

Utah CTSI Translational Innovation Pilot (TIP) Program



Required Letter of Intent (LOI) Due:
Monday, August 29, 2022 by 5pm MST

Invited Full Application Due:
Friday, November 11, 2022 by 5pm MST

The National Center for Advancing Translational Sciences' (NCATS) Clinical & Translational Science Award (CTSA) program seeks to develop and implement innovative solutions that will improve the efficiency, quality, and impact of the process for turning observations in the laboratory, clinic, and community into interventions that improve the health of individuals and communities.

Leveraging CTSA funding, the Utah Clinical & Translational Science Institute (CTSI) will award ~four \$30,000 pilots through its Translational Innovation Pilot (TIP) program. In alignment with NCATS, the Utah CTSI's TIP program will support **translational science** projects that focus *"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."*

NCATS definitions:

- **Translation:** 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:** The endeavor to traverse a particular step of the translational process for a particular target or disease.
- **Translational Science:** The field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process.

Application Focus

The Utah CTSI's TIP program will fund translational science projects aiming to identify and overcome barriers to the performance of translational research. Addressing critical barriers will allow subsequent translational research to accelerate the time from discovery to improved human health.

Applications should articulate a clear translational research barrier(s) and propose an innovative plan to overcome or ameliorate the barrier (a.k.a. a translational science innovation). The proposed innovations should be broadly generalizable to many different translational research questions. Proposed projects should align with one of the following project scopes:

Develop:	New methodology, technology, tool, resource, or training paradigm that has generalizable application to an identified translational roadblock
Demonstrate:	New methodology, technology, tool, resource, or training paradigm to improve the effectiveness or efficiency of the translational process (including feasibility to support future clinical or translational science or research projects)
Disseminate:	Tools to effectively move methodology, technology, tool, resource, or training paradigm that overcome an identified translational roadblock or improve the effectiveness or efficiency of the

translational process into broader use

It is expected that all research supported by Utah 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.

Key Information

Posted Date	Friday, July 1, 2022
Letter of Intent (LOI) Due Date	Monday, August 29, 2022 by 5:00 pm MST
Invitation to submit full application	Friday, September 30, 2022
Full Application Advisor and Design Consultations	September 30, 2022 – November 11, 2022
Application Due Date	Friday, November 18, 2022 at 5:00 pm MST
Notice of Intent to Fund	January 4, 2023
Just-in-Time (JIT) Period	January 4, 2023 – April 1, 2023
Earliest Start Date	April 1, 2023 *(pending JIT fulfilment)
Announcement Expiration Date	August 30, 2022
Award Budget	\$30,000 <i>Please note: All funds not spent by the end date of the CTSA TIP Award will be returned to the participating institution and NIH. Extensions are not allowed.</i>
Federal Prime Sponsor	National Institutes of Health (NIH) / National Center for Advancing Translational Sciences (NCATS)
Questions?	CTSI 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

TIP Program Eligibility Criteria

- Successful projects will exemplify NCATS's and the Utah CTSI's mission of advancing clinical and translational science as described above. 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.
- Applicants must hold a faculty or equivalent appointment at the University of Utah or a Utah CTSI partner organization. Both tenure-line faculty and Career-line faculty are eligible to apply.
- Applicants that have significant start-up, cash reserves, have received a previous intra-institutional pilot award within the past 2 years, or are seeking gap funding to bridge support between external grants or contracts are not eligible.
- The proposed project should not be funded by any other mechanism/research initiative at the time of submission.
- Preference will be given to early career investigators and those pursuing a demonstrably new research direction.
- Team science and new collaborations are encouraged (e.g., projects with two or more team members from different disciplines).

