/coronavirus/2019-ncov/community/community-mitigation.html) guidance (https://www.cdc.gov/coronavirus/2019-ncov/community/community-mitigation.html) (e.g., masks, hand washing, physical distancing, and limited indoor gatherings) in settings that serve vulnerable communities or (non-healthcare) frontline workplaces in combination with frequent testing to identify COVID-19, prevent transmission, and promote vaccine uptake
- Development and testing of implementation strategies that increase the reach, access, uptake, and sustainability of COVID-19 testing in community-, workplace-, school-, or family-based settings (e.g., technology-based approaches, mobile health units)
- Pragmatic or theory driven behavioral intervention trials, including culturally adapted versions of evidence-based interventions, to increase motivation, and health literacy for testing and vaccination uptake in environments with known low testing and vaccination base rates
- Research to examine and address disparities in the availability, ease of use, and/or accessibility of at-home testing options, or other new FDA-authorized or approved point-of-care testing technologies
- Modeling and/or simulation studies using testing data, including that from RADx^{SM}-UP Phase I, to understand drivers of COVID-19 disparities; to predict the impact of testing and contact tracing strategies and development of interventions based on modeling and simulation findings to reduce COVID-19disparities
- Multilevel interventions that address barriers, knowledge and attitudes, and testing and vaccine uptake at individual, interpersonal/family, and/or community levels
- Role of test distribution on health disparities, including the examination of access to healthcare and specific diagnostics and systems-level barriers and facilitators for equitable uptake
- Research on which types of distribution channels (or combinations of distribution channels) and supports (e.g., financial, informational, or technology) are needed to acilitate access to and uptake ofCOVID-19 self-testing kits
- Post-vaccination testing studies to understand the effect of vaccination on healthcare utilization for chronic medical conditions, mental health care, and antibody production
- Post-vaccination testing studies to understand the effect of vaccination on behavior (e.g., mitigation strategies) and subsequent infection and testing among individuals with and without prior infection
- Effective testing strategies implementable across a range of school/childcare reopening policies and protocols to inform in-person return or maintenance of in-person return to school/childcare settings
- Testing, mitigation, and follow-up protocols for safe school reopening efforts (early childhood education through grade 12), including comprehensive vaccination education programs in school-based settings (including special education settings)

Design, Analysis, and Sample Size for Studies: RADx^{SM}-UP Phase II projects must demonstrate relevance of the scientific questions to COVID-19 among underserved and vulnerable populations. Projects should utilize rigorous research designs (e.g., randomized controlled trials, stepped wedge designs, multiphase optimization strategy (MOST) designs, pragmatic clinical trials, interrupted time series, dynamic wait list design, hybrid effectiveness-implementation designs, sequential multiple assignment trial (SMART) designs, and adaptive designs). Group and individual randomization may not be feasible in nor acceptable to participants in some community-based interventions among populations who experience health disparities or express research distrust. Applicants should use methods that are appropriate given their plans for assignment of participants and delivery of interventions. Projects must describe research strategies that will reflect the evolving landscape and availability of COVID-19 vaccines. Projects must also demonstrate the ability to recruit and retain an adequate number of participants within the specified target populations and include sample size and power calculations. Given the RADx^{SM}-UP goal of population-level impact, projects should also delineate testing as a primary outcome (e.g., COVID-19 test completion). Vaccination uptake and other psychosocial or behavioral variables would be acceptable as secondary outcomes. Additional information is available at https://researchmethodsresources.nih.gov/ (https://researchmethodsresources.nih.gov/).

All projects are expected to demonstrate their ability to leverage existing resources and expand community partnerships (e.g., Tribal governments and agencies, academic, private, safety-net health systems, grassroots organizations, public health departments, community and faith-based organizations, and schools or childcare settings) to complete the study aims, specify strategies or intervention components that address relevant social determinants of health that present barriers to test and vaccination completion and follow-up, and conduct evidence-based outreach and dissemination activities to inform communities about the project and its findings. Approaches such as team science, community-engaged research, participatory action research, and related approaches should be used to engage stakeholders and underserved and/or vulnerable populations throughout the research process. Study budgets should include funds for the community partners to be fully engaged and successfully participate in research design and implementation.

