



## **Request for Applications**

**The New Jersey Alliance for Clinical Translational Science**

**NJ ACTS Pilot Program Year 3**

### **Funding Opportunity Purpose:**

This RFA solicits pilot project applications from investigators at Rutgers University, Princeton University and the New Jersey Institute of Technology.

**Release Date:** February 19, 2021

**Pre-submission Webinar:** March 2, 2021 from 5:00-6:00 pm.

<https://rutgers.zoom.us/j/9895789739?pwd=WVBydGVtNlgxdlpodncxRVU5cS9Sdz09>

**Letter of Intent Deadline:** March 19, 2021 (required)(midnight)

**Application Deadline:** April 16, 2021 (midnight)

**Award Notification:** TBD

**Earliest Start Date:** Dependent on regulatory approvals and when required, NIH/NCATS approval

## Table of Contents

<b>New for Year 3</b>	<b>3</b>
<b>Overview of Pilot Program</b>	<b>4</b>
<b>Partnership/Collaboration Requirements</b>	<b>6</b>
<b>Identifying Collaborators/Partners</b>	<b>7</b>
<b>Application Process</b> <ul style="list-style-type: none"><li>• Eligibility</li><li>• Letter of Intent</li><li>• Application Submission</li><li>• Institutional Review</li><li>• Requirements</li><li>• Application Requirements</li><li>• Budget Guidelines</li><li>• Regulatory Approvals</li><li>• NCATS Prior Approval</li><li>• Proposal Review</li></ul>	<b>8</b>
<b>Post-Award Management</b> <ul style="list-style-type: none"><li>• Budget and Financial Management</li><li>• Award Recognition</li><li>• Other Notices</li></ul>	<b>13</b>

## New for Year 3

1. **Mandatory Letter of Intent:** All applicants are required to submit a letter of intent. See page 8 for details regarding what must be submitted and a link to the on-line form.
2. **Pre-submission Webinar:** The leaders of the Pilot Program will host a webinar to explain the categories of funding, proposal requirements, regulatory requirements and NIH/NCATS approval processes, and to answer questions from participants.
3. **Changes to Funding Categories since last year's RFA:**
  - Translational and Clinical Sciences: No changes
  - Methodological and Infrastructure:
    - Funding increased from \$40,000 to \$50,000
    - Partnership encouraged/preferred but not required
  - Propel:
    - Funding increase from \$25,000 to \$50,000
    - Co-funding by the New Jersey Health Foundation
  - Valued Partnerships: No changes
  - Novel Approaches to Evaluation and Benchmarks for CTSA Hubs:
    - This category is being suspended for Year 3

# Overview of the NJ ACTS Pilot Programs

NJ ACTS, the New Jersey Alliance for Clinical and Translational Science, is committed to advancing clinical and translational science to develop new therapies and preventive approaches in order to improve health and health care in New Jersey. NJ ACTS is supported in part by a Clinical and Translational Science Award (CTSA) grant, from the National Center for Advancing Translational Science (NCATS) of the National Institutes of Health (NIH).

One of the major objectives of NJ ACTS is to successfully translate biomedical discoveries to clinical applications by promoting creative and innovative science, and by providing pilot support for hypothesis generation and testing, and building teams 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.

NJ ACTS will commit up to \$640,000 this year. The program is funded through the generous support of the NIH CTSA Award, the New Jersey Health Foundation (NJHF), and each of the academic partners.

The Pilot Program supports team and collaborative research to promote novel approaches and methodologies in translational medicine and science, to foster interdisciplinary research to generate and/or test novel hypotheses, create partnerships that leverage in-kind partner support, and to support high-risk/high-reward innovative projects. These projects are expected to provide key preliminary data for sustained extramural funding.

The funding will be used 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 entire range of the translational science continuum (T0-T4), including laboratory-based, clinical, health services, epidemiology, community engagement and diversity research. Proposals that focus on novel aspects of the heterogeneity of disease and response to therapy are encouraged. The projects must demonstrate potential for clinical relevance. Applications require Co-PIs from two or more NJ ACTS Partners (Rutgers, NJIT or Princeton). These awards, which are partially supported by New Jersey Health Foundation, may be eligible for follow-on funding from NJHF.

Budget Request: up to \$110,000

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 along the entire range of translational science, including laboratory-based, clinical, health services, epidemiology, community engagement and diversity research are encouraged. The projects must demonstrate potential for clinical relevance.

Applicants are encouraged, but not required to find a partner at a second NJ ACTS institution. Weight will be given to multiple factors, including the merit of the proposal, likelihood of future funding, and potential for current or future collaboration with another NJ ACTS institution.

Budget Request: up to \$50,000

Number of Awards: 2

## **3. Propel Awards**

The Propel Awards, the NJ ACTS equivalent of a high-risk, high-reward grant program, are designed to allow extraordinarily promising projects to explore new areas, augment studies, or pursue major new opportunities.

