The CDCC is pleased to solicit applications for its **Rapid Research Pilot Program**. This request for applications (RFA) describes the solicitation process for the CDCC Rapid Research Pilot Program. This pilot program provides an expedited funding mechanism (CDCC subawards) to evaluate the feasibility of implementing emerging COVID-19 testing technologies in underserved communities.

The CDCC Rapid Research Pilot Program seeks an applicant pool that draws from the rich diversity of communities, populations, and groups in the U.S including the U.S. territories, tribal nations or organizations (American Indians, Alaska Natives, Native Hawaiians, and Other Pacific Islanders). To this end, we encourage those who are interested in this funding opportunity to review the **FAQ list** and submit any questions not covered in the list to RADx-UPMiniGrant-PilotProgramAdmin@dm.duke.edu.

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Background

Duke University in partnership with the University of North Carolina, Chapel Hill, is serving as the Coordination and Data Collection Center (CDCC) for the National Institutes of Health (NIH)-supported Rapid Acceleration of Diagnostics- Underserved Populations (RADx-UP) program. The goal of the program is to improve access to and uptake of diagnostic COVID-19 testing in communities of underserved and vulnerable populations. The purpose of the overall program is to better understand factors that have led to the disproportionate impact of COVID-19 on these groups, and develop interventions to reduce those disparities. The RADx-UP program has multiple components, which are summarized here.

For the purpose of this RFA, populations that are underserved as well as populations that are COVID-19 vulnerable due to medical, geographic, and social factors, are defined below:

**Underserved:** NIH-designated health disparity populations known to experience barriers to accessing health coverage and basic health care services as well as disparities from COVID-19. A full description can be found here.

**COVID-19 medically and/or socially vulnerable populations:** 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; homeless populations; individuals involved with the criminal or juvenile justice systems (incarcerated or under community supervision); individuals with medical comorbidities known to increase risk of severe COVID-19, including heart failure and related cardiovascular conditions, diabetes mellitus, chronic lung disease, moderate or severe obesity, HIV/AIDS; pregnant and post-partum women; children and adolescents; individuals living in congregate housing such as shelters or residential treatment facilities; individuals in overcrowded or public housing; individuals with substance use disorders or serious mental illness; migrant and immigrant communities; residents of tribal lands or reservations; communities exposed to high rates of air pollution or other toxic exposures; and rural and remote communities.

Applicants to the Rapid Research Pilot Program should be familiar with principles of community engagement. Potential applicants unfamiliar with the principles of community engagement can find some initial information here. Community engagement is defined in the *Principles of Community Engagement Second Edition* as the process of working collaboratively with groups of people who are affiliated by geographic proximity, special interest, or similar situations with respect to issues affecting their well-being. The growing commitment to community engagement is reflected in a number of major federal initiatives, including the Clinical and Translational Science Awards (CTSA) program, and the Research/Centers in Minority Institutions program of the National Institutes of Health (NIH), the CDC’s Prevention Research Centers, and the practice-based research networks of the Agency for Healthcare Research and Quality (AHRQ).
**Purpose**

Evaluation of established as well as new diagnostic tests and their ultimate implementation by communities adversely affected by COVID-19 is critical to reducing the disease burden in the US. Clinicians, the public health community, advocates, policymakers, and the public require reliable, accurate information regarding the accessibility and effective utilization of COVID-19 diagnostic tests in underserved populations. This evaluation includes assessment of facilitators and barriers to utilization of current available tests such as nucleic acid detection, antigen detection, and antibody tests. Important implementation issues will include personal and community factors involved with obtaining and transporting the test, the optimal site and timing of tests, as well as returning information to individuals regarding the meaning of positive and negative test results. Information pertaining to post-test management, including the transmittal of action steps on receipt of a test result, possible isolation, participation in work or school, as well as conformance with local, state, and/or federal reporting requirements is also important. Given the number and variety of vulnerable populations, we anticipate that a range of testing methods will be necessary to understand how to best engage and test individuals in various underserved communities. As the number and types of commercially available tests increase, including point-of-care tests, we anticipate that both accessibility and challenges to their equitable utilization will need to be addressed.

