Rapid Research Pilot Program

Informational Slides
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Purpose:
- Provide an overview of the RADx initiative, RADx-UP, and the Coordination and Data Collection Center (CDCC)
- Provide an overview of the Rapid Research Pilot Program

Target Audience:
- Potential Rapid Research Pilot Program applicants
NIH RADx Initiative and RADx-UP
Welcome from the NIH!

The NIH RADx-UP CDCC Team

- Dottie Castille, PhD, Program Officer
- Beda Jean-Francois, PhD, Co-Program Officer
- Fabienne Santel, MD, MPH, COVID-19 Testing Core Project Scientist
- Nadra Tyus, Dr.PH, MPH, Community Engagement Core Project Scientist
- Partha Bhattacharyya, PhD, Data Science & Statistical Core Project Scientist
## RADx Overview

<table>
<thead>
<tr>
<th>Project</th>
<th>Description</th>
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<tbody>
<tr>
<td>RADx Tech</td>
<td>Highly competitive, rapid three-phase challenge to identify the best candidates for at-home or point-of-care tests for COVID-19</td>
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<tr>
<td>RADx-Advanced Testing Program (RADx-ATP)</td>
<td>Rapid scale-up of advanced POC technologies to accelerate and enhance and validate throughput – and support of ultra-high throughput machines and facilities</td>
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<tr>
<td>RADx-Radical (RADx-rad)</td>
<td>Develop and advance novel, non-traditional approaches or new applications of existing approaches for testing</td>
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<tr>
<td>RADx-Underserved Populations (RADx-UP)</td>
<td>Interlinked community-engaged projects focused on implementation strategies to enable and enhance testing of COVID-19 in underserved and/or vulnerable populations</td>
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</table>
Rapid Research Pilot Program
Purpose

• 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?
Eligibility

• Eligible Organizations
  • Institutions of Higher Education
  • Industry
  • State and Local governments
  • Community-based organizations
  • Historically black colleges and universities (HBCUs)
  • Tribally controlled colleges and universities (TCCUs)
  • Hispanic-serving institutions
  • Other minority-serving institutions

• Eligible Investigators
  • Applicants should have sufficient skills and experience to lead the work they are proposing.
Funding

- Multiple opportunities for application a year
- Covers expenditures of up to $200,000 in direct costs for a 12-month period
- Budget period will begin after applicable IRB approval has been received, other human subjects requirements have been met, and Duke University’s Notice of Award from NIH indicates approval of the project.
- May be budgeted for
  - support personnel
  - use of contract services, including, where applicable, salary support for investigators, biostatisticians, study staff or other experts
  - equipment (< $5k without prior approval)
  - research supplies and reagents, and lab costs
  - participant compensation
  - other purposes deemed necessary for the successful execution of the proposed project.
  - publication

- **May not be budgeted for**
  - travel to scientific meetings
  - meals (except for community discussions or informational sessions and in accordance with NIH policy)
Key Funding Considerations

- Projects serving **underserved and vulnerable communities** not currently engaged with existing RADx-UP awardees (see [www.radx-up.org](http://www.radx-up.org))
- Projects **collaborating with awardees of the NIH Community Engagement Alliance (CEAL) Against COVID-19 Disparities program** ([https://covid19community.nih.gov/about](https://covid19community.nih.gov/about))
- Organizations with a **track record of outreach and service** to underserved and vulnerable populations.
- Projects **partnering with existing RADx-UP awardees** who may be able to assist mini-grant sub-awardees with their outreach and communication, testing, and data collection and dissemination strategies.
- An **evaluation component** is encouraged to identify critical barriers and the best strategies for removing these barriers to facilitate COVID-19 communication and outreach, COVID-19 testing, and COVID-19 testing data collection and dissemination.
Underserved Populations

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

- Blacks/African Americans
- Hispanics/Latinos
- American Indians/Alaska Natives
- Asian Americans
- Native Hawaiians and other Pacific Islanders
- Socioeconomically disadvantaged populations
- Underserved rural populations
- Sexual and gender minorities
Covid-19 Vulnerable Populations

