

**2024 Request for Applications**

## The Tri-Institutional Clinical and Translational Research

## Pilot Program

**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:** October 14, 2024

**Pre-submission Webinar:** October 28, 2024 from 3:30-4:30 pm. Register at:

<https://rutgers.zoom.us/meeting/register/tJcvcumqqj8rGdQPKf7CdghU5HPYrXDVxUjy>

**Letter of Intent Deadline:** November 4, 2024 (required)(midnight) via REDCap link:

<https://redcap.rwjms.rutgers.edu/surveys/?s=RKJ9HNWX9M34CFAR>

**Application Deadline:** December 13, 2024 (midnight) via REDCap link

**Award Notification:** February, 2025

**Earliest Start Date:** March, 2025 (Dependent on regulatory approvals)

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**Highlights for 2024 RFA**

### Mandatory Letter of Intent (LOI):

* + The LOI requires both an abstract and specific aims (both can be in draft form).
	+ LOIs will be completed and submitted using REDCap. See page 7 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 meets the definition of clinical and translational research 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 approval processes, and to answer questions from participants. The Pre-submission Webinar will be held on October 28, 2024 from 3:30-4:30 pm. To register: <https://rutgers.zoom.us/meeting/register/tJcvcumqqj8rGdQPKf7CdghU5HPYrXDVxUjy>.

### Application:

### PIs/Co-PIs are limited to one application per cycle. The sole exception is clinicians who may have a specific expertise or patient population relevant to multiple proposals. A rationale for qualifying for this exception should be clearly described in both the LOI and the application.

* + By **November 8**, 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 not asked to suggest reviewers. Applicants can, however, indicate potential reviewers who they feel should be excluded due to conflict of interest.
	+ Additional demographic data is requested to support our review of the program.
* **Funding Amounts and Duration**
	+ Proposals from Princeton and Rutgers may request between $50,000 and $100,000; NJIT proposals may request $50,000. Collaborative proposals between institutions may request no more than $100,000.
	+ Awarded budget may be reduced based on the number of highly meritorious proposals.
	+ Project period is one year; one no-cost extension of 12 months is permitted (assuming sufficient progress and reasonable justification).

# Overview

# Tri-Institutional Clinical and Translational Research

# Pilot Program

The New Jersey Alliance for Clinical and Translational Science, the academic and clinical alliance comprised of Rutgers University, Princeton University, New Jersey Institute of Technology (NJIT), and RWJBarnabas Health is committed to advancing clinical and translational research to develop new therapies and preventive approaches in order to improve health and health care in New Jersey.

One of the major objectives of our alliance is to successfully translate biomedical discoveries to clinical applications by promoting creative and innovative science, by providing pilot support for hypothesis generation and testing, and building teams to address questions in translational research. Translational research is a 5 step continuum in which research findings are moved from the researcher’s bench to the patient’s bedside and community. In this continuum are three stages: 1) develop new approaches and the transfer of applying discoveries from basic research; 2) demonstrate their usefulness through clinical trials and studies, and 3) disseminate the findings to enhance best practices in the community and to impact policy to improve human health.

The Tri-Institutional Clinical and Translational Research (CTR) Pilot Program offers pilot grants to develop and advance innovative clinical and translational research, provide a path to sustainable, extramurally-funded independent research and encourage the development of innovations with the potential for commercialization. The projects are expected to develop the key preliminary data needed for sustained extramural funding.

Together, the three institutions have committed $250,000 toward pilot projects this year. The program is funded through the generous support of each of the academic partners: Princeton University, New Jersey Institute of Technology (NJIT), and Rutgers University.

The funding will be used to support pilot projects in the areas outlined below. All projects must demonstrate clinical relevance. Applications are encouraged, but do not require, Co-PIs from two or more alliance partners (Rutgers, NJIT, Princeton or RWJBarnabas Health).

* **Clinical and Translational Research Projects** can be anywhere along the entire range of the translational research continuum (T0-T4), including laboratory-based, clinical, health services, epidemiology, community engagement and diversity research. Projects that focus on novel aspects of the heterogeneity of disease and response to therapy are encouraged.
* **PROPEL Projects** are high-risk, high-reward, designed to advance 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.
* **Valued Partner Projects** support team research and build liaisons with key partners in industry, government, non-profits, other CTSAs and/or insurance companies. Projects must leverage institutional 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 number of awards is flexible and will depend on the quality of the applications submitted in each category. A faculty review committee comprised of representatives from all three academic institutions will evaluate all applications and submit its recommendations to the Pilot Program Leadership committee, which will make the final funding decision.

**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.

1. **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/](http://www.researchwithrutgers.com/)

RWJBH: <https://www.rwjbh.org/doctors/search-results/>

For additional help, contact:

* Princeton: Daniel Notterman, MD, MA dan1@princeton.edu
* NJIT: Guiling (Grace) Wang, PhD, guiling.wang@njit.edu.
* Rutgers: Reynold Panettieri, MD, rp856@rbhs.rutgers.edu
* RWJBH: Joseph Jaeger, DrPH, MPH, Joseph.Jaeger@rwjbh.org

### 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 form at: <https://go.rutgers.edu/CEC_ServiceRequest>.

### 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: Vincent Lombardo, Executive Director of Corporate Engagement, vincent.lombardo@njit.edu.
* Rutgers: Vincent Smeraglia, Executive Director, New Ventures, vincent.smeraglia@rutgers.edu or

Marika Dunn, Executive Director, Research Relationships, mdunn@rutgers.edu.

