

Request for Applications

The New Jersey Alliance for Clinical and Translational Science NJ ACTS Pilot Program 2024

Funding Opportunity Purpose: This RFA solicits pilot project applications from investigators at Rutgers University, Princeton University, New Jersey Institute of Technology and the RWJBarnabas Health System.

Release Date: April 25, 2024.

Pre-submission Webinar: May 13, 2024 from 3:00-4:30 pm. To register for the webinar: <https://rutgers.zoom.us/meeting/register/tJErd-2qqDgrHNzL3Y08PlbX-1VoxS635RqF>.

Letter of Intent Deadline: May 17, 2024 (required)(by 5:00 EST). Link to LOI form: <https://redcap.rwjms.rutgers.edu/surveys/?s=N3FHW8AJ43D7KPJL>.

Application Deadline: June 14, 2024 (required by 5:00 pm EST).

Award Notification: Summer, 2024.

Earliest Start Date: Dependent on regulatory approvals and NIH/NCATS approval.

Table of Contents

Overview of Pilot Program	Page 3
New for 2024	Page 8
Partnership/Collaboration Requirements	Page 10
Identifying Collaborators/Partners	Page 10
Application Process <ul style="list-style-type: none">• Eligibility• Letter of Intent• Application Submission• Institutional Review• Requirements• Application Requirements• Budget Guidelines• Regulatory Approvals• NCATS Prior Approval• Proposal Review	Page 12
Post-Award Management <ul style="list-style-type: none">• Budget and Financial Management• Award Recognition• Other Notices	Page 19

Overview of NJ ACTS CTS Pilot Program

NJ ACTS Innovations in Clinical and Translational Science

Purpose: The New Jersey Alliance for Clinical and Translational Science (NJ ACTS) is committed to enhancing, broadening, and bolstering its research endeavors in translational science. Translational science represents a dynamic domain that pioneers scientific and operational breakthroughs, surmounting persistent hurdles encountered along the translational research continuum. This field is dedicated to generating a spectrum of innovations—scientific, operational, regulatory, financial, and administrative—that revolutionize the research landscape, catalyzing speedier, more efficient, and more impactful advancements. Aligned with the mission of the National Center for Advancing Translational Science (NCATS), which provides support to NJ ACTS, we aim to translate biomedical research findings into tangible health solutions, spanning diagnostics, treatments, and interventions, through the application of translational science.

In harmony with NCATS' objectives and within the context of the NJ ACTS award, we have devised a pilot program designed to propel clinical and translational science initiatives throughout NJ ACTS, engaging our academic alliance partners (Rutgers, Princeton, and New Jersey Institute of Technology) and our health system partner, RWJ Barnabas Health. Our initiative seeks to furnish initial resources aimed at nurturing programs that can then vie competitively for expanded extramural support, leveraging funding opportunities such as Element E¹ or RC2² studies pertinent to NJ ACTS (refer to NJ ACTS website) or through independent extramural avenues (R or K series grants).

Goals of the programs: To catalyze and foster projects that enhance health through innovation in clinical and translational science. Successful Translational Science pilot projects should focus on approaches and processes, should be disease agnostic, and align with one of these themes:

Creating Efficiencies by Integrating Knowledge, Creating Partnerships, Working Across Diseases: Leverage broad expertise by engaging colleagues from across disciplines, fields, and professions to advance research along the translational

¹ Element E is a component of the CTSA UM1 award that selects especially promising translational science projects for up to 2 years of funding at approximately \$125,000 per year. NJ ACTS will issue an RFA for Element E projects.

² RC2s are a special CTSA category that allows each CTSA to have up to 2 active RC2 awards. RC2 awards can be for up to 5 years and a total of \$500,000 per year. NJ ACTS will issue an RFA for RC2 project ideas but require a formal NIH proposal.

continuum. This may involve leveraging scientific, administrative, financial, and operational expertise.

