OVERVIEW INFORMATION

Funding Opportunity Title	*CTSI Translational and Clinical Studies Pilot Program*
Awarding Organization	Utah Clinical and Translational Science Institute (CTSI)
Federal Prime Sponsor	National Institutes of Health (NIH) / National Center for Advancing Translational Sciences (NCATS)
Federal Award Number	UL1TR002538
Catalog of Federal Domestic Assistance #	93.350
Summary of the Funding Opportunity Purpose	The CTSI provides intramural awards to support the growth of interdisciplinary and investigator-initiated clinical and translational research across U Health's broad range of scientific disciplines. It is expected that all research supported by CTSI pilot project awards will result in one or more publications in a peer-reviewed journal and will provide critical preliminary data to support extramural applications.
Eligibility Criteria	Team science approaches will be supported and encouraged, particularly in the pilot program where two or more team members from different disciplines are **<u>required</u>** for all applications. Tenure-line faculty and Career-line faculty are eligible to apply. Faculty must be in residence at the University of Utah to be considered for Pilot funding. Proposals should exhibit high potential for leveraging extramural funding. Applicants that have significant start-up, cash reserves, or are seeking gap funding to bridge support between external grants or contracts are not eligible. Preference will be given to early career-investigators, investigators that have not received funding in the last three years, investigators pursuing a new research direction, and investigators who have participated in a CTSI Speed Collaboration event.

Key Dates

Posted Date	**August 2, 2021**
Letter of Intent Due Date	**September 13, 2021 by 5:00 p.m.**
Application Due Date	**October 11, 2021 at 5:00 pm**
Merit Review	**October 25, 2021 – November 19, 2021 (see Part 3, Section I)**
Award Notification	**December 10, 2021 (see Part 3, Section II)**
Earliest Start Date	**March 1, 2022 (**pending NIH/NCATS prior approval)
Announcement Expiration Date	**October 11, 2021 at 5:00 pm**

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FULL TEXT OF ANNOUNCEMENT

Section I. Funding Opportunity Description

The Translational and Clinical Studies Pilot Program focuses on multidisciplinary team science. It encourages new collaborations, creation of new therapeutics, and development of new tools to support translational research.

The aims are to accelerate scientific discovery to advance the Nation's clinical and translational (T0-T4) research.

Section II. Eligibility Information

- Applicants must hold a faculty or equivalent appointment at a Utah CTSI partner organization
- Two or more team members from different disciplines are **required** for all applications
- Successful projects will exemplify the CTSI's mission of developing clinical and translational research
- The proposed project should not be funded by any other mechanism/research initiative at the time of submission.
- Gap funding for any project to bridge support between external grants or contracts and support for existing facilities or resources will not be considered eligible.
- All investigators selected to receive funding will be expected to submit a Progress Report at six months and a Final Progress Report at the end of the funded project. An additional report one year later, detailing progress to date, all submitted publications and grant applications (pending or funded) relating to the pilot project.

Section III. Award Information

Funding Instrument	Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.
Application Types Allowed	New
Award Budget	Award budgets, $30,000 are composed of salary, benefits, and other program-related expenses, as described below.
Award Project Period	March 1, 2022 through February 28, 2023

Other Award Budget Information

The following costs are ***not*** covered by these awards:
- Faculty salaries
- Postdoctoral salaries of any Postdoc listed as a <u>trainee</u> on a Training Grant
- Non-institutional staff salaries
- Graduate student stipends or tuition
- Administrative or office costs (e.g., office supplies, telephone, etc.)
- Meals or hospitality (i.e., no food, beverages, or alcohol)
- Travel that is not directly related to the conduct of research
- Other items typically supported by indirect costs
- Monetary clinic incentives

Section IV. Letter of Intent Information

A Letter of Intent is **<u>required</u>** and must be provided by **<u>September 13, 2021</u>** to Breanne Johnson at <u>breanne.johnson@hsc.utah.edu</u>. This letter should be sent as a PDF attachment and include the following information:
- Principal Investigator (name, title, department, contact information)
- Key Personnel (name, title, department, contact information)
- Project Title
- Less than 500 word summary of proposed project
- Signature