# Application Process

## Eligibility:

* Each application must include at least one PI Investigator who holds a faculty appointment (or equivalent) at one of the three partner institutions: Rutgers, Princeton, or NJIT.
* RWJBH investigators may serve as Co-PIs, but cannot submit applications.
* Please note: Schools **within** an institution are not considered separate from the parent institution.
* Faculty members at all ranks are eligible. Junior faculty members are especially encouraged to apply.
* Co-principal investigators participating in the project need not be faculty, and may include postdoctoral fellows, residents, clinical fellows, and professional and terminal degree students.
* Past Pilot awardees are not eligible to apply unless or until their final project report is submitted. If a current awardee has not yet submitted a final report, contact njacts@rbhs.rutgers.edu if there are questions regarding eligibility.
* PIs/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 to ½ page); specific aims (limited to ½ page). The PI or first Co-PI listed will serve as the contact PI. LOIs do not require institutional review before submission.

The goal of the LOI process is to ensure that applications meet the definition of clinical and translational research and ensure that the rationale and research directions are competitive.

Applicants will be notified by **November 8** if there are concerns or if the project is not selected to advance to the application stage. Concerns may include, for example, an ineligible Co-PI, if a project does not appear to be clinical and translational research, or if the project is viewed to not be competitive.

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

<https://redcap.rwjms.rutgers.edu/surveys/?s=RKJ9HNWX9M34CFAR>.

## Application Submission:

By November 8, the contact PI for projects selected to advance to the application stage will be emailed a customized 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 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

This is an internal application and does not require submission in Princeton ERA. Princeton applicants must coordinate their proposals through their Departmental grants staff for all projects that include a Princeton PI or Co-PI. Submissions and earlier internal deadlines should be discussed with your Departmental grants staff.

To facilitate internal review, the final online application and attachments must be saved in progress, printed to pdf, and emailed to a departmental grants manager and Christian Molina (cm7638@princeton.edu) prior to submission  via REDCap. Please contact Bianca Freda (biancaf@princeton.edu) with any questions and if you plan to apply or serve as a Co-PI.

### 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.

**RWJ Barnabas Health**

Applications involving an RWJBH Co-PI must be facilitated through the RWJBH Research Office (research@rwjbh.org), and are subject to stakeholder approvals, including but not limited to clinical areas, Finance, Legal, and sites.

## 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].

|  |  |
| --- | --- |
|  | Page Limits |
| Clinical and Translational Research Pilot Application Form |  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 |
| 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. One no cost extension of 12 months is permitted, assuming sufficient progress to date and reasonable justification. All funds awarded must be used per the Scope of Work of the project.
		- PI effort: While faculty PI/Co-PI salary is not allowed, effort levels for the PI or each

Co-PI must be specified.

* + - Applicants may not request salary support for faculty PIs or Co-PIs. Salary support is allowable for staff, postdocs, and students, as well as Co-PIs who are postdoctoral fellows, residents, clinical fellows, and professional and terminal degree 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 partner institutions/organizations, complete a budget and budget justification for each institution and a cumulative budget page. Budgets should clearly show what project costs will be expended at each institution/organization.
		- 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.
		- Projects that involve human subjects research or live vertebrate animals require additional **approvals** before an award can be made and funding released. These projects **MUST** have IRB or IACUC approval **prior** to funding. **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 the [name of your institution] and the Tri-Institutional Clinical and Translational Research Pilot Program.
	+ 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 Tri-Institutional Pilot 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.

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

NIH Clinical Trial Definition

## 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 Leadership Committee, comprised of the Co-chairs of the Tri-Institutional Pilot Program Committee, Arnold Rabson, MD, Rutgers University, Samuel Wang, PhD, Princeton University, Guiling (Grace) Wang, PhD, NJIT and Joseph Jaeger, DrPH, MPH, RWJ BH and institutional leadership.

# 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 Tri-Institutional Pilot 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. Program Administrators will send a report form to PIs/Co-PIs for all completed projects.
	+ PI/Co-PIs 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 pilot grant. This is required for reporting and evaluation functions.
	+ Failure to submit any required progress reports will result in the grant being terminated.
	+ Co-PIs 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 a NJ ACTS Scientific Symposium or other similar event.
	+ PIs/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; receive a PMCID number: and be linked in My Bibliography:

“Research reported in this publication was supported by [name of institution(s)] through the Clinical and Translational Research Pilot Program. The content is solely the responsibility of the authors and does not necessarily represent the official views of the institution.”

## Other Notices:

* + Abstracts and names of Co-PIs may be posted on the RITMS and/or NJ ACTS or institutional websites.
	+ Awards are not transferable or renewable.

**Questions/Inquiries:**

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