Request for Application

The NJ ACTS Pilot Program

Funding Opportunity Purpose:

The purpose of this RFA is to solicit pilot project applications from investigators in Rutgers University, Princeton University and New Jersey Institute of Technology.

Release Date: June 4, 2019

Application Deadline: July 15, 2019

Award Notification: August 15, 2019

Earliest Start Date: Dependent on NCATS approval

Overview of the NJ ACTS Pilot Programs

One of the major objectives of NJ ACTS is to successfully translate biomedical discoveries to clinical applications by promoting creative and innovative science, which often requires pilot support for hypothesis generation and/or for team building to address questions in translational science. The NJ ACTS Pilot Program offers pilot grants to foster collaborative research among faculty in three institutions: Princeton University, New Jersey Institute of Technology (NJIT) and Rutgers University. We expect that the NJ ACTS Pilot Program will increase collaborative research and provide a path to sustainable, extramurally-funded independent research across the alliance.

The Pilot Program supports team research to promote novel approaches and methodologies in translational medicine and science, to foster interdisciplinary research to generate or test novel hypotheses, create partnerships that leverage in-kind partner support, and to inspire new methodologies to evaluate and assess NJ ACTS/CTSA Hub processes to improve outcomes.

NJ ACTS will commit a total of $400,000 this year to support pilot programs in the areas outlined below. The number of awards per category is flexible and will depend on the quality of the applications submitted in each category. NJ ACTS will evaluate all applications and submit its recommendations to NCATS, which will make the final funding decision.

1. Translational and Clinical Sciences Awards

For projects along the T0-T4 continuum that focus on novel aspects of the heterogeneity of disease and response to therapy. Proposals embracing community engagement and diversity research are encouraged. The projects must demonstrate clinical relevance.
Budget Request: up to $60,000
Anticipated Number of Awards: 3

2. Methodological and Infrastructure Awards

For projects that advance our ability to conduct translational research by developing novel methodologies or creating new infrastructure resources. Proposals embracing community engagement and diversity research encouraged. The projects must demonstrate clinical relevance.

Budget Request: up to $40,000
Anticipated Number of Awards: 2

3. Propel Awards

For projects that allow investigators to explore new areas or augment studies in high risk/gain manner by supporting novel ideas, new technologies, new research methods, pilot clinical data acquisition, licenses to databases, and purchase of small equipment or data sets. Proposals embracing community engagement and diversity research are encouraged. The projects must demonstrate clinical relevance.

Budget Request: up to $20,000
Anticipated Number of Awards: 2

4. Valued Partnership Grants

For projects that support team research and build liaisons with key partners in industry, government, other CTSA Hubs and/or insurance companies. Must leverage NJ ACTS support with partner in-kind services/funding. In kind contribution can include specialized data analyses, access to equipment, imaging, genomic or epigenetic testing, proprietary database access, etc. Proposals must include a detailed description of the in-kind support, and a letter of support from the partner institution.

Budget Request: up to $25,000
Anticipated Number of Awards: 2

5. Novel Approaches to Evaluation of and Benchmarks for CTSA Hubs

For projects that use state-of-the-art approaches to conduct systematic needs assessments, program evaluation, tracking studies and outreach analysis concerning translational research and science within a CTSA Hub. These projects will use an interdisciplinary team to establish benchmarks and metrics of success regarding specific CTSA outcomes. Provide comparative effectiveness assessments to inform CTSA Hubs of the most productive and cost effective paths to conduct translational research in consortia. Partnerships with other CTSA Hubs are welcomed. A detailed description of deliverables related to the evaluation of CTSA processes are required.

Budget Request: up to $25,000
Anticipated Number of awards: 2

Application Process

Eligibilities:

- Co-PIs must be faculty at Rutgers, Princeton or NJIT. Each project **must** have at least **2 Co-PIs**, representing **different NJ ACTS institutions;** for a Valued Partner **or** Benchmark/Evaluation grants, the Co-PI may be at the partner institution (Other CTSA Hub, industry, etc).
- Faculty members at all ranks are eligible. Junior faculty members are especially encouraged to apply.
- Clinical studies beyond Phase IIB are not allowed.
- Applicants may submit applications for different pilot grant categories provided that each project is different. Applicants may not submit identical projects to multiple pilot funding categories.

Application Submission:

All application materials must be submitted by the deadline to:
NJACTS@rbhs.rutgers.edu.

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

This is an internal application and **does not** require review by Rutgers Office of Research and Sponsored Programs (ORSP). Princeton and NJIT may have different requirements.

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 Pilot Application Form	Fillable PDF
Program Specific Form, if applicable	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 Pilot Program 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
Co-PI's NIH-formatted biosketch	Up to 5 pages
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:

- Project period is one year.
- Each pilot program has individual maximum allowable expenditures.
- 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.
- As these projects require involvement of at least two NJ ACTS institutions, 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:
- 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 will also need **prior approval 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:
    o Award number UL1TR003017
    o 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. Accordingly, while we expect to announce awards around August 15th, 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 NJ ACTS Pilots Program Administrator at BJACTS@rbhs.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 NJ ACTS pilot grant. 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:
  o "Supported (in part) by the New Jersey Alliance for Clinical and Translational Science"
  o "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.

<u>Proposal Review:</u>

Proposals will be reviewed by the NJ ACTS Pilot Project Management Committee, co-chaired by Chen Liu, MD, PhD of RWJMS/NJMS, Yael Niv, PhD of Princeton University and Reggie Caudill, PhD of NJIT.

<u>Questions/Inquiries:</u>

For Inquiries, please email: NJACTS@rbhs.rutgers.edu.