Request for Applications

The New Jersey Alliance for Clinical Translational Science

NJ ACTS Pilot Program Year 5

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: April 5, 2022

Pre-submission Webinar: April 19, 2022 from 5:00-6:30 pm
https://rutgers.zoom.us/meeting/register/tJArcOCsrzwsH9Cwge9zkG8fLQ7XR5-rFdN1

Letter of Intent Deadline: May 6, 2022 (required)(midnight) via REDCap link:
https://redcap.rwjms.rutgers.edu/surveys/?s=LJYKKM3J9A   or https://redcap.link/nc0eena5

Application Deadline: June 17, 2022 (midnight) via REDCap link

Award Notification: Early Fall, 2022

Earliest Start Date: March 1, 2023 (Dependent on regulatory approvals and when required, NIH/NCATS approval) (End date: February 29, 2024)

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Highlights for Year 5

1. **Mandatory Letter of Intent (LOI):**
   - The LOI will require both an abstract and specific aims (both can be in draft form).
   - LOIs will be completed and submitted using REDCap. See page 9 for details regarding what must be submitted and a link to the REDCap form.
   - LOIs will be reviewed not only to ensure that the project fits the category but also for competitiveness.

   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. The Pre-submission Webinar will be held on April 19, 2022 from 5:00-6:30 pm. To register:
   https://rutgers.zoom.us/meeting/register/tJArcOCsrzwsH9Cwge9zkG8fLQ7XR5-rFdN1 .

2. **Application:**
   - Co-PIs are limited to one application per cycle. The sole exception is clinicians who may have a specific expertise or patient populations and be relevant to more than one proposal. Eligibility for this exception should be clearly described in both the LOI and the application.
   - By May 16, applicants will receive a custom link to the REDCap application form or an email indicating they were not selected to advance to the application stage.
   - Applicants are no longer asked to suggest reviewers. Applicants can, however, indicate potential reviewers who they feel should be excluded.
   - Additional demographic data is requested to support our reporting to NCATS.

3. **Changes to Funding Categories since last year's RFA:**
   - Translational and Clinical Sciences:
     - Funding level - $100,000
   - Methodological and Infrastructure: No changes
   - Propel: No changes
   - Valued Partnerships: No changes
   - Improving Clinical and Translational Science through Process Innovation:
     - New category
     - One award at $40,000

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 research or translational science. NCATS defines these as follows:

- Translational Research (TR) as "the endeavor to traverse a particular step of the translational process for a particular target or disease"
- Translational Science (TS): The field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process or between steps in the translational process.

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.

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.

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 $100,000
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 research, 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.

These awards 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 CTSAs 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.

The projects must demonstrate potential for clinical relevance. 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

5. **Improving Clinical and Translational Science through Process Innovation**

NCATS is increasingly interested in the science of translational science – how do we improve the processes which should facilitate and support research, but often delay or challenge it. This award will support projects that test two or more approaches to solving one of these challenges. It must be hypothesis-driven, identify a roadblock to translational research, and demonstrate relevance for others doing research. An example might be testing out novel recruitment strategies or testing different modes of patient communication to determine which is more effective in enhancing progress of a research project or area.

Budget Request: up to $40,000
Number of Awards: 1

NJ ACTS Collaboration and Partnership Requirements

This chart summarizes the partnership/collaboration requirements for the

NJ ACTS Pilot Grant Program

Grant Program	Maximum Budget Request	Estimated Number of Awards	Partnership Requirements	Partners
Translational and Clinical Sciences Award	$100,000	3	Required	Two or more NJ ACTS Partners (Rutgers, NJIT or Princeton);
Methodological and Infrastructure Awards	$50,000	2	Not required, but preferred	One 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)
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
Improving Clinical and Translational Science through Process Innovation	$40,000	1	Not required, but preferred	One or more NJ ACTS Partners (Rutgers, NJIT or Princeton)

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.

  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

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

  Rutgers: Reynold Panettieri, MD, rp856@rbhs.rutgers.edu

B. Community Partners:

The NJ ACTS Community Engagement Core can connect you to experts in the NJ ACTS **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 f**orm at: 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.

