

Pilot Translational and Clinical Studies Program

Pre-submission Webinar
April 19, 2022

New Jersey Alliance for Clinical and Translational Science

<http://njacts.rbhs.rutgers.edu>

An NCATS-funded CTSA Hub: UL1 TR003017, KL2 TR003018, TL1 TR00301





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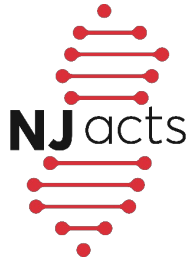
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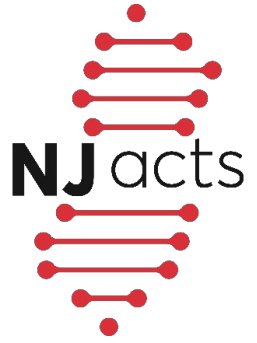




Aims of the Pilot Program

- Advance team research to promote novel approaches and methodologies in translational medicine and science
- Foster interdisciplinary research that leverages in-kind partner support to generate or test novel hypotheses
- Seed collaborations between the NJACTS partners

NIH defines Translation as “the process of turning observations in the lab, clinic and community into interventions that improve the health of individuals and the public—from diagnostics and therapeutics to medical procedures and behavioral change”



Year 5 Funding Categories

\$640,000 (NJHF, CTSA, Institutional Commitments)

Pilot Grant Program	Maximum Budget Request	Estimated Number of Awards	Are Collaborator or Partners Required?	Collaborators/Partners	Year 5 Deadline
Translational and Clinical Sciences Award	\$100,000	3	Required	Two or more NJ ACTS Institutions: Rutgers, NJIT or Princeton	June 17
Methodological and Infrastructure Awards	\$50,000	2	Not required, but preferred	One or more NJ ACTS Institutions: Rutgers, NJIT or Princeton	June 17
Propel Awards	\$50,000	2	Not required, but preferred	One or more NJ ACTS Institutions: Rutgers, NJIT or Princeton	June 17
Valued Partnership Awards	\$50,000	2	Required	Industry, government, community organizations, insurance companies, other CTSA Hubs	June 17
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)	June 17



Translational and Clinical Sciences

\$100,000 Max

- Includes the entire translational science continuum (T0-T4):
 - laboratory-based, clinical, health services, epidemiology, community engagement and diversity research.
- Encouraged: Proposals that focus on novel aspects of the heterogeneity of disease and response to therapy
- Requirements:
 - *The projects must demonstrate potential for clinical relevance.*
 - Applications require Co-PIs from two or more NJ ACTS Partners (Rutgers, NJIT or Princeton).
- Partially supported by New Jersey Health Foundation



Translational and Clinical Funded Projects

2021-2022 Awardees:

“Therapeutic Development of Patient Cell-derived Exosomes for Effective CVD Treatment,” KiBum Lee (Rutgers)/Xiaoyang Xu (NJIT)

“Development of CRISPR-based, multiplex, point-of-care testing pathway for tuberculosis and COVID-19,” Yingda Xie (Rutgers)/Cameron Myrhvold (Princeton)/Padmapriya Banada (Rutgers)

“The effects of cell and tissue-level heterogeneity on triple-negative breast cancer progression,” Celeste Nelson (Princeton)/Shridar Ganesan (Rutgers)

“Targeting of mitotic spindle assembly factor TPX2 for cancer therapy,” Sabine Petry (Princeton)/Zhiyuan Shen (Rutgers)



Translational and Clinical Projects, cont.

“Incorporating drug metabolism by the human gut microbiome into personalized medicine,” Luigi Brunetti (Rutgers)/Mohamed Donia (Princeton)

“Post-Release Outcomes of Prison Based Treatments and Interventions for Opioid Use Disorder,” Stephen Crystal (Rutgers)/Nathaniel Daw (Princeton)/Jason Roy (Rutgers)

“Investigating tissue-specific functional maps and its correlation with cognitive domains in Alzheimer’s Disease,” Bharat Biswal (NJIT)/Laszlo Zaborszky (Rutgers)



Methodological & Infrastructure

\$50,000 Max

- To develop novel methodologies or create new infrastructure resources
- Includes the entire range of translational science
- *The projects must demonstrate potential for clinical relevance.*
- Applicants are encouraged, but not required to find a partner at a second NJ ACTS institution.
- Partially supported by NJHF



Methodological and Infrastructure

2021-2022 Awardees:

“A Novel Expandable Endodontic Biomaterial,” Mohammad Saghiri (Rutgers)/Vivek Kumar (NJIT)

“Development of computational methods to identify oncogenic tyrosine kinase transcripts,” Chang Chan (Rutgers)



Propel Awards

\$50,000 Max

- A high-risk, high-reward category:
 - Explore novel ideas
 - New technologies or research methods to a project
 - Enable clinical data acquisition, purchase of small equipment or licenses to data sets
- *Must demonstrate clinical relevance*
- Partnership with a second NJ ACTS institution encouraged
- Partially supported by New Jersey Health Foundation



Propel Funded Projects

2021-2022 Awardees:

“Capturing the impact of SARS-CoV-2 evolution on human pulmonary responses,” Alexander Ploss (Princeton)

“Development of Computational Models to Explore Interactions of Coronavirus Virions with Lung Surfactant Films,” Alexander Neimark (Rutgers)

“Exercise blood pressure as a predictor of left ventricular hypertrophy in patients with type 2 diabetes mellitus,” Peter Kokkinos (Rutgers)/Joshua McGee (Rutgers)

“Novel mouse models for live imaging basement membrane dynamics and breach in melanocyte migration and melanoma,” Danelle Devenport (Princeton)



Valued Partner Awards

\$50,000 Max

- For research with key partners in industry, government, non-profits, community, other CTSA's and/or insurance companies.
- Must include:
 - A Co-PI from partners from industry, government, health care, community, non-profits, insurance companies, or other CTSA Hubs.
 - Partner in-kind services or funding:
 - 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.
- Partially supported by New Jersey Health Foundation.