Application Timeline and Process

The TIP application and review process is outlined as follows:

1. **Letter of Intent (LOI):** Applicants will submit a required LOI due August 29, 2022, containing standardized components outlined below. LOIs will be reviewed for scientific merit, significance, innovation, and focus on translational science. A subset of LOIs will be invited by September 30, 2022 to submit a full application. A summary of any weaknesses that should be addressed in the full application will be shared.
2. **Assistance in the Preparation of Invited Full Applications:** The following support will be available to enhance the preparation of invited full applications, with particular emphasis on refining the translational science focus.
 - **Advisors:** Applicants who have not previously been awarded their own R01 level extramural grant (or those that have and specifically request this support) will be assigned an Advisor from a pool of experienced clinical trial and research faculty. The Advisor will meet with the applicant(s) at least twice over the preparation period to review the application, suggest improvements, and help define achievable metrics for the one-year project period. These consultations will aim to help applicants better address translational science objectives.
 - **Design Consultations:** Applicants are also encouraged to consult with experts from the Utah CTSI's Cores and Services who will make their time and expertise available for this purpose during the application preparation period. These design consultations will help applicants consider and implement modifications that address weakness in their application structure (e.g. statistics, study design, community engagement). Services can be requested directly at ctsi.utah.edu or can be facilitated by the CTSI's Pilot Program Manager. CTSI's [cores and services](#) include:
 - Translational Research: Implementation, Analysis & Design Team
 - Study Design & Biostatistics
 - Cancer Biostatistics
 - Health Economics
 - Qualitative Services
 - Survey Design & Measurement
 - Systematic Review
 - Community Collaboration & Engagement Team
 - Clinical Research Unit (Space and nursing services for clinical research)
 - Biomedical Informatics Core
 - Cellular & Translational Research Core
 - Clinical Research Support Office
3. **Invited Full Applications:** The invited full application will be due November 11, 2022. The application will contain a brief description of how weaknesses in the LOI were addressed (and if relevant, how advisors and design consultations assisted in these revisions). For every application, reviewers will provide an NIH-style scientific content review, including impact score and an Overall Impact/Merit paragraph that summarizes the factors informing the Overall Impact score. A subset of full applications will be recommended for funding.
4. **Just-in-Time (JIT) Period and Notice of Award:** Applications recommended for funding that include human or animal research will receive a Just-in-Time request including:
 - a. Official IRB determination of non-human subjects' research.

- b. Human Subjects Documentation, IRB approval or congruency letter, and updated [Collaborative IRB Training Initiative \(CITI\)](#) and [Good Clinical Practice \(GCP\) Training](#) assurances for all key personnel (if applicable).
 - i. Human Subjects Documentation may include
 - Inclusion of Individuals Across the Lifespan
 - Inclusion of Women and Minorities
 - Recruitment and Retention Plan
 - Study Timeline
 - Protection of Human Subjects
 - Planned Inclusion and Enrollment Report
 - Single IRB Plan (if multi-site study)
 - Data and Safety Monitoring Plan
 - Overall Structure of the Study Team
 - Statistical Design and Power
 - Dissemination Plan
- c. Vertebrate Animal Section Document* and IACUC approval
 - i. * <https://olaw.nih.gov/guidance/vertebrate-animal-section.htm>

The applicant will work with the CTSI NCATS Prior Approval Navigator to submit the Just-in-Time documents to NCATS for review. This review is called the Prior Approval process. After the Prior Approval process is completed, the applicant will receive the formal Notice of Award (NoA). Awardees must comply with terms and conditions of the NoA and NIH [Grants Policy Statement](#).

TIP Submission Instructions

The Utah CTSI Translational Innovation Pilot (TIP) Program **requires** all applicants to adhere to the following instructions when preparing their letter of intent (LOI) and full application. Applications that fail to adhere to instructions or that are late may be administratively denied.

- University of Utah Internal Process: 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.
- Font: Arial, 11 point, not condensed
- Spacing: Single space or no more than six lines of type within a vertical inch (2.54 cm)
- Page Size: No larger than 8.5 inches x 11.0 inches (21.59 cm x 27.94 cm).
- Margins: At least 0.5 inch (1.27 cm) in all directions
- Internet URLs: 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 not allowed.
- Organization: The content of the LOI and full application should be structured as outlined in the instructions below. The start of each section should be on a *new page and clearly labeled with the section title*.
- Tables, Graphs, Figures, etc.: All tables, graphs, figures, diagrams, and charts must be included within the overall page limit. If included, figures and tables may have a font size as small as 8 points.
- Notice of Proprietary Information: 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, either financial or commercial, or that is confidential or privileged, please 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.*”

Letter of Intent (LOI) Instructions

A Letter of Intent (LOI) is **required** and must be provided by **August 29, 2022 by 5:00 pm MST.** Contact Principal Investigator will submit LOI via a Redcap survey [link](#).