Projects are also expected to specify how the proposed project will: a) address individual, interpersonal, community, psychosocial, and social determinants of health (SDOH) (see https://www.nimhd.nih.gov/about/overview/research-framework/nimhd-framework.html (https://www.nimhd.nih.gov/about/overview/research-framework/nimhd-framework.html) and https://www.phenxtoolkit.org/collections/view/6 (https://www.phenxtoolkit.org/collections/view/6)) that present barriers to participating in testing, follow-up, and retesting; b) create sustainable infrastructures that support rapid deployment of evidence-based approaches to testing, testing follow-up, and referral to treatment delivery or isolation systems; and c) conduct effective outreach, communication, and dissemination activities to inform communities about the project and its findings.

Testing capacity includes access to FDA-authorized or approved test kits and related supplies (including point-of-care testing), and Clinical Laboratory Improvement Amendments (CLIA) certified laboratories (e.g., hospital, public health, or commercial) to administer the tests and return test results as quickly as possible. The proposed (and implemented) COVID-19 testing must be fully FDA EUA or approved. This includes sample collection, assays, and test performance. Strategies to maximize return of test results, plans for follow up, and familial and caregiver testing (when indicated) should consider literacy, health literacy, numeracy, cultural preferences, and language barriers.

To address expected impacts of COVID-19 on the scientific workforce, projects are also strongly encouraged to support early stage investigators, specifically targeting diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html) in their research and practice workforce.

NIH is striving for consistency and high levels of rigor and reproducibility in all research, particularly in programs related to the COVID-19 pandemic. All 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. Projects responding to this funding opportunity are required to collect the NIH RADx[SM]-UP Tier 1 Common Data Elements (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 Form (ICF).

Recipients will work closely with the CDCC on data sharing activities as part of the RADx[SM]-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, allow recruitment and retention of participants, and 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 possible 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 external data sets, such as the Centers for Medicare & Medicaid Services (CMS), electronic health records (EHR), or other identifiable datasets, 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 strongly encouraged to use the following resources for the assessment of other constructs:

Data Harmonization for Social Determinants of Health via the PhenX Toolkit: Investigators involved in human-subject studies are strongly encouraged to employ a common set of tools and resources that will promote the collection of comparable data on social determinants of health (SDOH) across studies. In particular, studies with human participants should incorporate SDOH measures from the Core and Specialty collections that are available in the Social Determinants of Health Collection of the PhenX Toolkit (https://www.phenxtoolkit.org/collections/view/6 (https://www.phenxtoolkit.org/collections/view/6)).

- 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 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/).

- Recipients are required to work with the RADx[SM]-UP Coordinating and Data Collection Center (CDCC) to submit CDEs on COVID-19 testing-related outcomes and implementation to the CDCC. Recipients should identify a dedicated unit responsible for these data reporting activities and at least one dedicated staff member for coordinating and data sharing activities.
- Recipients are expected to obtain and retain personal identifiers on all research participants where it is not prohibited (e.g., Tribal data sovereignty) and where it is possible, for future longitudinal follow-up, to be leveraged for intervention research and for potential linkage to other sources of population health data. 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 appropriate 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 (https://www.nih.gov/research-training/medical-research-initiatives/radx/radx-programs#radx-up) consortium members, as appropriate.
- Recipients must include measures and reporting of relevant testing implementation outcomes, to inform future community, local, state, and federal policies.
- 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.
- Projects must include an evaluation plan demonstrating how the proposed COVID-19 diagnostic testing access and uptake strategies/activities will be assessed for effectiveness and impact.
- Applications must include milestones towards progress and a timeline for completion. The timeline must include plans for regular reports of progress to be submitted to the CDCC and meetings with Community Advisory Boards. These reports will include both testing results and information regarding barriers and facilitators of COVID-19 testing, and vaccination where appropriate, and emerging challenges to implementation of the proposed research.
- As with all NIH supported research, details regarding human subjects research are expected, including data safety and monitoring plans and, if needed, plans for a Data Safety and Monitoring Board (DSMB). Studies that have a DSMB are expected to coordinate with the CDCC (RFA-OD-20-013 (https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-20-013.html)) for DSMB activities.
- Recipients are expected to disaggregate and analyze study results by sex/gender; race and ethnicity; age, a measure of socioeconomic status, birthplace, and other relevant demographic factors, and to consider intersectionality as appropriate.
- 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.

