

Utah CTSI Translational Innovation Pilot (TIP) Program



Required Letter of Intent (LOI) Due:
August 3, 2026 by 5 pm MST

Invited Full Application Due:
October 12, 2026 by 5 pm MST

The National Center for Advancing Translational Sciences' (NCATS) Clinical & Translational Science Award (CTSA) program seeks to develop and implement innovative solutions that will measurably 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 up to five \$30,000 one year pilot grant awards 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."* Translational science (TS) solutions can span the spectrum from highly technical innovations that facilitate preclinical investigation to very pragmatic measures that improve the efficiency, broad population relevance, or structure of clinical trial performance. TS solutions are measurable and applicable to multiple diseases and human health states.

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 in order to develop solutions that overcome barriers or increase efficiency in the translational process.

Application Focus

The Utah CTSI's TIP program will fund TS 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.

The CTSI welcomes applications that promote and/or leverage the integration of **Biostatistics, Biomedical Informatics, and/or Data Science (BIDS)** to overcome translational research barriers.

Projects that seek pragmatic TS solutions with insights derived from and in **collaboration with administrative research professionals** are also encouraged.

All applications should articulate a clear translational research barrier(s) and propose an innovative plan to overcome or ameliorate the barrier (a.k.a. a TS innovation). The proposed innovations should be broadly generalizable to many different translational research questions. Implied in the principles of generalizability and scalability is that a TS solution should include consideration of dissemination of the solution to other researchers who might find the solution useful in their own work.

Proposed projects should broadly align with 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 TS 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 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 applications for extramural funding.

For a list of previously funded TIP program awardees, visit our [website](#).

Resources to Understand Concepts of Translational Science

- Zoom Presentation: What is Translational Science? By Dr. J. Rob Singleton, MD of the University of Utah, CTSI TIP Pilot Director
- Utah CTSI Translational Science Summary:
<https://ctsi.utah.edu/about-us/what-is-ctsi/what-is-translational-science>
- NCATS Translational Science Principles:
<https://ncats.nih.gov/training-education/translational-science-principles>
- Distinguishing between translational science and translational research in CTSA pilot studies: A collaborative project across 12 CTSA hubs. J Clin Transl Sci. 2023 Dec 18;8(1):e4. doi: 10.1017/cts.2023.700. PMID: 38384905; PMCID: PMC10877521.
<https://pmc.ncbi.nlm.nih.gov/articles/PMC10877521/>
- "Translating Translation" by Christopher P. Austin
- "Divining the Venn Diagram of Translational Research versus Translational Science" by Michael Kurilla, NCATS Director
- "Introduction to Translational Science": a 10-hour virtual course, available through Coursera, produced and taught by Martin Zand, MD PhD at the University of Rochester. The course can be taken for credit (cost \$49.95) or audited.
- "Translational Science Benefits Model": Contains slides with definitions, brief examples, and vignettes. From the University of Washington.

Key Information

Zoom Presentation: What is Translational Science & Effectiveness of Integrating BIDS	Monday, June 22 @ 2-3 pm MST https://utah.zoom.us/j/83150439843
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<i>By Dr. Rob Singleton, MD and Dr. Yue Zhang, PhD</i>	
Letter of Intent (LOI) Due Date	Monday, August 3, 2026 by 5.00 pm MST
Invitation to submit full application	Monday, August 31, 2026 by 5.00 pm MST
Full Application preparation during Advisor and Design Consultations	August 31 – October 12, 2026
Zoom Presentation for Invited TIP Applicants to submit full app	Tues, September 8, 2026 @ 12.00 pm MST – invitation sent to those invited
Application Due Date	Monday, October 12, 2026 by 5.00pm MST
Notice of Intent to Fund	December 4, 2026
Just-in-Time (JIT) Period	Dec 4, 2026 – April 1, 2027 <u>Required JIT Deliverable timeline:</u> • Meet with regulatory coordinator & pilot manager – 12/19/26 • IRB Submission – 01/15/27 • NCATS submission – 02/15/27 (if applicable) • Pilot kick-off meeting w. pilot director – 03/2027
Earliest Start Date	Wed, April 1, 2027 *(pending; 1) JIT fulfilment, and 2) CTSI receipt of their parent UM1 NOA)
Announcement Expiration Date	December 5, 2026
Award Budget	\$30,000 <i>Please note: All funds not spent by the end date of the one-year 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?	FAQ information available on the last page. If you have further questions, email utahctsi_pilots@hsc.utah.edu & allow 1-2 business days for replies

