Clinical and Translational Science Award Pilot Award Program
Scripps Research Translational Institute
Request for Applications

SUBMISSION AND REVIEW DATES

Letter of Intent (LOI) Due	January 15
Application Due	February 12
Initial Screening (Stage 1)	February 24
Reviewer Critique Due	April 9
Scientific Review (Stage 2)	April 21
Earliest Funding Start Date	May 1

Funding Opportunity Description

Scripps Research Translational Institute

The Scripps Research Translational Institute (SRTI) is committed to advancing translational science and supports researchers who strive to conduct transformative, innovative, and translational research with the potential to change medicine.

Overview

The Pilot Study Award Program provides modest research support for new and innovative research projects relevant to Clinical and Translational Science (CTS). Pilot projects must be focused on translational science, i.e., focused on understanding a scientific or operational principle underlying a step of the translational process with the goal of developing generalizable principles to accelerate translational research. Translational research projects, i.e., projects focused on crossing a particular step of the translational process for a particular target or disease, are not allowed.

Projects are intended to: (1) explore possible innovative new leads or new directions for established investigators; (2) stimulate investigators from other areas to lend their expertise in research in CTS; and (3) provide initial support to establish proof of concept. Projects must be feasible within the proposed timeframe, have high methodological and scientific quality, and answer important scientific questions. Pilot project support is not intended for large projects by established investigators that would otherwise be submitted as separate research grant applications. Pilot projects funded through this program may not involve an NIH-defined clinical trial.

The program is a component of the UM1 TR004407-05 Clinical Translational Science Awards from the National Institute of Health (NIH). Four grants will be awarded with budgets limited to $50,000 in direct costs (excluding consortium F&A). Final funding decisions will be made based on award of UM1 grant to SRTI. Research proposed in the application must be completed with all funds spent by April 30, 2028, with the earliest start date May 1, 2027. All projects must align with current NIH priorities.

Eligibility

This program is open to faculty, staff scientists, and institute investigators at Scripps Research. Eligibility for postdoctoral fellows/associates will be determined on a case-by-case basis. Please refer to *Policy 401: Eligibility to Serve as PI*. Scripps Health physicians and San Diego State University research scientists and faculty may serve as Co-Investigators via a subaward. However, a Scripps Research PI must serve as the Prime Awardee.

Project Criteria

Applicants should design studies that meet the following criteria:

- Advance Clinical and Translational Science (CTS)
- Integrate Community Engagement principles into study design
- Agnostic and multi-disciplinary; connect basic and clinical science
- Potential to impact clinical practice in a relatively short span of time
- Sound hypothesis, research methodology and statistical considerations
- Track record of the applicant and the co-investigator(s)
- Likelihood of leading to future independent funding and publication

Application Review and Scoring

Review Process: Recipients of the pilot study awards must adhere to all Federal, state and local guidelines with respect to scientific conduct, conflict-of-interest policies, participation of human subjects, the use of animals, hazardous or radioactive materials and recombinant DNA in their research studies.

There will be a two-stage review process. First, all applications will be screened by the Management Committee to ensure that the pilot projects advance CTS principles. Next, the selected applications (finalists) will pass into the second stage peer review process. In this stage, the finalists will receive 2-3 written critiques followed by an NIH-style study section review and ranking by the Scientific Review Committee (composed of 15-20 scientists and physicians). *Please note:* Only the applications that are selected for the second stage peer review (finalists) will undergo PreAward review at OSP.

Scoring: Applications will be scored on a 1-to-5 scale where "1" is excellent and "5" is poor. Half points may be given (i.e., 2.5). Applications that receive an overall average score of 1.5 are generally funded.

Submission Information

Letter of Intent (LOI): Provide a **s**hort summary of the proposal (1 page maximum) that includes a) title; b) project site(s); c) names/affiliations of collaborators; and d) specify whether human subjects or vertebrate animals will be used. All applicants that submit an LOI will be invited to submit a full application. The LOI is solely used to determine administrative workload.

Please send the LOI to Michelle Miller (mmiller@scripps.edu) by January 15, 2027.