- **Across Multiple Projects or Initiatives:** Advance research by identifying, developing, and/or testing solutions to common bottlenecks or roadblocks that have hindered multiple projects. These may be scientific, operational, or administrative in nature.
- **Across Diseases or Conditions:** Approach research challenges and develop solutions by seeking commonalities across research projects on a range of diseases or conditions.
- **Cross-Sectoral Partnerships:** Form partnerships across government, universities, and industry to leverage varied expertise and resources to accelerate translational progress. Implement evidence-informed practices for effective cross-sectoral partnerships.
- **Integrate Knowledge:** Integrate concepts, theories, methods, technologies, and approaches from the range of disciplines, fields, and professions that can contribute to advancing research goals. Leverage knowledge integration to produce more holistic research designs and findings that are therefore more relevant to real-world applications.
- **Scientific Efficiencies:** Develop and implement innovations in scientific approaches, methods and technologies that accelerate the pace of translational research.
- **Collaboration Efficiencies:** Implement evidence-informed practices to enhance the speed at which collaborations and teams form, develop a shared vision and goals, effectively communicate, and coordinate work tasks.
- **Project Management Efficiencies:** Implement milestone-based decision making to enable rapid agreement on go/no-go decisions, to enable resources to be used most efficiently.

Expanding Patient and Community Engagement: Develop and test new and innovative ways to involve impacted patients, communities and community organizations as research collaborators to enable research advances across the translational continuum (e.g., via disease registries, clinical trial participation, intervention design, policy development and advocacy). Implement evidence-informed practices for patient- and community-engaged research.

Exploring Bold Scientific Approaches:

- Explore ambitious research goals that have the potential to produce major advances and/or paradigm shifts. These may be in areas of research that have been historically intractable or where there are high risks of failure.

- Integrate DEIA (Diversity, Equity, Inclusion and Accessibility) into the development of research resources and design and implementation of studies, across the translational research continuum.
- Research Priority Setting: Include diverse perspectives in research priority setting, such as through partnerships with diverse collaborators, so research investments represent diverse population and patient health needs.
- Research Design, Implementation and Data Analysis: Pose innovative research questions and develop and implement innovations in research methods (including measurement, new approaches to study design and/or analytic methods), technologies, and approaches that increase the impact of the research, as through the pursuit of paradigm-changing goals, or innovations that are generalizable to advancing research across multiple initiatives, diseases, and conditions.
- Research Processes and Structures: Develop and implement innovations in research team interactions, leadership and management, partnerships, and operations that facilitate and support the quality and impact of the research.

Training and Education:

- Workforce Development: Develop and test effectiveness of new training mechanisms and/or modules for any component of the research workforce.
- Rigor and Reproducibility: Create novel training in Rigor and Reproducibility that encompasses any parameters utilized to conduct the research (e.g., materials, subjects), research methods and conditions, authentication of reagents and biological resources, data sets, metadata, analytic approaches, and statistical tools used for experimentation and data interpretation, results and conclusions, to facilitate reproducibility and/or inform future study designs.
- Regulatory Knowledge: Evaluate new approaches to regulatory knowledge and compliance across the spectrum of clinical and translational research and across all sectors of the research workforce.

Organizational Environment:

- Reward efficiency, enable rapid failures and encourage redirection of resources to subsequent attempts.
- Enable and incentivize boundary-crossing partnerships via leadership, policies, and recognition and reward systems.

- Advance DEIA in the scientific workforce to leverage maximum expertise. Implement best practices in outreach, recruitment and hiring, development, and retention to sustain a diverse and talented workforce.
- Enable rigorous testing of bold, paradigm-challenging ideas, including high-risk high-reward opportunities. Encourage reporting of information necessary for reproducibility toward informing future studies.
- Enable team science via organizational policies, team leadership and management, shared instrumentation and space, and recognition and reward systems.
- Enable creativity and innovation through policies that encourage innovations and do not penalize failures.
- Enable development and testing of generalizable solutions through organizational policies, organizational structure, and shared resources.

Budget and Timelines: Total funding support (direct costs only are supported by this RFA) may not exceed \$40,000 for 6-9 months.³ According to NCATS and NJ ACTS guidelines, **carryover of funding is prohibited as are no cost extensions**. Therefore, applicants are encouraged to propose a project duration period that is reasonable and appropriate for completion of the research project.

Eligibility: The PD(s)/PI(s), collaborators, and other researchers should be well suited to the project and can devote sufficient effort to complete the proposed aims. The PD(s)/PI(s) have the appropriate experience and training to lead this project and have demonstrated an ongoing record of accomplishments in their field(s). If the project is collaborative or multi-PD/PI, the investigators should have complementary and integrated expertise and their leadership approach, governance, and organizational structure should be appropriate for the project. PD(s)/PI(s) must have a primary affiliation with the Alliance Partners of NJ ACTS (Rutgers, Princeton, NJIT, or RWJ Barnabas Health), and hold a faculty or equivalent position. In some instances, a senior postdoctoral fellow may apply if mentored by senior faculty or equivalent.

