Request for Application

New Jersey Alliance for Clinical and Translational Science: NJ ACTS

BERD Mini-Methods Grant Program
Year 2

Funding Opportunity Purpose:

The purpose of this RFA is to solicit applications for mini-methods grants from investigators in Rutgers University, Princeton University and New Jersey Institute of Technology.

Release Date: March 16, 2020

Application Deadline: May 15, 2020

Award Notification: June, 2020

Earliest Start Date: Dependent on NIH/NCATS approval

Overview of the Mini-Methods Grant Program

NJ ACTS is an NIH Clinical and Translational Science Awards Program (CTSA) partnership between Rutgers, Princeton University and New Jersey Institute of Technology (NJIT). The Biostatistics, Epidemiology, and Research Design (BERD) core of NJ ACTS is pleased to announce a funding program to encourage and support methodological innovations for clinical and translational research.

The Mini-Methods-Grant program offers one-year awards of up to $25,000 to investigators developing methodology in study design, measurement, statistical analysis, and approaches to the integration of quantitative and qualitative data analysis (i.e., mixed methods) relevant to translational research. The methodologic developments should have the potential for implementation by other researchers (i.e., it should not be methods that are particular to a single lab). Funding priority will be given to grant applications that: (1) develop innovative measurement and/or analytic methods that identify disparate patterns of disease or identify factors that might be key in leading to differential responses to therapy; (2) solve health challanges encountered by existing translational research projects within NJ ACTS; and (3) demonstrate the potential for future independent funding. We especially encourage proposals that (4) relate to studies being undertaken by TL1/KL2 trainees with methodological challenges and/or (5) include researchers from two or more of the participating institutions (Rutgers, Princeton, and NJIT).

The program is distinct from that of the CTSA Pilot Grant Program.

Criteria

The primary criteria for evaluating the proposals are:
- Scientific merit, including importance of the measurement and/or analytic gap addressed by the approach.
- Potential future impact on clinical and translation research as they relate to health challanges.
- Potential for future independent external funding.
- Evidence of interdisciplinary collaborations, preferably involving multiple participating institutions and related to TL1/KL2 trainee research.
- Feasibility of the work being successfully completed within the timeframe. (Cost extensions will not be permitted.)

The BERD Advisory Council of the Rutgers University Biostatistics and Epidemiology Services Center (RUBIES) will submit its recommendations to NCATS, which will make the final funding decision.

Application Process

Eligibility:

The competition is open to all investigators at Rutgers, Princeton University, and NJIT who are eligible to apply for external funding with principal investigator status through their home institution. Awards are not available for international projects.

Application Submission:

All application materials must be submitted by the deadline to:
Jennifer Zabala (zabalaje@sph.rutgers.edu)

Subject line should be: [Contact PI Name]-Application to the Mini-Methods Grant Program.

Institutional Review Requirement:

NJIT
For any NJIT participants for pilot project proposals they must go through the normal proposal preparation and submission protocols, including adhering to the NJIT proposal timeline and guidelines requirements by working with their assigned College director and using Streamlyne for internal documentation and approvals for budget and compliance checks.

Princeton
Princeton **does not** require internal review by the Office of Research and Project Administration (ORPA) as this is an internal award. Submissions should be coordinated through your Departmental grants staff.

Rutgers
This is an internal application and **does not** require review by Rutgers Office of Research and Sponsored Programs (ORSP).

The application may require approval of the Dean/Chair of the Co-PIs based on school/departmental policy or if the project involves in-kind support.

Application Requirements:

The Application Form should be in one pdf, and all other materials should be in a single pdf in the order stipulated below and in the Application Form.

To be considered complete, a proposal **must** contain the following elements in this order:

	Page Limit
NJ ACTS Mini-Methods Grant Form	Fillable PDF
Additional elements to be submitted as a single PDF in this order:	
Research Strategy	6 pages
• Project Abstract	Up to ½ page
• Specific Aims	Up to ½ page
• Background/Preliminary Data	Up to 2 pages
• Research Plans	Up to 3 pages
How will funding lead to independent or sustainable funding?	Up to 1 page
Project Timeline by month	Up to 1 page
Selected references	As needed
If the project involves human subjects, prepare a "Protection of Human Subjects" attachment as outlined by NIH, addressing: 1.the risks to subjects; 2.the adequacy of protections against risk; 3. potential benefits of the research to subjects and others; and 4.the importance of the knowledge to be gained; 5.for clinical trials, data and safety monitoring plan, Include planned enrollment form.	As needed
If project involves vertebrate animals, follow the directions at: NIH Worksheet for Applications Involving Animals	As needed
Resources and Environment	Up to 1 page
Other Support	As needed
Detailed Budget (NIH PHS 398)	As needed for each PI/Institution
Budget Justification	As needed
Key personnel biosketches	Up to 5 pages each
Letters of support from affiliates, partners, or others	Up to 1 page each
Additional Documents Required from Other CTSA Hubs	
• Detailed Budget (NIH PHS 398)	As needed for each PI/Institution
• Budget Justification	As needed
• Scope of Work	As needed
• Rutgers Subrecipient Commitment Form	If awarded

Candidates MUST use the application and budget templates.