Application Form

Cover Page: Complete all fields as accurately as possible, including Project Title, Diseases Targeted, Principal Investigator (PI), Co-Investigator (Co-I) if applicable, eRA Commons ID(s), Institution, Translational or Clinical Liaison (if applicable), as well as contact information. Cover Page needs to be signed and dated.

eRA Commons ID: List the eRA Commons ID for all investigators listed on the Cover Page. If you do not have a registered eRA Commons ID, please submit a request to the Office of Sponsored Programs (OSP) via the intranet: https://scrippsresearch.sharepoint.com/sites/ospc/SitePages/eRA-Commons.aspx
For additional assistance, contact the NIH eRA Commons Help Desk at commons@od.nih.gov.

Type of Investigator – Clinical or Translational
Check the box for 'Clinical' and/or 'Translational' to categorize the PI and Co-I's expertise. If neither is appropriate, check 'N/A' and then designate a translational and/or clinical research liaison. A liaison is someone who is simply advising or mentoring the basic scientist or clinician researcher (PI or Co-I) on the proposed project, but is not integrally involved in the project (i.e., is not included on the budget and does not receive pay). A liaison is not required in the presence of a clinical/translational investigator. If there is no clinical/translational investigator, a liaison is required. *Please note:* If a liaison is selected, you must include a letter of support from this individual.

Type of Research

Human Subjects Research: Pilot projects funded through this program may not involve an NIH-defined clinical trial. If the proposed project involves Human Subjects, indicate whether the IRB protocol is Approved or Pending

in the checkbox. If the proposed project does not involve Human Subjects, please indicate Not Applicable in the checkbox. If the proposed project does involve Human Subjects, a copy of

the IRB approval letter must be submitted to NCATS at a later date. Please note NCATS requires the title on institutional IRB approval letter to match the title of the proposed pilot project.

If the project is awarded, then a complete NCATS Human Subjects Prior Approval application is REQUIRED within 30 days of funding notice. The time commitment for preparing the NCATS Human Subject Prior Approval application is substantial. If your study receives a fundable score and it involves human subjects, you are required to submit a complete NCATS Human Subject Prior Approval application to Emily Todd (etodd@scripps.edu). A Notice of Award will not be issued until approval is received from NCATS. Please see "Prior Approval" section on page 7 for specific requirements.

Animal Subjects Research: If the project involves Animal Subjects Research, indicate whether the IACUC protocol is Approved or Pending in the checkbox. An IACUC review is required and a copy of the IACUC approval letter is required as part of the application. If the project is awarded, then a complete NCATS Live Vertebrate Animals Prior Approval application is REQUIRED within 30 days before the proposed implementation of research. A Prior Approval Request application includes: the NCATS Prior Approval Checklist, vertebrate animals study justification, and IACUC approval letter. *Please note:* NCATS requires the title on institutional IACUC approval letter to match the title of the proposed pilot project.

If your study receives a fundable score and it involves vertebrates animals, you are required to submit a complete NCATS Vertebrate Animal Prior Approval application to Emily Todd (etodd@scripps.edu). A Notice of Award will not be issued until approval is received from NCATS. Please see "Prior Approval" section on page 7 for specific requirements.

Stem Cell Research: If the project involves Stem Cell Research, check whether the ESCRO protocol is approved or pending. If the project does not involve Stem Cell Research, please check Not Applicable.

If the project involves Stem Cell Research, submit a copy of the ESCRO, or full approval face page, as part of the application. IRB review may be required in addition to ESCRO review. Please note that NCATS requires title on institutional IRB letter to match the title of proposed pilot project. If the project is awarded funding, then a copy of the approved protocol page(s) will be REQUIRED within 30 days of funding notice.

Abstract/Project Summary

The abstract should provide a brief and concise summary of the proposed study (approximately 500 words).

Relevance to Clinical and Translational Science (CTS)

The relevance to Clinical and Translational Science (CTS) section should explain how the proposed study has the potential to elucidate a scientific or operational principle underlying a step of the translational process with the goal of developing generalizable principles to accelerate translational research. Translational research projects, i.e., projects focused on crossing a particular step of the translational process for a particular target or disease, are **not** allowed.