Requests exceeding $750,000 for direct costs in any year

Applicants requesting greater than $750,000 in direct costs in any year (excluding consortium F&A) must submit a request to the NIH for prior approval. Such requests may be considered for approval if the following conditions are met:

1. The applicant(s) will collaborate with one or more investigators from institutions that received no more than an average of $6 million NIH RPG[1] funding (https://report.nih.gov/award/index.cfm) (Total Costs) per year over the fiscal years 2018 through 2020 who may serve as either multi-PI(s) or key collaborator(s) of the proposed study.
2. The applicant(s) agree that no less than 40% of the funds of the award will go to the collaborator institutions(s), that receive no more than $6 million NIH RPG funding.

Eligible applicants for requests exceeding $750,000 in direct costs in any year include the following, and must meet criterion 1 listed above:

- Public/State Controlled Institutions of Higher Education
- 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)
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- Native American Tribal Organizations (other than Federally recognized tribal governments)

The request must be signed by the principal investigator(s), the partner(s), and the AORs of their home institutions and submitted to the scientific contact Lindsey Martin, Ph.D., lindsey.martin@nih.gov, 6 weeks prior to the application due date. After NIH's review, the scientific contact will inform the principal investigator(s) and the AOR(s) of NIH's decision no less than 4 weeks prior to the application due date.

Applications nonresponsive to the 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 without a focus on one or more underserved and COVID-19 vulnerable populations
- Projects that have limited population reach (considering the size of the target populations and its COVID-19 epidemiologic profile)
- Projects that do not demonstrate a relationship with or engagement strategy with the populations of interest
- Projects that involve COVID-19 testing interventions outside of the United States
- Projects that are exclusively qualitative (though mixed quantitative and qualitative are acceptable)
- Projects that do not have an infrastructure to rapidly report study findings and impact to the CDCC
- Projects that have limited testing capacity, that do not include FDA-authorized or approved testing strategies or present a plan to incorporate approved testing strategies
- Project focusing exclusively on vaccination

[1] For the last Fiscal Year noted, research project grants are defined as projects with the following activity codes: DP1, DP2, DP3, DP4, DP5, P01, PN1, PM1, R00, R01, R03, R15, R21, R22, R23, R29, R33, R34, R35, R36, R37, R61, R50, R55, R56, RC1, RC2, RC3, RC4, RF1, RL1, RL2, RL9, RM1, UA5, UC1, UC2, UC3, UC4, UC7, UF1, UG3, UH2, UH3, UH5, UM1, UM2, U01, U19, and U34.

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

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

NIH OD intends to commit $100,000,000 in FY 2022 to fund 25-50 awards.

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

Award Budget

Application budgets in general are limited to $750,000 per year in Direct Costs and need to reflect the actual needs of the proposed project. Application budget requests over $750,000 in Direct Costs for any year must meet the additional criteria described in Section 1.

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:

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

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).

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.

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 Plan 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.

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 Approach 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.

- 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 (mailto: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 this FOA in support of the NIH mission (//grants.nih.gov/grants/guide/url_redirect.htm?id=11149) will be evaluated for scientific and technical merit through an administrative review.

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

In accordance with these 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,

How will successful completion of the aims contribute to or complement public health efforts for the control of SARS-CoV-2 (COVID-19) infection and related pathogenic processes? Will successful completion of the aims reduce COVID related health disparities and enhance overall resilience of underserved populations? Does the proposed research fit within the mission of an emergency response to provide critical expertise, resources, or activities? To what extent can the project contribute to the development and implementation of interventions that address factors associated with COVID-19 testing and vaccination in U.S. populations that experience health disparities? In some small but vulnerable populations, the findings may be highly significant even if they do not apply to the general US population (e.g., Tribal, rural populations).

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 appropriate breadth and inclusiveness of expertise and disciplines (such as for social science, or public health or health disparities expertise)? Does the team include expertise in community-engaged research? Nontraditional indices of competence such as years of experience in the index community or successful delivery of health programs to underserved communities can be considered for community-engaged researchers and community partners.

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, 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,

Does the project propose approaches to integrate social determinants of health disparities causal pathways and related processes in a meaningful, appropriate and culturally sensitive way to improve minority health and/or reduce disparities in COVID vulnerable populations? To what extent do the intervention approaches consider the multilevel and or multi-domain influences to reduce COVID-19 disparities in underserved and vulnerable populations? Is the overall research design compatible with the needs and preferences of the community? Is the emergency timeframe (with milestones) appropriate and feasible to support the aims and goals of the study? Is the management plan well-described and commensurate with the level of complexity required?