Milestones and Deliverables: Proposals must include well-defined milestones and/or deliverables on topics described under the *Goals of the Program, as stated above*. Projects should clearly state how and when approaches can be measured. All projects are assumed to promote publications and foster the submission of extramural funding applications. A

³ In most years, the project period will be 12 months, but as this is the first year of the renewal award, the project period is shortened.

discussion on how the findings of the project will be impactful, build new collaborations across Alliance partners, and use of NJ ACTS resources is required.

Application Process: A two-phased application process will facilitate review. Phase 1 requires a letter of intent describing the project, PD/collaborators, and deliverables. NIH Biosketches of key personnel should also be submitted. The review of letters of intent is administrative to ensure eligibility, competitiveness, and conformity with the guidelines for CTS. Phase 2 applications will include an up to three-page research strategy that details the objective, approach, milestones, deliverables, and impact.

Pre-submission Webinar: A webinar will be held on May 13 from 3:00-4:30. Please register at: <https://rutgers.zoom.us/meeting/register/tJErd-2qqDgrHNzL3Y08PlbX-1VoxS635RqF>.

Review Process: The application will be reviewed by the primary review committee comprised of internal and external peers with expertise in the proposal topic. Applications will be scored according to:

- Impact.
- Use of NJ ACTS resources (<https://njacts.rbhs.rutgers.edu/>).
- Collaboration-building potential.
- Potential for sustainability measured by the likelihood of obtaining extramural support and/or adaptation of the outcomes by the health system to improve healthcare delivery (if relevant).
- Rigor and robust approaches with the potential to generate reproducible findings and high-quality data that will enable the research to advance translational progress regardless of whether the initial research objective is met (e.g., learning from failures).
- An Executive Committee of Co-Leads from the Alliance partners will make the final decision for funding based on priorities and the recommendations of the primary review committee.

New for 2024

Highlights for 2024 Clinical and Translational Science Pilot Program

Topic and Themes: NJ ACTS will have two Pilot Programs – one centering on Clinical and Translational Science (CTS) and the other (to be announced at a later date) on Clinical and Translational Research (CTR).

Key CTS-related topics and themes include:

- Creating efficiencies by integrating knowledge, creating partnerships, working across diseases
- Expanding patient and community engagement
- Exploring bold scientific approaches
- Training and education
- Organizational environment

Distinguishing Clinical and Translational *Science* from Clinical and Translational *Research*

Whereas translational research focuses on a specific disease target or disease, translational science is focused on a best approach (process) that applies to any target or disease.

NIH defines **translational research** as “a unidirectional continuum in which research findings are moved from the researcher’s bench to the patient’s bedside and community and divides it into 6 translational phases. It can also be seen as 1) the process of applying discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials and studies in humans, and 2) research aimed at enhancing the adoption of best practices in the community.

Translational Science, in contrast, generates innovations that overcome longstanding challenges along the translational research pipeline. These include scientific, operational, financial, and administrative innovations that transform the way that research is done, making it faster, more efficient, and more impactful. Think the processes of science broadly and how to improve them, whether in the lab, the clinic, from a regulatory or administrative point of view. NCATS has generated the graphic below to highlight key principles that inform translational science.

For example, identifying biomarkers for one specific disease mechanism would be an example of translational research, whereas developing an assay that predicts clinical efficacy better than current animal models, or developing systems to merge clinical datasets from different sources accurately and efficiently, would be examples of translational science. For further examples see:

<https://www.einsteinmed.edu/centers/ictr/translational-science/>.

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 definition of clinical and translational science, as well as for competitiveness.
- Link to the LOI:
<https://redcap.rwjms.rutgers.edu/surveys/?s=N3FHW8AJ43D7KPJL>.

Pre-submission Webinar:

The leaders of the Pilot Program will host a webinar to explain the Clinical and Translational Science (CTS) Pilot Program, including topics and themes, proposal requirements, regulatory requirements and NIH/NCATS approval processes, and to answer questions from participants. The Pre-submission Webinar will be held on May 13, 2024, from 3:00-4:30 pm. To register: <https://rutgers.zoom.us/meeting/register/tJErd-2qqDgrHNzL3Y08PlbX-1VoxS635RqF>.