**Project Objectives and Scope**

We anticipate that new tests and testing modalities will become available over the course of the RADx-UP initiative. This Rapid Research Pilot Program is intended to provide an expedited mechanism to assess the feasibility of integrating novel or emerging technologies into RADx-UP in coordination with the NIH-supported RADx initiatives. Applicants should address a number of potential challenges including the following three (3) key areas:

- **Potential barriers to effective testing should be identified and addressed.**
  
  **Specific barriers may include:**
  
  - Requirement of self-collection and self-administered testing versus the availability of a health professional for collection
  - Limited health literacy and ability to understand and interpret test methods, results, and follow up recommendations.
  - Secured return of test results and a requirement of online or digital delivery of test results
  - Test costs and reimbursement

- **Alignment of the testing to the target population, or: is the test method appropriate, accounting for the interests, needs, and beliefs of the underserved community?**

- **Testing workflow and access. Are the tests administered in or outside the home? Are the tests scalable in terms of testing supplies shelf life, storage conditions, and vendor inventories? What are the requirements to report test results?**

The methods supported in this research should include the delivery of clearly described tests and testing strategies to identified populations. Testing must be performed as indicated in laboratories and test settings with CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. Proposals should not be limited to test delivery, but also include evaluation of their uptake and factors such as perceived risk and benefit, understanding of positive and negative results, and role of testing in daily activities. As pilot studies, the proposals should identify the anticipated products and knowledge to be gained, and how those data might be used for future, larger scale research or implementation projects.
All proposals should involve testing or evaluation of testing strategies with engagement of the populations at risk. Public-private partnerships and partnerships with existing NIH Programs, such as the Community Engagement Alliance against COVID-19 Disparities Program (CEAL) are encouraged. To ensure that testing strategies will be appropriate for use in practice with underserved populations, all proposals should also include a community engagement component.

**Proposals considered responsive to this RFA:**
- Prioritize and engage underserved and vulnerable communities
- Include a community engagement approach to ensure mitigation of barriers to access and testing
- Address gaps in testing or the types of communities already included in the RADx-UP program
- Propose SARS-CoV-2 tests with any of the following characteristics:
  - FDA-cleared
  - On-label use with an FDA emergency use authorization (EUA)

**Note:** Off-label use of FDA-cleared/EUA test is not supported by NIH funds.

**Proposals not considered responsive to this RFA include:**
- Proposals involved in the early development of new tests or assays
- Proposed research studies conducted outside the United States or that propose foreign components
- Proposals intending to seek bridge funds or to use this mechanism as a supplement to an existing grant
- Proposals that are exclusively focused on community engagement should apply for the companion engagement Community Collaboration Grant

More information is available in the FAQs.

**CDCC Contact Information**

Overall information regarding the CDCC components of the RADx-UP may be found [here](#). The CDCC will post information regarding upcoming application deadlines on [RADx-UP’s Rapid Research Pilot Program page](#), page. We anticipate up to 4 funding opportunities each year. We will respond to written questions addressed to this email address and post a Q&A document to share responses.

The Frequently Asked Questions (FAQ) will be updated periodically on our website in order to share responses.

**Eligibility**

Eligible organizations are institutions of higher education, industry, state and local governments, and community-based organizations that have the infrastructure to manage such funding. Historically black colleges and universities (HBCUs), tribally controlled colleges and universities (TCCUs), Hispanic-serving institutions, and other minority-serving institutions are encouraged to apply. We are particularly interested in receiving proposals developed jointly with community-based organizations and encourage partnerships across these different types of organizations to form interdisciplinary teams, including public-private partnerships. Applications with multiple PIs (“co-PIs”) must identify one PI as the main contact PI, with primary responsibility for the administrative aspects of the pilot subaward.
Rapid Research Pilot Program Funding