➤ The redcap survey link will activate on Monday, August 1, 2022.

Required LOI Components, 4-page maximum*:

1. Introduction (1-page limit)
 - Project Title
 - Principal Investigator(s) (name, title, department, contact information)
 - Key Personnel (name, title, department, contact information, project role)
 - Brief description of the composition and qualifications of the research team
2. Research Strategy (3-page limit)
 - Specific Aims
 - Significance and rationale
 - **Include an explicit explanation of the translational research barrier(s) the project is designed to address or overcome**
 - Potential benefits and innovation of the proposed projects
 - The importance of the knowledge to be gained
 - Overview of the proposed methods
 - Expected results and metrics for success of the project

*References excluded from 3-page maximum
3. Principal Investigator(s) Biosketch, NIH Biosketch required to follow the new instructions for submission on or after 01/2022 (5-page limit, *excluded from 4-page maximum)

Full Application Instructions

Full application components are due by **November 11, 2022 by 5:00 pm MST.** Contact Principal Investigators will be given a link to submit the full application when invited.

Full Application, 8-page maximum*:

1. Cover Page (1-page limit)
 - Project Title
 - Principal Investigator(s) & Key Personnel
 - Summary/Abstract (30 lines)
 - Project Narrative (250 words)
2. Research Strategy (6-page limit)
 - Specific Aims
 - Background/Significance/Preliminary Studies
 - **Include an explicit explanation of the translational research barrier(s) the project is designed to address or overcome**
 - Research design and methods
 - Expected results and metrics
 - Analysis plan
 - Specific plan to obtain extramural funding including a **timeline** of grant submission

- References excluded from 5-page maximum and attached as a separate document
- Detailed milestones for each Aim to be achieved at 3 and 6 months into the one year project.
- 3. Description of changes/improvements from LOI concept following advisor consultations and design sessions (1-page limit)
 - Responds to the issues and criticism raised in the LOI summary statement
- 4. Principal Investigator(s) Biosketch(s)*
- 5. Key Personnel NIH Biosketch(s)*
- 6. Principal Investigator Other Support Document*
- 7. Key Personnel Other Support Document*
- 8. Authentication of Key Biological and/or Chemical Resources (if applicable, 1-page limit*)
- 9. Letters of Support (optional)
- 10. Bibliography and Literature Cited (no page limit; *excluded from 8-page maximum)
- 11. PDF of completed draft IRB/IACUC application ****don't submit yet, leave in 'in progress' state!****
 - Don't submit to IRB/IACUC until notified by CTSI (process will commence after award notification/JIT period).
 - Please note: the IRB/IACUC application title must match exactly the title of the CTSI pilot application
 - If your proposed pilot is an ancillary study to an existing IRB/IACUC approval, a congruency letter will be required during the JIT period
 - If your proposed pilot will involve human specimens and/or data, but is not considered human subjects research, an official IRB determination of non-human subjects' research will be required during the JIT period.
- 12. Budget
 - Use the PHS 398 Form Page 4 detailed budget page for initial budget period (<https://grants.nih.gov/grants/funding/phs398/phs398.html>).
 - Requested budgets should be based on the proposed project needs.
 - No proposal may exceed a request of \$30,000.
 - Awards will be given based on merit and funding availability.
- 13. Budget Justification *excluded from 8-page maximum
 - The following costs are **not covered** by TIP programs:
 - Faculty salaries
 - Postdoctoral salaries of any Postdoc listed as a trainee 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

* NIH Biosketch required to follow the new instructions for submission on or after 01/2022, found here: <https://grants.nih.gov/grants/forms/biosketch.htm> (5-page limit, *excluded from 8-page maximum)

Letter of Intent and Full Application Review Criteria

All applications are evaluated for scientific and technical merit. Both Letters of Intent and Full Applications will be reviewed for scientific merit and translational science potential using the NIH Review Criteria listed below.

1. **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.

2. **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? How do these innovations overcome barriers to the performance of translational research? 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?
3. **Significance:** Does the project address an important problem or a critical barrier to progress in the field and to the performance of translational research? 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?
4. **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?
5. **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?
6. **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.
7. **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?