Application:

- 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. Eligibility for this exception should be clearly described in both the LOI and the application.
- By May 22, 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 NIH/NCATS.

Who may serve as PI or Co-I: NJ ACTS now has four partner institutions: Rutgers, Princeton, NJIT and RWJBH, our clinical partner. Proposals from all four institutions are welcomed.

- Faculty at all levels from Rutgers, Princeton and NJIT
- Physicians and other health care providers at RWJBH
- Postdoctoral fellows, residents and clinical fellows may serve as Co-I's, provided their mentors are from one of the four partnering institutions.

NJ ACTS Collaboration and Partnership Requirements: Although collaborations across schools and departments within an institution, and especially with other NJ ACTS Institutions (Rutgers, Princeton, NJIT and RWJ Barnabas Health) are encouraged, they are not required for the NJ ACTS CTS Pilot Program. Collaborations with other partners, such as community-based organizations, industry, and government agencies, are also encouraged but not required.

Funding:

- Funding level - \$40,000 (Direct Only).
- 4-6 awards anticipated.

NJ ACTS Collaboration and Partnership Requirements

Although collaborations across schools and departments within an institution, and especially with other NJ ACTS Institutions (Rutgers, Princeton, NJIT and RWJ Barnabas Health) are strongly encouraged, they are not required for the NJ ACTS CTS Pilot Program.

Identifying Collaborators/Partners

If you have a project idea, and are looking for a collaborator, the information below may be of help. You may also email njacts@rbhs.rutgers.edu.

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/>

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, PhD, 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: Rick Rosenberg, Director of Corporate and Foundation Relations, rnr@njit.edu.

Rutgers: Vincent Smeraglia, Executive Director, New Ventures, vincent.smeraglia@rutgers.edu or Marika Dunn, Executive Director, Research Relationships, mdunn@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:

- Each application must include at least one Co-Principal Investigator who holds a faculty appointment (or equivalent) at one of the four NJ ACTS partner institutions: Rutgers, Princeton, NJIT and RWJ Barnabas Health.
- 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.
- Clinical studies beyond Phase IIB are not allowed.
- 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); 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 topics and themes of the NJ ACTS CTS Pilot Program, that the rationale and research directions are competitive, and to allow the Pilot Program leaders to identify potential reviewers.

Applicants will be notified by May 22 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 CTS 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=N3FHW8AJ43D7KPJL>.

Once eligibility is confirmed, 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 22 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, serve as a Co-PI, or have any questions.

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 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. Some information is entered into the REDCap form. Other information is uploaded as pdfs; this includes Supplemental packet, Sustainable fundings, timeline, resources/other support, budget, biosketches and letters of support.

Please label the pdf as [Contact 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:	
Project Abstract	Up to ½ page
Specific Aims (note: abstract/specific aims should equal 1 page)	Up to ½ page
Research Strategy	Up to 3 pages
Background/Preliminary Data	
Research Plan <ul style="list-style-type: none"> • Objective • Approach • Milestones • Deliverables • Anticipated impact 	
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 I/Institution
Co-PI's NIH-formatted biosketch	Up to 5 pages
Key personnel NIH formatted biosketches	Up to 5 pages
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 6-9 months;** no cost extensions are not permitted. All funds awarded must be used per the Scope of Work of the project. The project must be completed by [add date].
- 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.
- If the project involves a partner organization a separate scope of work, budget and budget justification will need to be included. The budget will need to adhere to RFA guidelines.
- 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 may 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 UM1 TR004789, 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

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 CTS Pilot Program Executive Committee. This process is overseen by the Co-chairs of the NJ ACTS Pilot Project Module: Arnold Rabson, MD, Rutgers University, Samuel Wang, PhD, Princeton University, Guiling (Grace) Wang, PhD, NJIT, and from RWJBH, Joseph Jaeger, DrPH, MPH.

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.
- If the IRB approval is active additional information may be required to be reported to NCATS.
- 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.
- All awardees and pilot projects are required to adhere to the NJ ACTS Resource, Data and Software Sharing, and Dissemination Plan

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 UM1TR 004789. 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:

Email: NJACTS@rbhs.rutgers.edu