Section V. Application and Submission Information

General Instructions

The Utah CTSI *Translational and Clinical Studies Pilot Program* **requires** all applicants to adhere to the following instructions when preparing their application. Failure to adhere to instructions may result in administrative rejection of the application. Please see Checklist at end of instructions for attachment compiling guidance*.*

- <u>University of Utah Internal Process</u>: The Pilot Program Application ***does not*** require prior consideration by the University of Utah Office of Sponsored Projects (OSP). An eProposal should not be created for this application.
- <u>Font Size</u>: 11 point, not condensed
- <u>Font Type</u>: Arial
- <u>Spacing</u>: Single space or no more than six lines of type within a vertical inch (2.54 cm)
- <u>Page Size</u>: No larger than 8.5 inches x 11.0 inches (21.59 cm x 27.94 cm).
- <u>Margins</u>: At least 0.5 inch (1.27 cm) in all directions
- <u>Internet URLs</u>: Other than the NIH Biographical Sketches or Bibliography & References Cited documents, URLs directing reviewers to websites that contain additional information about the proposed research are unallowable. Inclusion of such URLs may be perceived as an attempt to gain an unfair competitive advantage.
- <u>Narrative Organization</u>: The content of the narrative should be structured as outlined in the Program Application instructions below. The start of each section should be on a *<u>new page</u> <u>and clearly labeled with the section title</u>*. ***Organize application as the checklist at end of FOA outlines***.
- <u>Tables, Graphs, Figures, etc.</u>: All tables, graphs, figures, diagrams, and charts must be included within the overall page limit.
- <u>Notice of Proprietary Information</u>: Applicants are discouraged from submitting information considered proprietary unless it is deemed essential for proper evaluation of the application. However, when the application contains information that constitutes trade secrets, that is financial or commercial, or that is confidential or privileged, identify the pages in the application that contain this information by marking those paragraphs or lines with an asterisk (*) at the beginning of the

paragraph. Indicate at the beginning of the Research Plan which pages contain asterisks and a note stating: "*The following sections marked with an asterisk contain proprietary/privileged information that [name of applicant] requests not be released except for purposes of review and evaluation.*"

- Recommended Document Size: Size of each document cannot exceed 15 MB.

Program Application

Application documents:
- Summary/Abstract
- Project Narrative
- Research Plan
  - Specific aims
  - Background/Significance/Preliminary Studies
  - Research design and methods
    (Please note: this does not include references. References can be placed at the end of the Research Plan and will not be counted towards the page limits)
- Specific plan to obtain extramural funding including a **timeline** of grant submission
- Principal Investigator NIH Biosketch*
- Key Personnel NIH Biosketch(s)*
- Principal Investigator Other Support Document*
- Key Personnel Other Support Document*
- Proof of IRB submission or proof of non-human subjects research
  - All applicants will be required to submit IRB submission proof by the application deadline. **Please note all pilot IRB protocol titles must match <u>exactly</u> the title of the CTSI pilot application**
- Proof of IACUC Submission
  - All applicants will be required to submit proof of IACUC submission by the application deadline. **Please note all pilot IACUC protocol titles must match <u>exactly</u> the title of the CTSI pilot application.**
- Authentication of Key Biological and/or Chemical Resources *(if applicable)*
- Letters of Support

*Biosketches and Other Support documents must be prepared using the new instructions for submission on or after January 25th, 2022.

Budget and Budget Justification:
Please use the PHS 398 Form Page 4 detailed budget page for initial budget period (https://grants.nih.gov/grants/funding/phs398/phs398.html). Include the initial budget period form and the budget justification in the application (see Checklist).

Section VI. Submission Process

Applicants must log into the University of Utah's CTSI RedCap and complete the online application. The application will become live on September 13, 2021 after the Letter of Intent Due Date.
APPLICATION REVIEW AND AWARD INFORMATION

Section I. Criteria Review

The Utah CTSI Internal Advisory Committee and Ad-Hoc reviewers with expertise specific to an application will review applications utilizing the NIH Review Criteria. Only the review criteria described below will be considered in the review process. As part of the NIH mission, all applications submitted in support of biomedical and behavioral research are evaluated for scientific and technical merit.