The amount of the subaward for each Rapid Pilot is up to $200,000 in direct costs, to be expended over one year. Applications that involve multiple organizations should include budgets for each organization, with one serving as the sub-awardee and direct recipient of funds from CDCC. To protect the rights and welfare of human subjects, all research projects involving non-exempt human subjects activities require Institutional Review Board (IRB) approval, data and safety monitoring plan (if applicable), and Federal-wide Assurance and certification of human subjects research training prior to release of project funds. All pilot projects deemed greater than minimal risk by their IRB of record require NIH prior approval.

Pilot subawards will not be approved without unconditional IRB approval. Pending IRB approval is expected at time of application submission. To learn more about IRB approval, please read here.

CDCC Support, Oversight and Data Sharing

The CDCC will provide oversight and progress monitoring of subawardees throughout the life of the project. This includes review of study protocols, manuals, and informed consent forms as needed. At the completion of the pilot, subawardees will upload the complete dataset to the CDCC. Submission of a final progress report will be required that includes reporting of analytical results, any abstracts and publications, follow-on grant applications or policy changes resulting from the research conducted.

Data Sharing Language in Consent

To enable data upload to the CDCC, informed consent(s) for pilot projects must include the Data Sharing Language using this template.

Common Data Elements

In order to ensure consistency in data collection and to support rapid data analysis, the NIH is requiring all RADx-UP projects to collect a defined set of Common Data Elements (CDEs). All Rapid Research Pilot Program projects should plan to collect the full set of NIH RADx-UP Tier 1 CDEs.

For more information and complete list of NIH RADx-UP Tier 1 CDEs, please visit the RADx-UP Resource Center.

Review Criteria

Applications should be presented in a clear and logical manner that states the significance of the project and describes proposed approach and methods in sufficient detail to allow for evaluation. Quantitative research and mixed methods are all acceptable. Involvement of a statistician or appropriate analyst should be documented. All proposals will be reviewed by a multidisciplinary study section, including experts engaged in COVID-19 research and diagnostics. The CDCC assembled a group of expert scientists, clinicians, and community members from the RADx programs, academia, industry and community organizations to serve on 3-member review panels. Proposals will undergo an initial administrative review to assure applications are complete and meet the minimum grant requirements, followed by a rigorous scientific review. Review panels will score each proposal according to the NIH 1-9-point standard scale. The funding range may vary for each funding cycle depending on availability of grant funds, number of submitted proposals, and quality of submitted proposals. Written feedback will be provided for proposals within the fundable range.
Review Criteria

Each application will be scored using a 9-point rating scale (1 = exceptional; 9 = poor) in whole numbers (no decimals). The table below provides a detailed description of what each score means.

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<thead>
<tr>
<th>Score</th>
<th>Description</th>
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<tr>
<td>1</td>
<td>High-Exceptional</td>
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<tr>
<td>2</td>
<td>High-Outstanding</td>
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<tr>
<td>3</td>
<td>High-Excellent</td>
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<td>4</td>
<td>Medium-Very Good</td>
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<td>5</td>
<td>Medium-Good</td>
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<tr>
<td>6</td>
<td>Medium-Satisfactory</td>
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<td>7</td>
<td>Low-Fair</td>
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<tr>
<td>8</td>
<td>Low-Marginal</td>
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<tr>
<td>9</td>
<td>Low-Poor</td>
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Applications are addressing a problem of high importance/interest and have few or no weaknesses.

Applications are addressing a problem of high or medium importance/interest but have some critical weaknesses in their aims, approach, research team, feasibility, or overall fit.

Applications are addressing a problem of medium or low importance/interest and have several critical weaknesses in their aims, approach, research team, feasibility, or overall fit.