TIP Program Criteria

- Successful projects will exemplify NCATS and the Utah CTSI mission to advance clinical and TS as described above. NCATS has specified that these pilots must include TS relevance. Thus, translational research projects, projects that describe only methods to address study of or development of treatment for a particular target or disease, are not sufficient.
- Applications that include a clinical trial (including BESH-defined CTs) **are not eligible** and will be administratively rejected.
 - o If you are unsure if your proposed pilot meets the NIH definition of a clinical trial [use this NIH tool](#).
 - o What is a Basic Experimental Study involving Humans ([BESH Clinical Trial](#))?
 - o If after reviewing these NIH rules you remain uncertain if your proposed project may represent BESH, we invite you to reach out to TIP staff to discuss.

- Applications that promote or leverage the integration of BIDS to overcome translational research barriers are strongly encouraged. This may include, but is not limited to advanced data management, and/or the development of novel statistical, artificial intelligence, and machine learning methods.
 - Prospective applicants with BIDS-focused project ideas are encouraged to attend the TIP/BIDS zoom presentation on June 22nd and/or register for a personal 1-1 virtual office hour slot – details provided above.
- Applicants are required to 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. The CTSI recognizes that non-faculty research staff and administrators are well positioned to recognize barriers to performance of translational research, and to develop pragmatic solutions to ameliorate these barriers. Collaborative proposals between faculty and research staff are encouraged.
- 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).
- Foreign collaborations that will require the transfer of funds or inclusion of foreign investigators in research publications cannot be permitted.
- See below for full review criteria.

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 3, 2026 by 5pm MST, containing standardized components outlined below. LOIs will be reviewed for scientific merit, significance, innovation, and focus on TS. A subset of LOIs will be invited by August 31, 2026 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 TS 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 TS objectives. Performance mentors will

also meet quarterly with awardees through the one-year project period to provide guidance and help overcome performance roadblocks.

- **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:
 - TRIAD - Translational Research: Implementation, Analysis & Design Team
 - SCOT – Study Collaboration & Opportunities Team
 - RES – Research Ethics Consults
 - PET – Practice Engagement & Translation
 - ORPA – Office for Research Participant Advocacy
 - Design Studios
 - CTRC – Cellular Translational Research Core
 - CRSO – Clinical Research Support Office
 - CRU – Clinical Research Unit
 - CCET – Community Collaboration & Engagement Team
 - BMIC – Biomedical Informatics Core
3. **Invited Full Applications:** The invited full application will be due October 12, 2026 by 5pm MST. 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). Applications will be reviewed by 2-3 reviewers, and discussed at an NIH-style, in-person review panel session. Reviewers will provide a multipoint scientific content review, and review panel members will vote an overall impact score. Funding decisions will be made by CTSI leadership based on scientific merit and institutional priorities. All applicants will receive their reviews, together with an overall Impact/Merit paragraph that summarizes the panel discussion.
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. Required JIT Deliverable timeline:
 - i. Meet with regulatory coordinator & pilot manager - 12/19/26
 - ii. IRB/IACUC application submission completed – 01/15/27
 - iii. NCATS prior approval submission – 02/15/27 (if applicable)
 - iv. Pilot kick-off meeting with PM – 03/01/2027
 - b. Provide or create a backup 2500 fund activity chartfield to be used in the case of over-expenditure
 - i. We **cannot** accept a 6000-fund activity chartfield.
 - c. Official IRB/IACUC Determination
 - i. Any pilot found to be a clinical trial, including BESH-defined CTs administratively rejected and JIT rescinded immediately.
 - ii. 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).
 1. Human Subjects Documentation may include:
 - a. Inclusion of Individuals Across the Lifespan
 - b. Inclusion of Women and Minorities
 - c. Recruitment and Retention Plan

- d. Study Timeline
- e. Protection of Human Subjects
- f. Planned Inclusion and Enrollment Report
- g. Single IRB Plan (if multi-site study)
- h. Data and Safety Monitoring Plan
- i. Overall Structure of the Study Team
- j. Statistical Design and Power
- k. Dissemination Plan
2. Vertebrate Animal Section Document* and IACUC approval
 - a. *<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 may 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. The following are stylistic details:

- University of Utah Internal Process: The Pilot Program Application **does not** require prior consideration by the University of Utah Office of Sponsored Projects (OSP).
 - i. **An OSP 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
- Footer: Label each page in the footer with the PIs name and the title of the document. Align the first letter of this text with the left margin. **No Headers**
 - i. Example: (PI)LastName_Name of document; "(PI)Doe_CoverPage"
 - ii. Excluded from Biosketch(s), Other Support, IRB/IACUC draft application & budget excel file
- Single-pdf component upload: both the LOI and full application will be uploaded as a single pdf file as directed in RedCap.
- 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 as directed in the footer*.
- 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 3, 2026 by 5:00pm MST.**

Contact Principal Investigator will submit LOI via RedCap [HERE](#).

☐ The redcap survey link will activate on July 15th – Aug 3rd until 5.01pm MST.

Required LOI Components (6-page maximum):

1. Investigators introduction (1-page Maximum)
 - 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. Translational Science statement/ rationale (2-page Minimum)
 - a. Provide an explicit statement of the translational research barrier(s) the project is designed to address or overcome together with appropriate background context to allow the reader to understand the barrier. (1/2 page minimum)
 - b. Provide a statement describing how the proposed project will advance toward or contribute to a solution to overcome the stated barrier. (1/2 page minimum)
 - c. Provide a statement describing how this solution be generalizable to other diseases, investigators, interested stakeholders, etc. (1/2 page minimum)
 - d. Briefly outline Specific Aims to accomplish these objectives. (1/2 page minimum)
3. Research Strategy (2-page limit)
 - Background/preliminary data
 - Overview of the proposed methods
 - Expected results and metrics for success of the project
4. Bibliography and Literature Cited (*no page limit, excluded from page limit)
5. Statement of Human Subjects Involvement (1-page minimum)
 - a. Answer the 4 NIH clinical trial determination questions with a Yes or No:
 - i. Human Participants?
 - ii. Prospectively Assigned Intervention?
 - iii. Evaluate Effect of Intervention?
 - iv. Health-Related Outcome?
 - b. Brief justification under each answer explaining why this pilot does NOT constitute a CT and/or BESH study
 - i. [NIH Clinical Trial questions](#)
 - ii. [4 Clinical Trial Questions for BESH Studies](#)
6. Principal Investigator(s) Biosketch, NIH Biosketch required to follow the instructions for submission here: <https://grants.nih.gov/grants/forms/biosketch.htm> (5-page limit, excluded from page maximum)

Full Application Instructions

Full application components are due by **October 12, 2026 by 5:00 pm MST.**

☐ Contact Principal Investigators will be given a link to submit the full application when invited.

Full Application components, 8-page maximum*:

1. Cover Page (1-page limit)
 - Project Title
 - Principal Investigator(s) & Key Personnel
 - Summary/Abstract (max 30 lines)
 - Lay Public Project Narrative (250 words) (will be published for CTSI use)
2. Translational Science statement/rationale (minimum 2 pages)
 - Provide an explicit statement of the translational research barrier(s) the project is designed to address or overcome together with appropriate background context to allow the reader to understand the barrier. Label this section “TS Barrier”.
 - Provide a statement describing how the proposed project will advance toward or contribute to a solution to overcome the stated barrier. Label this section “TS Solution/Innovation”.
 - Provide a statement describing how the solution be generalizable to other diseases, investigators. Label this section “Generalizability”.
 - Explain how the solution will be disseminated to other stakeholders. Label this section “Dissemination”
 - Briefly outline Specific Aims to accomplish these objectives.
3. Research Strategy (5-page limit)
 - Background/Significance/Preliminary Studies
 - Research design and methods
 - Expected results and metrics
 - Analysis plan
 - Detailed milestones for each Aim to be achieved at 6 and 12 months into the 12-month funding period.
 - Specific plan to obtain extramural funding including a **timeline** of grant submission
4. Bibliography and Literature Cited (no page limit; *excluded from page maximum)
5. 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
6. Principal Investigator(s) Biosketch(s)*
7. Key Personnel NIH Biosketch(s)*
8. Principal Investigator Other Support Document*
9. Key Personnel Other Support Document*
10. Authentication of Key Biological and/or Chemical Resources (if applicable, 1-page limit)
11. Letters of Support (optional & excluded from page maximum)
12. PDF of completed draft IRB/IACUC application ****don't submit yet, leave in 'in progress' state!****