They catalyze scientific discovery by supporting proposals to explore novel ideas, adding new technologies or research methods to a project (such as developing innovative laboratory correlates of clinical studies; e.g. single cell RNA sequencing, etc.), enable clinical data acquisition, purchase of small equipment or licenses to data sets. The projects must demonstrate clinical relevance. Applicants are encouraged, but not required to find a partner at a second NJ ACTS institution (Rutgers, NJIT or Princeton). These awards, which are partially supported by New Jersey Health Foundation, may be eligible for follow-on funding from NJHF.

Budget Request: up to \$50,000

Number of Awards: 2

## **4. Valued Partnership Grants**

For projects that support team research and build liaisons with key partners in industry, government, non-profits, other CTSA's and/or insurance companies. These projects must leverage NJ ACTS support with partner in-kind services or funding. In-kind contribution can include specialized data analyses, access to equipment, imaging, genomic or epigenetic testing, proprietary database access, staffing, etc. Proposals must include a detailed description of the in-kind support, and a letter of support from the partner organization. Applications require Co-PIs from industry, government, health care, community, non-profits, insurance companies, or other CTSA Hubs. These awards, which are partially supported by New Jersey Health Foundation, will be eligible for follow-on funding from NJHF.

Budget Request: up to \$50,000

Number of Awards: 2

## NJ ACTS Collaboration and Partnership Requirements

**This chart summarizes the partnership/collaboration requirements for the  
NJ ACTS Pilot Grant Program**

<b>Grant Program</b>	<b>Maximum Budget Request</b>	<b>Estimated Number of Awards</b>	<b>Partnership Requirements</b>	<b>Partners</b>
Translational and Clinical Sciences Award	\$110,000	3	Required	Two or more NJ ACTS Partners (Rutgers, NJIT or Princeton); (Awardees may also become eligible for an additional NJHF award at the end of the NJ ACTS award. These additional funds would be granted at the discretion of the Foundation after meeting with the awardees.)
Methodological and Infrastructure Awards	\$50,000	2	Not required, but preferred	Two or more NJ ACTS Partners (Rutgers, NJIT or Princeton)
Propel Awards	\$50,000	2	Not required, but preferred	One or more NJ ACTS Partners (Rutgers, NJIT or Princeton) (Awardees may also become eligible for an additional NJHF award at the end of the NJ ACTS award. These additional funds would be granted at the discretion of the Foundation after meeting with the awardees.)
Valued Partnership Awards	\$50,000	2	Required – non-institutional partner	One NJ ACTS Partner (Rutgers, NJIT or Princeton) plus a partner from industry, government, health care, community, non-profits, insurance companies, or other CTSA Hubs (Awardees may also become eligible for an additional NJHF award at the end of the NJ ACTS award. These additional funds would be granted at the discretion of the Foundation after meeting with the awardees.)

# Identifying Collaborators/Partners

If you have a project idea, but are looking for a collaborator, the information below may be of help. You may also email [njacts@rbhs.rutgers.edu](mailto:njacts@rbhs.rutgers.edu).

**A. Academic Partners:** Each of the partner institutions has a faculty search mechanism:

Princeton: <https://researchwith.princeton.edu/>

NJIT: <https://research.njit.edu/researchers>

Rutgers: <https://www.researchwithrutgers.com/>

For additional help, contact:

Princeton: Daniel Notterman, MD, [dan1@princeton.edu](mailto:dan1@princeton.edu)

NJIT: Guiling (Grace) Wang, PhD, [guiling.wang@njit.edu](mailto:guiling.wang@njit.edu).

Rutgers: Reynold Panettieri, MD, [rp856@rbhs.rutgers.edu](mailto:rp856@rbhs.rutgers.edu)

**B. Community Partners:**

The NJ ACTS Community Engagement Core can connect you to experts in our **Network of Networks** and resources you need through an introductory email or telephone call. Community Engagement staff can even help foster and facilitate the development of long-term partnerships. [Request a referral to get connected by completing the form at: https://research.njms.rutgers.edu/redcap/surveys/?s=PL3LAWNM84.](https://research.njms.rutgers.edu/redcap/surveys/?s=PL3LAWNM84)

**C. Industry Partners:**

Each of the academic partners have institutional officials who help develop and nurture relationships with industry. These include:

Princeton: Dean R. Edelman, Corporate Engagement and Foundation Relations, [Dean.edelman@princeton.edu](mailto:Dean.edelman@princeton.edu).

NJIT: Rick Rosenberg, Director of Corporate and Foundation Relations, [rmr@njit.edu](mailto:rmr@njit.edu).

Rutgers; Kara Moore, Director, Corporate Intelligence & Assessment, [kara.moore@rutgers.edu](mailto:kara.moore@rutgers.edu).

In addition, the New Jersey Health Foundation has excellent multiple relationships with companies and other entities across New Jersey. They have offered to help identify partners, as well. Contact Mike Wiley at [mwiley@njhf.org](mailto:mwiley@njhf.org).