Overall Impact:

Reviewer will assess the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following scored review criteria, and additional review criteria will be assigned. An application does not need to be strong in all categories to be judged likely to have major scientific impact.

Innovation:
Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Significance:
Does the project address an important problem or a critical barrier to progress in the field? Is there a strong scientific premise for the project? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Approach:
Are the overall strategy, methodology, and analyses sections well-reasoned and appropriate to accomplish the specific aims of the project? Has the investigator presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented?

Environment:
Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Investigator:
Are the PD/PIs, collaborators, and any other researchers well suited to the project? Preference will be given to early career-investigators, investigators that have not received funding in the last three years, and investigators pursuing a new research direction.

Probability that this project will lead to extramural funding:
Is the plan for future extramural funding clear and realistic? Are there opportunities or barriers that may increase or decrease the likelihood for future funding?

Section II. Anticipated Announcement, Just-in-Time Information, and Award Dates

After the criteria review of the application is completed, the Translational and Clinical Studies Pilot Program Navigator will contact the applicant with decision details. For applicants being considered for funding, the manager will contact the applicant to provide 'Just-in-Time' content, including:

1. Documents required to complete the NCATS Prior Approval process
   - Human Subjects Documentation (if applicable)
     o Including IRB approval
   - Vertebrate Animal Documentation (if applicable)
     o Including IACUC approval
2. Updated [Collaborative IRB Training Initiative (CITI)](#) and [Good Clinical Practice (GCP) Training](#) Assurances for all key personnel (if needed).

Once all Just-in-Time documents are received, the CTSI Translational and Clinical Studies Pilot Program Navigator will submit application to NIH NCATS for consideration. Within 45 days, NCATS will provide their decision. If approved, the manager will contact the applicant to provide the formal Notice of Award (NoA). Awardees must comply with terms and conditions of the NoA and NIH [Grants Policy Statement](#).

Section III. Reporting

Awardees will be required to timely submit a 6-month written progress report and a final progress report to the Utah CTSI Translational and Clinical Studies Pilot Program. In addition to the reports, other requested

documents for either or both the awardee or mentor(s) will include updated NIH formatted biographical sketch, Other Support Forms, and copies of any publications, abstracts, and/or presentations completed during the project period.

Section IV. Program Contacts

CTSI Translational and Clinical Studies Pilot Program Manager
Breanne Johnson
Grants and Contracts Officer
27 S. Mario Capecchi Dr., Salt Lake City, Utah   84132
Office: 801-585-2385; Email: breanne.johnson@hsc.utah.edu

Application Checklist

Application	Submission Method	Length/Limit
☐ **Applicant and Project Information**		
• Applicant & Contact Information	Enter into R**edCap**	Not Applicable
• Other Project Information	Enter into R**edCap**	Not Applicable
☐ **Pilot Application**	Save file as "Pilot Application_PI Last Name.pdf" and upload as a **single file**	
• Summary/Abstract		30 lines of text
• Project Narrative		6 lines of text
• Research Plan		5 page limit
• Specific aims		*1 page – NOT Part of the 5 page limit*
• Background/Significance/Preliminary Studies		*Part of the 5 page limit*
• Research design and methods *(Please note: this does not include references. References can be placed at the end of the Research Plan and will not be counted towards the page limits)*		*Part of the 5 page limit*
• Specific plan to obtain extramural funding including a timeline of grant submission		2 page limit
• Principal Investigator NIH Biosketch, new version		5 page limit
• Key Personnel NIH Biosketch(s), new version		5 page limit each
• Principal Investigator Other Support Document, new version		No page limit
• Key Personnel Other Support Document, new version		No page limit
• Proof of IRB Submission *(If applicable)*		No page limit
• Proof of IACUC Submission *(If applicable)*		No page limit
• Authentication of Key Biological and/or Chemical Resources *(if applicable)*		No page limit
• Letters of Support		No page limit
• Detailed Budget & Justification		No page limit