- Residents of nursing homes and assisted living facilities;
- community-dwelling older adults;
- individuals with intellectual, developmental, sensory, or physical disabilities,
- Individuals with cognitive impairment or dementia, or communication disorders;
- homeless populations;
- individuals involved with the criminal or juvenile justice systems;
- individuals with medical comorbidities known to increase risk of severe COVID-19,
- 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.
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-authorized
  - On-label use with an FDA emergency use authorization (EUA)
  - Off-label use with an FDA emergency use authorization (EUA) that is compared against a reference standard or standard-of-care
  - Laboratory developed test (LDT) with the appropriate validation under CMS CLIA program applied to a unique population
  - Validation of new Laboratory developed test (LDT) methods against current reference standard or standard-of-care under CLIA waiver
- Note: All aspects of the testing process must have an EUA and be processed under CLIA certified conditions. If a project proposes to use an emerging test (and/or process) that does not have an EUA, the test results would have to be confirmed using a test with EUA authorization and participants would have to be made aware that they’re submitting to both tests. The purpose of this confirmatory process is to avoid a situation in which an experimental test is conducted among underserved and vulnerable individuals, and there is no confirmation or return of results to study participants.
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
Application Process

• Applications must be submitted online through the NC TraCS system

• Application sections (except the Abstract and Impact) will be uploaded as individual PDF files
Required Documents Overview

- **Abstract** (250 word maximum)
- **Overall Impact** (50 word maximum)
- **Approach** (1.5 line spacing, font Arial 11 pt., and 1-inch margins all around)
- **Cited References** (No page limit)
- **Description of the Organization and Environment** (250 words)
- **Budget** (Use PHS 398 Form Page 4)
- **Budget Justification** (No page limit)
- **Timeline**
- **NIH Biosketches or Brief curriculum vitae/resumes** (5-page max)
- **Letters of Collaboration** (if applicable)
Impact and Research Plan

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

• **Research Plan:** The research plan section should include:
  • a description of the proposed Specific Aims;
  • 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
  • and a Project Milestone Timeline plan for the 12-month project
Human Subjects

• Although Institutional Review Board (IRB) approval is not required at time of submission, the application should briefly describe any human subjects issues.

• Within 4 months of a conditional subaward offer, and prior to receiving funds, research involving human subjects must have appropriate approvals from an IRB, other human subjects requirements met, and NIH approval indicated in Duke University’s Notice of Award.
Budget

- See page 26 of the pdf U.S. DHHS Public Health Service Grant Application (PHS 398) (nih.gov) for detailed budget instructions
- **Direct Costs Include**: Personnel, Consultants, Equipment, Supplies, Travel, Inpatient Care, Outpatient Care, Alternations and Renovations, Other Expenses (e.g., Contracted Services), Consortium/Contractual Costs.
- **Indirect Costs include**: Negotiated Facilities and Administrative Costs (F&A). If your organization does not have a negotiated F&A rate with NIH, then the default NIH F&A rate is 10% of Direct Costs.

**Direct costs cannot exceed $200,000.**
Budget Justification

• Include sufficient detail for reviewers to assess whether appropriate resources have been requested. For example,
  
  • **Personnel**: Name, role on project, calendar months of salary support, and fringe benefits
  • **Consultants**: Describe the services to be performed, the number of days of anticipated consultation, the expected rate of compensation, travel, per diem, and other related costs.
  • **Equipment**: Itemize tangible property that costs $5000 or more
  • **Supplies**: Purchases costing less than $5000 (e.g. software, computer equipment)
  • **Other Expenses**: These might include contract services from outside vendors (e.g. translation costs).

• Transfer of funds from the sub-awardee organization to subcontractors should be described. If new subcontracts are anticipated after the mini-grant has started, permission of the CDCC is needed.

• 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).
**Example Timeline**

- Clearly lay out what you will work on and accomplish in each month to implement your project during the 12-month project period.

<table>
<thead>
<tr>
<th>MONTHLY GOALS/STEPS</th>
<th>M1-M3</th>
<th>M4-M6</th>
<th>M7-M9</th>
<th>M10-M12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1: What will you do in the first 3 months?</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Step 2: What will you do in months 4-6?</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Step 3: What will you do in months 7-9?</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Step 4: What will you do in months 10-12?</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
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What to Expect After You Apply

• Once your application is submitted, you will receive an email confirming receipt.

• Each grant will be reviewed by a three-person panel with expertise in Covid-19 testing and community engagement.

• Within approximately 6-8 weeks after receipt of their application, applicants will be notified by email whether their application has been selected for funding.

• At any point during the process, please do not hesitate to reach out to the CDCC with questions or concerns at

  RADx-UPMiniGrant-PilotProgramAdmin@dm.duke.edu
Questions, Concerns & Answers

Visit https://radx-up.org/apply-for-grant/#pilotfaq for a repository of questions asked & answered.

Please email all questions regarding the research pilot programs to RADx-UPMiniGrant-PilotProgramAdmin@dm.duke.edu