***If your pilot will use an existing IRB study with clinical trial (CT) determination (including BESH-defined CTs) – this will automatically disqualify the application. A new IRB application without CT components is required.**

- 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

13. Budget *review FAQ at the bottom of this document if you have further questions

- Use the PHS 398 Form Page 4 detailed budget page for 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
 - Participant Payment Reimbursements budget line items are required to be handled through OnCore or an exception letter obtained and provided. Begin this process early and [here](#).
14. Budget Justification (*2-page limit, excluded from 8-page maximum)
- The following costs are **not covered** by TIP program:
 - Faculty salaries (including adjunct & visiting)
 - Postdoctoral salaries of any Postdoc listed as a trainee on a Training Grant
 - Non-institutional staff salaries
 - Graduate student stipends or tuition (stipends: funds from a grant or another award)
 - 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 & Other Support required to follow the instructions found here:

<https://grants.nih.gov/grants/forms/biosketch.htm> & <https://grants.nih.gov/grants/forms/othersupport.htm>
(5-page limit, *excluded from page maximum)

Letter of Intent and Full Application Review Criteria

Both Letters of Intent and Full Applications will be reviewed for TS relevance, scientific merit and feasibility using the NIH Review Criteria listed below. LOI review will emphasize conceptual strength and feasibility, while full application review will focus on TS relevance and scientific rigor/merit.

1. **Translational Science Relevance:** How successfully does the proposed project embody TS qualities: Identification of a TS barrier, and a generalizable solution across multiple projects and/or disease states?
2. **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.
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. **Metrics & Feasibility:** Clear timeline, deliverables, measurable metrics of success; clear metrics for success? Are potential problems, alternative strategies, and benchmarks for success presented? Are the milestones and metrics for success clearly defined? Are they appropriate for a 1-year project?
6. **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?
7. **Investigator/ Environment:** Are the PI(s), collaborators, and any other team members well suited to the project? Will the scientific environment in which the work will be done contribute to the probability of success? Are the equipment and other physical resources available to the investigators adequate for the proposed project? Will the project benefit from unique features of the scientific environment, the populations available for carrying out the study, or collaborative arrangements? (should include evaluation of the integration of special populations, approaches to articulated research barriers, and demonstration of feasible and generalizable TS solutions, team science and interdisciplinary collaboration).

Frequently Asked Questions (FAQ)

Question 1:

Can staff participate as Principal Investigator(PI) or Co-PI in a TIP proposal?

Q1 Answer – Univ Employees: No. Staff can participate as Co-Investigator. This funding mechanism requires a faculty member as PI on the pilot.

Q1 Answer – Utah CTSI Partners: Personnel at our partner sites who are eligible to receive federal funding can serve as PI or co-PI. Contact utahctsi_pilots@hsc.utah.edu if you have questions.

Question 2:

Is travel allowed on the budget?

Q2 Answer: Allowable requests for travel expenses to support research activities may be requested with detailed justification (e.g., traveling to southern Utah for participant enrollment with justification why virtual efforts are not possible). Travel expenses are not allowed for project meetings/planning, or to present results at conferences.

Question 3:

Do key personnel need an ERA Commons ID before full application submission, or can it be obtained during the JIT period?

Q3 Answer: No, an ERA Commons ID isn't required with submission if the key personnel do not have one. It can be obtained during the JIT period.

Question 4:

If I already have IRB approved for the work done during my pilot, am I required to make an amendment to update the scope, aims? If so, do I need to change the title of the IRB approval to match the pilot? Or vice versa?

Q4 Answer: Yes, and amendment is required to update the scope/aims. Yes, the IRB title and proposed pilot title must match.

Question 5:

Only pages 4 and 5 of PHS 398 are required for my budget and justification?

Q5 Answer: Yes, please provide the budget on page 4 and the justification on page 5 of the PHS 398 forms. If additional space is needed for the justification, please create the document in a word doc.

Question 6:

I plan to use an existing IRB/IACUC reviewed determination study that has approval as a clinical trial (CT). May I use this IRB approval if the proposed TIP will not be a CT?

Q6 Answer: No. TIPs that are derived from previously IRB-approved projects that meet the NIH definition of a CT (including BESH-defined CTs) cannot be funded, and must be administratively rejected, even if the CT makes up only a portion of the overall project. The PI and team will be required to submit a new IRB/IACUC application for their TIP that excludes CT work.