Request for Applications

CLINICAL & TRANSLATIONAL SCIENCE (CTS) PILOT GRANT PROGRAM *

A JOINT INITIATIVE
SPONSORED BY INDIANA CTSI PARTNER INSTITUTIONS

INDIANA UNIVERSITY
AND
PURDUE UNIVERSITY
AND
UNIVERSITY OF NOTRE DAME
AND
REGENSTRIEF INSTITUTE

ELECTRONIC RECEIPT DATES
LOI Due: June 3, 2024
Application Submission: September 4, 2024
1st Review: October 11, 2024
Presentations: November 8, from 12:00 pm – 5:00pm EST (Applicants must attend)
Funding Begins: May 1, 2025

***Please note this grant mechanism has some unique criteria for scope of proposed work. As such, each applicant MUST meet with Tammy Sajdyk after submission of the LOI, but prior to submitting the full application.**

You will be submitting through the Indiana CTSI's grants management software WebCAMP. The WebCAMP user's guide is available under the funding announcement here:
https://indianactsi.org/translational-research-development/open-funding-opportunities/

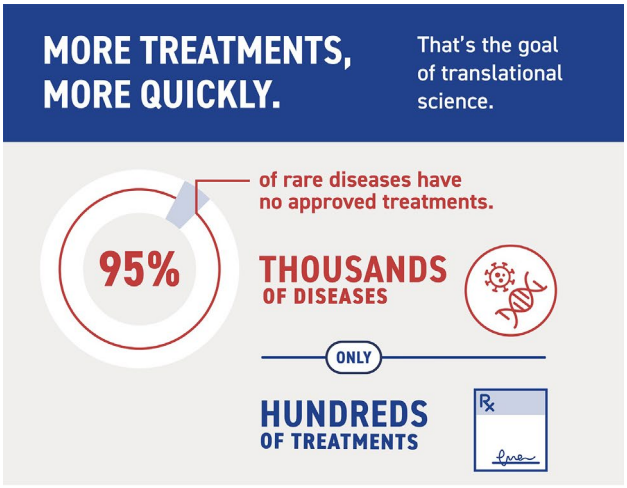
Modified March 2024

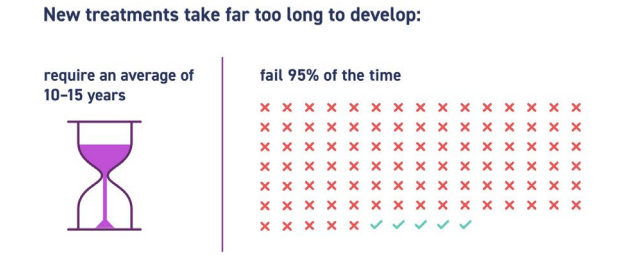
INFORMATION FOR APPLICANTS

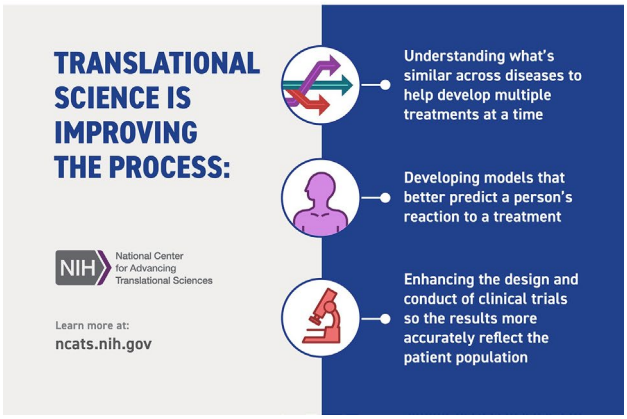
WHAT IS CLINICAL AND TRANSLATIONAL SCIENCE AND HOW IS IT DIFFERENT FROM TRANSLATIONAL RESEARCH?

This grant mechanism is focused on translational science and *NOT* translational research. What is the difference?

Translational science is the field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process and is not focused on any specific disease state. It is the process of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public — from diagnostics and therapeutics to medical procedures and behavioral changes. The goal is to reduce, remove or bypass significant bottlenecks across the entire continuum of translation (https://ncats.nih.gov/translation).







Examples of Translational Science projects:

Biochemical and biological investigations with potential therapeutic connections – such as cell mechanisms for resistance to anticancer agents.

Mathematical and engineering applications – such as new materials for tissue replacement/augmentation.

Chemical methods pertaining to synthesis of therapeutic agents – such as synthesis of nanomaterials for targeted drug delivery.