'Translation' is defined by NCATS as the process of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and communities – from diagnostics, preventions, and treatments to medical procedures and behavioral changes.

'Translational research' (TR) is defined by NCATS as the endeavor to traverse a particular step of the translational process for a particular target or disease.

'Translational science' (TS) is the field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process.

Whereas translational research focuses on the specific case of a target or disease, translational science is focused on the general case that applies to any target or disease; advances in translational science are the focus of this FOA. A key tenet of translational science is to understand common causes of inefficiency and failure in translational research projects (e.g., incorrect predictions of the toxicity or efficacy of new drugs, lack of data interoperability, ineffective clinical trial recruitment). Many of these causes are the same across targets, diseases, and therapeutic areas; therefore, advances in translational science will increase the efficiency and effectiveness of translational research to enhance health, lengthen life, and reduce the burdens of illness and disability. Like any other science, translational science seeks to elucidate general operative principles to transform translation from an empirical, phenomenological process into a predictive science. The application of scientific and operational innovation and strategies to improve the efficiency and effectiveness of all research is at the heart of developing, demonstrating, and disseminating the science of translation.

An example – for illustration only – may help clarify the distinction between TR and TS. An investigator who wishes to test whether a particular drug improves outcomes in diabetes will need to recruit sufficient desired participants; this is a TR problem and will be addressed from the standpoint of effectiveness for the drug's effects and the diabetes community, using established recruitment methods. By contrast, an investigator who wishes to understand the fundamental underlying mechanisms to recruitment for clinical trials generally, and test an intervention directed at those hypothesized causes and mechanisms, is engaging in TS. To test the hypothesis, the TS investigator may choose a use case that may in fact be the same as that used by the TR researcher – in this example a drug for diabetes – but the question to be answered is primarily whether the TS innovation accomplishes full recruitment of the desired population more effectively and efficiently.

For more information about translational science, please use the following link: https://ncats.nih.gov/about/about-translational-science

Community Engagement

Community Engaged Research (CEnR) is a collaborative process wherein community members—who are often the targets of research studies—are involved in the development, execution and dissemination of research endeavors that may affect them. The ultimate goal of CEnR is to improve the health of community members while simultaneously advancing research discovery in multiple areas of health and wellness.

In this section, explain how the proposed project involves input from community members to advance health and wellness (approximately 200 words). For questions or assistance with this section, please email the Community Engagement team at: CommunityEngagement@scrippshealth.org

Research Proposal

The project/research proposal must include the following sections (3 pages maximum):

- Specific Aims
- Background and Medical Significance
- Preliminary Data (if any)
- Research Design and Methods
- Figures are allowed within the proposal, but must remain within the page limit
- Margins must remain at 0.5 inches on all sides with SRTI Logo in the header

Budget and Justification

Research proposed in the application must be accomplished by April 30, 2028, with an earliest start date of May 1, 2027. Budget justification may be itemized by category, but must include the following sections:

- Personnel (list title, percent effort on project and requested salary including benefits)
- Supplies (itemized)
- Other Expenses (itemized)
- Indirect Costs at Current Federally Negotiated Rate

References/Literature Citations

List references for the proposal (maximum of 10 references).

Biographical Sketch

Biosketches are required for all **KEY** personnel and liaisons in the application. This is a standardized document used to summarize the qualifications, experience, and relevant contributions of key personnel for federally funded research projects. The NIH requires all biosketches to be generated, managed, and digitally certified directly inside SciENcv. There is not a blank template that can be downloaded and completed outside of SciENcv.

Application Submission

Please send your application to Michelle Miller (mmiller@scripps.edu) by February 12, 2027.

Review Process for Finalists (OSP PreAward)

Only those applications selected for the second stage peer review process (finalists) will undergo the PreAward review process at OSP. Finalists must submit their applications to OSP PreAward by March 5, 2027. To initiate the process, create the record in the Streamlyne Proposal Development module (use the Non S2S template):

Complete all required fields of the PD record and provide as attachments: Animal and Human Subject Compliance (including Human Subjects Education Certification for all Key Personnel involved in Human Subjects Research)

- If applicable, TSRI is Prime with a Subaward (required forms are available on the OSP website)

Attach the completed SRTI Pilot Award Application

- Face/Cover/Title Page
- Abstract Page/Performance Site/Key Personnel
- Budget and Budget Justification
- Biographical Sketch (for Key Personnel and Liaisons only)

Finalists only: Route your application for review through the Streamlyne system by March 5, 2027. Once review is complete and PI approval has been received, PreAward will email completed final applications to Michelle Miller.