Valued Partner Funded Projects

2021-2022 Awardees:

“dNANOSIS, a Rapid and Reliable Nucleic Acid Assay for Detecting Infectious Diseases,” Jinglin Fu (Rutgers)/Bo Wang (Delaware Diagnostics)

“Skin Deep: a Rutgers-Unilever partnership for topical pain relief,” Victoria Abaira (Rutgers)/Jian-Ming Lee (Unilever)

“Deep Learning Methods for Identifying Copy Number Variations,” Zhi Wei (NJIT)/Joseph Glessner (Children’s Hospital of Philadelphia)

“Risk Environment Analysis to Inform Overdose Education and Naloxone Distribution (OEND),” Amesika Nyaku (Rutgers)/ Erin Zerbo (Rutgers)/Jenna Mellor (NJ Harm Reduction Coalition)



Improving Clinical and Translational Science through Process Innovation

\$40,000

- NIH defines **Translational Science**: understanding the scientific and operational principles underlying each step of the translation process
- For research that address the question of how do we improve the processes which are intended to facilitate or support translational research
- This award supports 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.



Application Review Process

- LOI Review:
 - Appropriateness to the category
 - Competitiveness within the applications in that category
 - Reviewed by Co-Leads
- Proposal Review
 - Administrative Review
 - Initial Review:
 - Reviewers selected from:
 - Academy of Mentors
 - Previous pilot awardees
 - Prominent scientists in the field
 - Review by the Pilot Project Management Committee
 - Each proposal is assigned a PPMC primary and secondary reviewer
 - Discussed at PPMC meeting
 - Recommendation for funding made to NJ ACTS Program Director



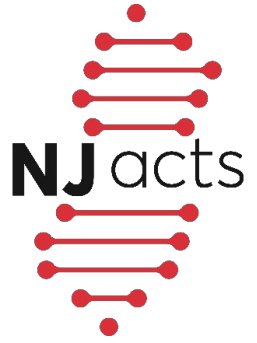
Pilot Project Management Committee

- A committee composed of standing and ad hoc members
- Selected from the NJACTS scientific community
- Represents three partner institutions
- Various scientific disciplines and fields
 - spectrum of translational research and translational science

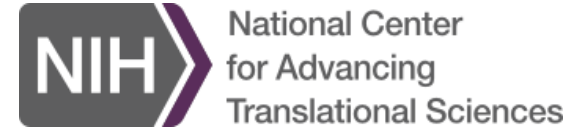


Review Criteria

- Excellence of the science
- Potential for translation
- Likelihood of success
- Strength of collaboration with another NJ ACTS institution
- **Potential for:**
 - **Publications**
 - **NIH funding**



Application Process



Letter of Intent:

- **Required**
- Due May 6th
- REDCap Form: Pilots Category, Title, Co-PIs, Draft Abstract and Draft Specific Aims
- Purpose:
 - Ensure match between category and project
 - Assess competitiveness
 - Allow leaders to start matching reviewers to projects
- Notification by May 16 of approval to submit application



Application Process: Due June 17th

	Page Limit
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	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 for Co-Pis (NIH format)	As needed
Detailed Budget (NIH PHS 398) 1 for each participating institution plus cumulative	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



Institutional Sign-off

- Not required for LOI
- Application: Required by Princeton and NJIT (see RFA for specific instructions)



When Will We Hear? How Soon Can We Start?

Notification: Early fall

Earliest start date: March 1, 2023

Actual Start Date and Release of Funds Depend On:

- Not involving human subjects or vertebrate animals or foreign components:
 - As soon as any modifications required by the committee are received
- Involving human subjects or vertebrate animals or foreign components:
 - Institutional regulatory approvals required (animals/humans)
 - Requires NCATS review and approval



How Long is the Project?

- Project Period
 - 12 months
 - May be made shorter depending on regulatory and NCATS approvals
- Are No Cost Extensions Grants Allowed?
 - NCEs are not allowed due to the nature of the CTSA funding



Summary of Changes since Last Year

- **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.

- **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 are requested to support our reporting to NCATS.

- **Changes to Funding Categories since last year's RFA:**

- Translational and Clinical Sciences:
 - Funding level - \$100,000
- New Category: Improving Clinical and Translational Science through Process Innovation:
 - One award at \$40,000



Where do we go for help?

- Matching project to category:
 - Pilots Co-leads
- Identifying potential Co-PIs
 - RFA contains a helpful list
- Budgets, Subcontracts, NCATS Approvals, Institutional approvals
 - Email: njacts@rbhs.rutgers.edu
 - Princeton: biancaf@Princeton.edu
 - NJIT: guiling.wang@njit.edu
- Any of the Pilots program administrative staff
- Pilots grant program web page
- <https://njacts.rbhs.rutgers.edu/investigator-resources/funding-opportunities/pilot-grants-2/>

Q&A