# Application Process

## Eligibility:

- Co-Principal Investigators must hold faculty appointments at one of the three NJ ACTS partner institutions: Rutgers, Princeton or NJIT. The **Translational and Clinical Science Awards** must have at least **2 Co-PIs**, representing **different NJ ACTS institutions**. For the **Methodological Awards and Propel Awards**, partners are not required but are preferred. **Co-PIs for the Valued Partner** grants may be at the partner organization (non-profit, other CTSA Hub, industry, etc.), but do not have to hold a faculty appointment.
- Please note: Schools **within** an institution are not considered as separate from the parent institution. For example, a proposal with one Co-PI from New Jersey Medical School and one from the School of Engineering at Rutgers would be considered ineligible as both schools are units of Rutgers.
- Faculty members at all ranks are eligible. Junior faculty members are especially encouraged to apply.
- Co-investigators participating in the project need not be faculty.
- 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.

## Letter of Intent:

All applicants are required to submit a brief Letter of Intent (LOI) form by the deadline. The Letter of Intent comprises: Co-PI names, titles, and institutional affiliations; project abstract (limited to 30 lines of text); and funding category. LOIs do not require institutional review prior to submission.

The goal of the LOI process is to ensure that applications fit within the chosen funding category and to allow the Pilot Program leaders to identify potential reviewers.

Applicants will be notified within one week if there are concerns, including for example an ineligible Co-PI, or if a project does not appear to fit within the parameters of the selected funding category.

To submit the LOI materials, applicants should use the LOI on-line form accessed at:

[https://rutgers.ca1.qualtrics.com/jfe/form/SV\\_ddmwPLeQGnSArvU](https://rutgers.ca1.qualtrics.com/jfe/form/SV_ddmwPLeQGnSArvU)

The data in the form will be automatically transferred to NJ ACTS.

## **Application Submission:**

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

Subject line should be:

[Co-PI Last Name\_Co-PI Last Name\_Pilot Program category]

Example: Highlander\_Tiger\_Propel

## **Institutional Review Requirements:**

### **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 **requires** internal review of the full proposal by the Office of Research and Project Administration (ORPA) for all projects that require a Princeton Co-PI. Submissions and internal deadlines should be coordinated through your Departmental grants staff. For the internal routing in ERA, the Prime Sponsor should be listed as Rutgers University.

### **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 Pilot Application Form <ul style="list-style-type: none"> <li>• Include the names and contact information for up to four potential reviewers. Two may be from within the institution(s) and two from outside. Potential reviewers may not include department chairs, prior or current mentors, or prior or current collaborators, co-investigators and co-authors.</li> </ul>	Fillable PDF
Program Specific Form, if applicable	Fillable PDF
<b>Additional elements to be submitted as a single PDF in this order:</b>	
Research Strategy	6 pages
• Project Abstract	30 lines of text
• 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
Resources and Environment	Up to 1 page
Other Support	As needed
Detailed Budget (NIH PHS 398) 1 for each participating institution	As needed for each PI/Institution
Budget Justification (1 for each participating institution)	As needed
Co-PI's NIH-formatted biosketch	Up to 5 pages
Key personnel NIH formatted biosketches	Up to 5 pages each
Letters of support from affiliates, partners, or others	Up to 1 page each

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; no cost extensions are not permitted.
- 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 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](mailto: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](http://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.

NJ ACTS staff will communicate with each successful pilot proposal Co-PI about the NCATS requirements once the selection process is completed.

Information on NCATS requirements for projects with human subjects can be found here: <https://ctsa.ncats.nih.gov/governance-guidelines/guidelines/new-projects-with-human-subjects-research/>.

For animal studies, see: <https://ctsa.ncats.nih.gov/governance-guidelines/guidelines/prior-approval-of-planned-research-involving-live-vertebrate-animals/>.

## **Proposal Review Process**

The review process includes: administrative review for completeness of the application and meeting eligibility requirements; solicitation of external and internal reviews; and final review by the NJ ACTS Pilot Project Management Committee. This process is overseen by the Co-chairs of the NJ ACTS Pilot Project Management Committee, Arnold Rabson, MD, Rutgers University, Samuel Wang, PhD, Princeton University and Guiling (Grace) Wang, PhD, NJIT.

## **Post-Award Management**

### **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 NJACTS@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 scientific report is required for all completed awards. NJ ACTS will send a report form to all completed projects.
- Co-PI's will be expected to complete an annual report that summarizes progress on the project, as well as all 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.
- Failure to submit any required progress reports 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.

### **Award Recognition:**

Any publication or patent that results from this funding must include the following language and must receive a PMCID number:

“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.”

Additional recognition is required for those awards, partially supported by NJHF. The required language will be shared on the award letter.

### **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.

**Questions/Inquiries:**

For Inquiries, please email: [NJACTS@rbhs.rutgers.edu](mailto:NJACTS@rbhs.rutgers.edu)