Prior Approval: Human Subjects & Vertebrate Animals

Prior Approval for Human Subject Research

Pilot projects funded through this program may not involve an NIH-defined clinical trial. Applicants should review this definition carefully when designing their study, as it is based on function (intervention, prospective assignment, and evaluation of a health-related outcome) rather than study size or setting.

If the project is awarded, then a complete NCATS Human Subjects Prior Approval application is REQUIRED within 30 days of funding notice. Insitituional IRB review is required for every proposal involving human subject research. The risk level assigned by the Scripps IRB determines the NCATS Prior Approval package. A Prior Approval application can involve the following:

- NCATS HSRPA Application submission in eRA HSS
- NCATS HSRPA Addendum
- IRB Approval letter or Institutional Exemption Determination (Note: NCATS requires title on institutional IRB letter to match the title of proposed pilot project.)
- Human Subjects Training Certificates for PI and Key Persons
- Inclusion Enrollment Report (including gender, race, ethnicity, and age for all subjects)
- Biosketches for PI and Key Persons not contained in the CTSA grant application (greater than minimal risk only)
- IRB-Approved Protocol (greater than minimal risk only)
- IRB-Approved Consent (greater than minimal risk only)

A common misunderstanding we see when receiving pilot award applications is incorrectly assigning 'non human subjects research' to studies. A study does not have to prospectively enroll subjects into a clinical trial to be considered human subjects research. Some examples of human subjects research that will likely be exempt research or minimal risk are: a) using previously collected samples to do an assay; b) creating a biorespository; or c) retrospective chart reviews. *Please note:* All these examples are human subjects research and will require prior approval to NCATS. Some examples of non-human subjects research are: a) research involving all deceased individuals; b) research from commercially available cell lines; or c) interviews or surveys that do not collect identifiable information. Scripps IRB will determine if your project is non-human subjects research, exempt research, minimal risk research, or greater than minimal risk research. Greater than minimal risk studies do require an extra level of review at NCATS and will require 30 buisness days for NCATS review.

Due to the current IRB turnaround times, we suggest submitting your pilot project for institutional IRB review as soon as possible. Therefore, if your project is funded, the 12-month award period is not affected by waiting for

IRB review. If your proposed pilot project is already IRB approved under a larger encompassing project, you still must submit for IRB review to match the pilot project title. If you have any questions regarding this requirement or definitions of human subjects research as they apply to your project, see NCATS guidelines or email Emily Todd at etodd@scripps.edu at any time.

Prior Approval for Vertebrate Animal Research
NCATS Prior Approval for research involving Live Vertebrates is required for any study conducting vertebrate animal research. Requests for Prior Approval must be submitted in writing to NCATS no later than 30 days before

the proposed implementation of research. See NCATS guidelines for more details or contact Emily Todd at etodd@scripps.edu.

If you receive a fundable score and your study involves human subjects or vertebrate animals, you will need to complete an NCATS Prior Approval. The NCATS Prior Approval packet must be submitted to Emily Todd (etodd@scripps.edu), which will then be forwarded to NCATS for review.

> *Please note:* Approval can take 30-60 days, so please get started on this early, otherwise the Notice of Award will be delayed.

Important Considerations

- NCATS does not allow mixed funds to be used for their funded grant projects.
- The project must be feasible to complete within the year grant cycle.
- Pilot projects must not meet the definition of an NIH-defined clinical trial.
- K12 scholars are encourage to apply for pilot funding, however the proposals must be different and funding not mixed.
- Ensure your proposal fits the definitions of translational science, described on page 5. Projects centered around a single target are not translational science.

Please send your application to Michelle Miller (mmiller@scripps.edu) by February 12, 2027.