Digital health technologies – such as development of a wearable device that can monitor symptoms and disease progression in patients with chronic diseases.

Animal models – such as the development of a zebrafish model of rare genetic diseases that can be used to test the safety and efficacy of gene therapies before moving into clinical trials.

Devices that mimic the human state - such as the development of a microfluidic device which models the blood-brain barrier and enables screening of drug candidates for central nervous system disorders.

Informatics – such as creation of a decentralized digital platform that can facilitate patient recruitment and data collection for clinical trials, allowing for more diverse and representative study populations.

For additional information about translational science and whether or not your study is a good candidate for this mechanism, please, contact Tammy Sajdyk tsajdyk@iu.edu.

GENERAL INFORMATION

The four premier research institutions within the State of Indiana – Indiana University, Purdue University, the University of Notre Dame, and Regenstrief Institute with support from the National Institutes of Health (NIH), have formed an institute called the Indiana Clinical and Translational Sciences Institute (CTSI); conceived as a statewide laboratory to conduct innovative research and education in health sciences. The mission of the Indiana CTSI is "to bring together Indiana's brightest minds to solve the state's most pressing health challenges".

The objective of the new Indiana CTSI Clinical & Translational Science (CTS) pilot grant mechanism is to initiate or continue translational science projects that help identify translational methods and processes relevant across a range of diseases, treatments, and interventions. The key objective of the projects should be to develop methodological innovations and/or produce crosscutting solutions for common and persistent challenges to reduce, remove, or bypass significant bottlenecks across the continuum of translation.

Applications through this mechanism will be evaluated on the quality of the proposed science as well as the application's strength in clarifying the plan for achieving the primary CTS objective.

Applications to this program are limited to a total of **$40,000** and are **12 months (1 year)** in duration. There will be **no** ability to apply for a no cost extension with this new grant. Because these awards are (NIH) NCATS awards, they must comply with NIH guidelines. NIH has specified that **ALL THESE PROJECTS MUST BE COMPLETED IN 12 MONTHS.**

WHO MAY APPLY

IUSM: All full-time faculty, regardless of tenure status, having a primary appointment within the School of Medicine as Assistant Professor or Assistant Scientist and above. This includes those faculty appointed as part-time Assistant Professor or above, if they are geographically full-time. Faculty at the IUSM regional centers for medical education are eligible to apply (assuming they meet all other eligibility criteria) and are considered IUSM faculty for purposes of identifying the sponsoring affiliate as described above.

IBRI: All IBRI investigators eligible to receive funding according to the institution's central research office.

IUI / PUI / IUB: All tenured or tenure-track faculty at or above the Assistant Professor level regardless of tenure status, if approved to serve as a PI by the institution's central research office; faculty at all levels of the Scientist or Scholar tracks.

Purdue: All tenured or tenure-track West Lafayette faculty at or above the Assistant Professor level; all research professors; all clinical faculty. Non-faculty approved for PI status.

Notre Dame: All tenured or tenure-track faculty; all research faculty; all special professional faculty.

Regenstrief Institute: All Regenstrief investigators eligible to receive funding according to the institution's central research office.

APPLICATION PROCESS

LOIs are due by end of day June 3, 2024. Email them to: trnsldev@iu.edu
If you have any questions about the LOI please contact Tammy Sajdyk at tsajdyk@iu.edu

Once the LOI is submitted you will be scheduled for a brief (30 minutes or less) zoom meeting with Tammy Sajdyk to go over the LOI. Following the meeting, you will receive an email with a link to start your full submission.

Full applications are due on September 4, 2024.

APPLICATIONS SEQUENCE

You MUST use the application forms available here Indiana CTSI CTS Link

1. **Face Page**
   The face page specifies the title of the proposal, principal investigator and his/her affiliation, collaborator(s) and affiliation, where work will be performed, and the total budget. Department / School support must be indicated by **completion of all appropriate signatures on the face page(s) FOR EACH PI and CO-PI (if applicable).** As submission will be electronic only, facsimile or electronic signatures are appropriate.

2. **Abstract & Keywords**
   - The abstract should be a brief (500 word maximum) abstract in layman's terms.
   - Provide 5 keywords that describe the research content of your project

3. **Budget**
   Budget page listing all direct costs. This page may be duplicated and a separate budget page included for each performance site / collaborating institution. Requested grant funding period cannot exceed **12 months**.
   - Projects should have a start date no earlier than **May 1, 2024.**
   - Supplies and other costs must relate directly to performance of the project.
   - All costs should be specifically justified, and expenditures clearly denoted. Limit budget justification to ½ page.
   - NEW FOR THIS MECHANISM: Salaries for PIs and co-investigators may be included for Indiana CTSI investigators and affiliates (Visiting status not eligible).