NJIT: Rick Rosenberg, Director of Corporate and Foundation Relations, rmr@njit.edu.

Rutgers; Kara Moore, Director, Corporate Intelligence & Assessment, 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.

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.
- Current Pilot awardees are not eligible to apply until the award ends and their final project report is submitted. If a current awardee has completed their project but not yet submitted a final report, contact njacts@rbhs.rutgers.edu.
- Co-PIs are limited to one application per cycle. The sole exception is clinicians who may have a specific expertise or patient populations and be relevant to more than one proposal. The rationale for this exemption must be clearly stated in the LOI and application.

Letter of Intent:

All applicants are required to submit a brief Letter of Intent (LOI) form via a REDCap link by the deadline. The Letter of Intent comprises: Co-PI names, titles, and institutional affiliations; project abstract (limited to1/2 page); and funding category. The first Co-PI listed will serve as the contact PI. 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, the rationale and research directions are competitive, and to allow the Pilot Program leaders to identify potential reviewers.

Applicants will be notified by May 16 if there are concerns or the project is not selected to advance to the application stage. Concerns may include, for example, an ineligible Co-PI, or if a project does not appear to fit within the parameters of the selected funding category or if the project is viewed to not be competitive for the chosen award mechanism.

To submit the LOI materials, applicants should use the LOI on-line form accessed via REDCap at: https://redcap.rwjms.rutgers.edu/surveys/?s=LJYKKM3J9A   or https://redcap.link/nc0eena5. The data in the form will be automatically transferred to NJ ACTS.

You can save the LOI form and access it as often as you need before submitting it to NJ ACTS. You must re-use the same code each time to return to the saved LOI. Should you encounter technical problems, contact:

njacts@rbhs.rutgers.edu. Upon submission of the LOI, you will automatically be emailed a customized link to submit the application via REDCap.

Application Submission:

The contact PI for projects selected to advance to the application stage will be emailed a customized link by May 16 to an on-line Application Form that can be accessed via REDCap. You can save the on-line Application Form and access it as often as you need before submitting it to NJ ACTS via REDCap. You must re-use the same code each time to access the saved Application Form. Should you encounter technical problems, contact: njacts@rbhs.rutgers.edu..

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 include a Princeton PI or 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.

To submit the application to Princeton ERA, the final online application and attachments must be saved in progress, printed to pdf and routed through a departmental grants manager in Princeton ERA for approval prior to submission to NJ ACTS. Please contact NJ ACTS manager Bianca Freda (biancaf@princeton.edu) with any questions and if you plan to apply.

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:

To be considered complete, a proposal **must** contain the following elements entered into REDCap.

Please label the pdf as [Co-PI Last Name_Co-PI Last Name_Pilot Program category].

	Page Limits
NJ ACTS Pilot Application Form	REDCap Form
Program Specific Form, if applicable	REDCap Form
Additional elements to be submitted as a single PDF in this order:	
Research Strategy	6 pages
• Project Abstract	Up to ½ page
• Specific Aims (note: abstract/specific aims should equal 1 page)	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
References	As needed
Resources and Environment	Up to 1 page
Other Support Information for Co-PIs (NIH Format)	As needed
Detailed Budget (NIH PHS 398): 1 for each participating institution and Budget Justification (1 for each participating institution), plus cumulative Budget	As needed for each PI/Institution
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**. All funds awarded must be used per the Scope of Work of the project
- 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.
- For those projects which have NJ ACTS partner 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.

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.
- Awardees are required to have a regulatory consult with Anthony Gonzalez, the NJACTS QA/QC Manager, who will guide awardees through the required processes.
- Projects that involve human subjects research or live vertebrate animals require additional **approvals by NIH/NCATS** before an award can be made and funding released. 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.

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 expert 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.

Additional Requirements:

- All awardees will be invited to present their results at the NJ ACTS Scientific Symposium or other similar events
- Pilot Co-PIs will be asked to serve as reviewers of future applications.

Award Recognition:

Any publication or patent that results from this funding must include the following language, must receive a PMCID number, and must be linked in My Bibliography:

"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