The following review criteria will be evaluated:

1. **Overall Impact and Innovation**
   - Significance of the work
   - Novelty/innovation of the research idea
   - Relevance of the proposed study to improving access to and effectiveness of COVID-19 diagnostic tests to underserved populations

2. **Research Approach**
   - Fit of the project into the overall RADx-UP project portfolio, which is committed to working with communities that are geographically, racially and ethnically diverse
   - Strength of the research team that is integral to the conduct of the research
   - Scientific rigor of the proposed methods, including feasibility of the testing platform
   - Clear understanding of the barriers to access and testing, and mitigation strategies to overcome the challenges
   - Appropriateness of community engagement plan and recruitment plan
   - Feasibility of accomplishing the stated project goals within the 12-month project period
   - Documentation of availability of the proposed testing technology

3. **Future Potential**
   - Potential for the project to lead to either future implementation projects, research projects, grant opportunities, or insights that will aid in improved utilization of COVID-19 diagnostic testing strategies
   - The potential for broad commercialization and scalability
Application Procedure

Applications must be submitted online here. Application sections (except the Abstract) will be uploaded as individual PDF files. Please include where applicable clear evidence of how the application meets the review criteria (Section VII). Formatting should be 1.5 line spacing, font Arial 11 pt., and 1-inch margins all around. (5-page limit, including tables and figures. References do not count towards the page limit.) The application sections include:

1. **Scientific Abstract**: A summary of the application for use by the CDCC (250-word maximum). Abstracts of funded applications will be

2. **Impact**: Brief description of the likelihood for your project to exert a sustained, powerful influence on the research field(s) involved (50 word maximum).

3. **Research Plan (5 pages)**: The research plan section should include:
   - a description of the proposed Specific Aims (1 page);
   - a Significance and Innovation statement;
   - the Research Approach, including eligibility criteria and participant recruitment plan, the target population, community engagement or collaboration plan, the testing platform including the manufacturer, expected test performance (e.g., sensitivity, specificity, reproducibility), and supplies and reagent requirements and vendor source(s), a description of the testing plan including specimen type, collection method, specimen processing and storage requirements, test turn-around time, transporting requirements, and reporting test results to participants;
   - a discussion describing barriers and mitigation to effective testing and addressing the questions above in section II;
   - a description of the Future/Commercial Potential of the test platform; and
   - a Project Milestone Timeline plan for the 12-month project

4. **Cited References** (No page limit).

5. **Description of the Organization and Environment**: Brief description of the organization(s) that will be conducting the work (one page).

6. **Budget**: Use PHS 398 Form Page 4 (see Section VIII “Budget Guidelines” below for more details). The budget must not exceed $200,000 in direct (F&A) costs are allowable under standard NIH guidelines.

7. **Budget Justification**: Must include sufficient detail for reviewers to assess whether appropriate resources have been requested (see “Budget Guidelines” below). (No page limit).

8. **Timeline**: Should cover the 12-month funding period. The CDCC and the NIH expect all funds to be expended within one year of the initiation of the projects, which will occur when IRB approval has been received by the IRB of record, other human subjects requirements have been met, and Duke University’s cooperative agreement Notice of Award from NIH indicates approval of the projects. Multi-year projects are discouraged and will require approval by the CDCC RP2 Selection Committee and the NIH.

9. **Human Subjects**: Confirmation of local Institutional Review Board (IRB) approval or the date of anticipated IRB review. In addition, the application should briefly describe any potential human subjects issues. Provide assurance that the project will be reviewed and approved by an IRB, use a single IRB if the project is multicenter, and comply with HIPAA and other human subjects research requirements. Please note that IRB approval from the IRB of record is required for project initiation. (No page limit).

10. **NIH Biosketches or brief (5-page)** curriculum vitae/resumes for the key members of the research team. Biosketches/brief resumes are not required for staff members such as research assistants (see here for the NIH Biosketch form and examples).