- *Community 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?
- *Coordination plans:* How feasible and appropriate are the plans to submit data, data collection instruments and outcomes/products to the CDCC? How feasible and appropriate are the plans to collaborate with other RADx^{SM}-UP sites? Are there plans to explain to participants data sharing and safeguards to confidentiality ?
- *Outcomes:* Will outcomes or products proposed advance and improve acceptability and uptake of COVID-19 testing? How feasible and appropriate are the plans for measures and reporting of relevant outcomes, including assessment of testing implementation outcomes and population measures of COVID-19 related morbidity and mortality? Is there evidence that outcomes of interest to the community are included in the outcomes measured and the products reported?
- *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?
- *Testing:* How feasible and appropriate are the plans for access to FDA-authorized/approved test kits and related activities? How feasible and appropriate are the plans to support follow up testing and contact tracing? Is there evidence of adequate support being provided to the community to fully understand the testing process, especially for self-testing, and act on test results when they are returned to individuals and community members?
- *Post-vaccination testing studies:* How feasible and appropriate are the plans to evaluate access to and the effect of vaccination?
- *Evaluation*: Is the evaluation plan feasible and appropriate? Is the evaluation informed by community input?

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, 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 will be evaluated for scientific and technical merit by an appropriate internal NIH review group using the stated review criteria (file:///C:/Users/mckenziene/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/13V4QPZR/Research%20Draft.doc#_1._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 Program Director(s)/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. Designating Protocol Chairs. The Program Directors/Principal Investigators (for studies involving multiple protocols) shall designate a single Protocol Chairperson (if the Program Director/Principal Investigator does not assume this role) for each protocol to be carried out by the study group. The Protocol Chairperson shall function as the scientific coordinator for the protocol and shall assume responsibility for obtaining approval to implement the protocol from the Steering Committee and for developing and monitoring the protocol. Significant modifications to approved protocols must be approved by the Steering Committee.
4. Ensuring that appropriate Institutional Review Board approvals and certifications for research involving human subjects for all participating sites, collaborators or partners are obtained.
5. Consulting with NIH to ensure compliance with relevant grant policies and regulations
6. Provision of information to the NIH Program Official and NIH Project Scientists.
7. 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.).
8. Management of a dedicated unit responsible for data acquisition, collection, curation and data reporting activities to the CDCC.
9. 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 Data Coordinating Center. Additionally, individual investigators/sites must demonstrate the ability to implement the strategy specifically designed for their individual study population.
10. 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. For research involving multiple sites, a plan for analysis of pooled data will be developed by the Steering Committee.
11. 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.
12. 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.
13. 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.”

14. 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.
15. 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.
16. Study investigators are required to comply with NIH Policy on the Dissemination of NIH Funded Clinical Trial Information as stated athttps://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 athttps://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.

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)
NIH OD plans to make awards using funds provided in the emergency supplemental appropriations for COVID-19 and coronavirus research: “American Rescue Plan Act of 2021 ”. Funds awarded using appropriations provided by the “American Rescue Plan Act of 2021 ” 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 (AM) tool 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)

Judith A. Arroyo, PhD
Telephone: 301-402-0717
Email: jarroyo@mail.nih.gov (mailto:jarroyo@mail.nih.gov)

Wilson M. Compton, MD. MPE
Telephone: 301-443-6480

Email: Wilson.compton@nih.gov (mailto:Wilson.compton@nih.gov)

Tiffani Bailey Lash, PhD
Telephone: 301-451-4778
Email: tiffani.lash@nih.gov (mailto:tiffani.lash@nih.gov)

Lindsey Martin, PhD
Telephone: 984-287-4036
Email: lindsey.martin@nih.gov (mailto:lindsey.martin@nih.gov)

Peer Review Contact(s)

Nick Gaiano, Ph.D.
National Institute of Mental Health (NIMH)
Telephone: 301-827-3420
Email: nick.gaiano@nih.gov (mailto:nick.gaiano@nih.gov)

Financial/Grants Management Contact(s)

For Grants Management Questions Specific to RADx^{SM}-UP:

Brian Albertini
Telephone: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)

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

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

USA.gov (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).