Font and Margin Requirements: 0.5" margins and Arial 11 Font

Budget Guidelines:

We strongly recommend that you prepare your budget with the support of your department or unit's budget/financial administrator.

- Project period is one year.
- Maximum allowable expenditures: $25,000
- PI effort: Effort levels for each co-PI must be specified.
- Applicants may not request salary support for themselves or Co-PIs; salary support is allowable for staff, postdocs, and students.
- Name, title/role, percent effort, salary and benefits for each participant must be provided.
- Supplies and other costs should be itemized in detail by type and number in the budget and budget justification.
- Equipment requests and service contracts must be detailed in the budget and budget justification; quotes must be attached.
- If two or more NJ ACTS institutions are involved, complete a budget for each institution and a cumulative budget page. Budgets should clearly show what project costs will be expended at each institution.
- Facilities and Administration costs are not permissible.
- In-Kind support is permitted and requires School Dean/Department Chair approval.
- Foreign subcontracts are not permitted under this mechanism, and research at foreign sites will require prior approval by NCATS.

Regulatory Approvals:

- **All Pilot Projects require approval of the NIH/NCATS prior to award of funds from NJ ACTS.**
- Prior to NCATS approval, each project must demonstrate it has met regulatory requirements for human and animal research. Each awardee will be required to meet with Casandra Burrows to review the NIH/NCATS compliance requirements.

Requirements Include:

- Awardees must obtain all regulatory approvals (e.g. IRB, IACUC, or Radiation Safety) and meet all compliance requirements prior to receiving funds and maintain approvals during the entire length of the award.
- Projects that involve human subjects research or live vertebrate animals require additional **approvals by NIH/NCATS** before an award can be made. The project **MUST** have IRB or IACUC approval **prior** to submitting to NCATS for its approval. **Therefore, all applicants are urged to seek IRB or IACUC approval concurrent with the submission of the pilot application.**
- When you apply for IRB/IACUC approval, indicate that your research is supported by NJ ACTS: Award number UL1TR003017, Funding source: NIH/NCATS
- You must keep your IRB/IACUC approval(s) current and active for the

duration of the award period. Copies of the approval letters need to be sent to the NJ ACTS Pilots Program Administrator at NJACTS@rbhs.rutgers.edu.

- If your project is an NIH-defined clinical trial (see below), you must register your project and report results on clinicaltrials.gov.

NIH Clinical Trial Definition
A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes

NCATS Prior Approval:

NCATS, the NIH Center that manages the CTSA program, requires that all pilots receive its approval prior to award activation. If the project involves humans or vertebrate animals, the project MUST have IRB or IACUC approval prior to submitting to NCATS for its approval. Therefore, all applicants are urged to seek IRB or IACUC approval concurrent with the submission of the pilot application.

No federal funds may be spent prior to the completion of NCATS review. The actual start dates will be dependent on the NCATS approval process, which can take 30+ days.

We will communicate with each successful pilot proposal PIs about the NCATS requirements once the selection process is completed.

Attached for your information is a table showing the required NCATS Prior Approval Requirements.

Budget and Financial Management:
- Funds must be spent according to the approved budget. Prior approval is required to amend the budget.
- If you wish to amend your budget, send a copy of the original budget and the proposed amended budget with a justification for the budget changes to the BERD Mini-Methods Grants Administrator zabalaje@rutgers.edu.
- If your project runs over budget or you charge something that is not allowable, you/your department/school are responsible for the charges and will be asked to provide an alternate project number for those costs.

Reporting Requirements:
- A final report is required for all awards.
- Failure to submit a progress report will result in the grant's being terminated.
- Co-PI's with outstanding final reports will not be allowed to compete for any other pilot program.
- Co-PI's will be expected to complete an annual report that summarizes

abstracts, presentations, publications, and proposals/funded awards that resulted from the BERD Mini-Methods Grant Program. This is required for the NJ ACTS grant renewal reporting and evaluation functions.

Award Recognition:
- Any publication or patent that results from this funding must reference:
    - "Supported (in part) by the New Jersey Alliance for Clinical and Translational Science"
    - "Research reported in this publication was supported by the National Center for Advancing Translational Sciences (NCATS), a component of the National Institute of Health (NIH) under Award Number UL1TR0030117. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH."

Other Notices:
- Abstracts and names of Co-PIs will be posted on the NJ ACTS website, and may be posted or submitted to the national CTSA website.
- Awards are not transferable or renewable.

Proposal Review:

Proposals will be reviewed by the BERD Advisory Council.

Questions/Inquiries:
For questions about the BERD mini-methods-grant program, you may contact Jason Roy (jason.roy@rutgers.edu) or Perry Halkitis (perry.halkitis@rutgers.edu), BERD Co-Directors