11. **Letters of Collaboration (if applicable)**: Letters of Collaboration may be included if they clearly state a commitment of resources required for the project’s success, such as assistance by a partner organization in participant recruitment. Generic letters of support are neither required nor encouraged. (No page limit).
12. Resubmission Summary (if applicable): The CDCC does permit one resubmission to a future funding cycle. Resubmission applications should include a summary that details changes to the original application. Applicants are limited to two submissions (an original submission and one resubmission to a different funding cycle) for a given research project. The Resubmission Summary is in addition to the research plan, but is limited to 2-pages, with 1.5 line spacing, 1-inch margins, and font no smaller than Arial.

13. Appendix materials are not permitted beyond examples of qualitative interview protocols, focus group protocols, or surveys to be used for proposals involving research. Applications with other appendix materials will not be reviewed.

You can access a sample of the complete submission packet here.

Budget Guidelines

1. The Rapid Research Pilot Program budget covers subawardee expenditures up to $200,000 in direct costs for a 12-month period. For studies determined as ‘no greater than minimal risk’ by the institution’s IRB of record, the budget period will begin when applicable IRB approval has been received, other human subjects requirements have been met, and the aforementioned compliance and administrative documentation is in order so Duke University can submit the completed document package to the NIH. For studies determined as ‘greater than minimal risk’ by the institution’s IRB of record, the budget period will begin when applicable IRB approval has been received, other human subjects requirements have been met, and NIH has completed its compliance review of the document package and provided approval of the project.

2. If the PI is not ready to start within 4 months of an offer of subaward funding, the CDCC reserves the right to withdraw its offer. The expectation is that all subaward funds will be expended by the end of the subaward’s project period. At the end of the 12-month project period, any unexpended funds will be retained by the CDCC to be used in other pilot subawards. Indirect (F&A) funds will be awarded in accordance with NIH policy.

3. Approved expenses will follow NIH guidelines. Pilot grant funds may be budgeted for (1) research support of personnel, (2) use of services, including, where applicable, salary support for investigators, biostatisticians, study staff or other experts, (3) travel necessary to perform the research, (4) equipment (< $5k without prior approval), research supplies and reagents, and lab costs, (5) participant compensation, (6) other study-related expense with relevant justification, and (7) publication.

4. Pilot grant funds may not be budgeted for (1) travel to scientific meetings, or (2) meals (except during focus groups and other data collection/informational sessions and in accordance with NIH policy).

Other Guidelines

1. Awardee must receive IRB approval from their IRB of record within 4 weeks of being notified that they have been selected by the RP2 review and selection committee unless alternative timing is arranged with the CDCC; provisions may be made for awardees seeking approval through Tribal Council. Pilot subawards that are unable to receive unconditional IRB approval within this timeframe may have the offer withdrawn.

2. If a principal investigator leaves their position, they should immediately contact the CDCC to initiate close-out procedures or determine if the work can proceed under new leadership with appropriate documentation (e.g., investigator biosketch, updated IRB approval including informed consent form, amended contract, etc.).
Submission Instructions

RADx-UP CDCC Rapid Pilot Program applications will be solicited up to 4 times per year. Applications will be accepted online here. Applications are due by 5:00pm ET on the due date. After submitting the application, applicants will receive email confirmation that the application was received. It is expected that applicants will be notified within approximately 12 weeks of the submission deadline of a funding decision.

Terms and Conditions

Chapter 15 of the NIH Grants Policy Statement, available here, includes the requirements for the recipient under consortium agreements in which the recipient collaborates with one or more other organizations in carrying out the grant-supported research. Duke University, as the direct and primary recipient of NIH grant funds, is accountable to NIH for the appropriate expenditure of grant funds and applicable reporting requirements, among other things, as specified in the NIH Grants Policy Statement (NIHGPS). In general, the requirements that apply to the recipient, including the intellectual property requirements in Part II Subpart A and the program income requirements of the award, also apply to consortium participant(s). Exceptions are noted in Chapter 15. Duke University will include the applicable requirements of the NIHGPS in its agreements with collaborating organizations (see Written Agreement in Chapter 15), which are incorporated herein by reference.