The **Specific Aims and Research Plan** should have at least 1/2 inch margins (top, bottom, left and right) and must NOT exceed **6 single-spaced pages**, excluding references. Font must be clear and readily legible and reasonable size. *Use an Arial, Helvetica, Palatino Linotype or Georgia typeface, a black font color and a font size of 11 points or larger*. Make every effort to write these sections toward a general scientific audience; avoid field-specific jargon and undefined abbreviations. Every attempt will be made to find proposal reviewers with expertise in the general area of the proposal, but applicants should be aware that highly specialized expertise may not be available within the Indiana CTSI system.

5. Specific Aims (one page maximum): Describe the specific aims of the proposal, how the aims relate to each other and the expected outcomes, the methods of procedure and how the complementary expertise of the applicants contributes to these aims.

6. Research Plan: The Research Plan narrative **should not exceed 5 pages** and should be structured in accordance with the following format:

A. Objectives of the current proposal: State the overall objective or goal of the proposed research.

B. Translational potential for the project: Describe the project's potential impact on human health and/or how it may be translated to impact human health concerns in the future. Examples of measurable benefits and indicators of clinical & translational science projects are listed below and can be utilized to describe the impact of your project. https://pubmed.ncbi.nlm.nih.gov/28887873/

C. **<u>Significance and Innovation</u>:** What is the potential importance of the proposed project? What is its potential impact on human health and/or how may it be translated to impact human health concerns in the future? Discuss any novel ideas or contributions that the proposal offers.

D. **<u>Approach:</u>** Discuss the approach and rationale behind the chosen approach to the problem. The purpose of the approach section is to describe how the research will be carried out. This section is crucial to how favorably an application is reviewed. The research design and methods section should include the following:

- PI's preliminary studies, data, and experience relevant to the application and the experimental design;
- the overview of the experimental design;
- a description of methods and analyses to be used to accomplish the specific aims of the project;
- a discussion of potential difficulties and limitations and how these will be overcome or mitigated;
- expected results, and alternative approaches that will be used if unexpected results are found;
- a projected sequence or timetable (work plan);
- if the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work;
- a detailed discussion of the way in which the results will be collected, analyzed, and interpreted;
- a description of any new methodology used and why it represents an improvement over the existing ones;

E. **<u>Project timeline:</u>** The following (or similar) table should be completed and inserted at the end of the research plan.

Tasks	Months			
	1-3	4-6	7-9	10-12
Task 1 – enter description and mark appropriate period(s)				
Task 2 – enter description and mark appropriate period(s)				
Task 3 – enter description and mark appropriate period(s)				
Complete Requisite Progress Report				X

7. References Cited

8. Protection of Human Subjects; Vertebrate Animals Section; and/or Recombinant DNA: The appropriate details, where applicable, must be addressed. If unclear what to address in this section please see page 8 & 9 below.

9. Biosketch: Biographical sketch (5-page maximum) of the principal investigators and co-investigator/collaborator in the NIH format available at https://grants.nih.gov/grants/forms/biosketch.htm.

10. Other support for the principal investigator and each co-investigator / collaborator: Include detail on any overlap that this proposal has with active or pending awards. This information must be provided in NIH format. The new NIH format may be used but MUST include the amount of funding awarded to the PI.

11. Supporting documentation: If this is a resubmission, include a one-page response to the reviewers' comments and include the review documents.

The Indiana CTSI offers a resource that can help strengthen submissions by providing valuable feedback and critiques.

To engage with this resource, please contact your campus Navigator below to discuss meeting with one of the project development teams (PDTs):

Bloomington: Joel Ybe jybe@indiana.edu
Indianapolis: Tammy Sajdyk tsajdyk@iu.edu
Notre Dame: Prakash Nallathamby Prakash.D.Nallathamby.1@nd.edu & Jessica Brookshire jbrooksh@nd.edu
Purdue: Tommy Sors tsors@purdue.edu & Natasha Nikolaidis nnikolai@purdue.edu
Evansville: Kara Garcia karagarc@iu.edu
Terre Haute: Ellen Ireland eireland@indiana.edu

For financial questions related to budgeting and grant submissions, please contact:

- IU / Regenstrief / IBRI**:** Indiana CTSI Office (trnsldev@iu.edu)
- Purdue**:** Erica Cox (ericacox@purdue.edu)
- Notre Dame: NDp3

REVIEW, AWARD SELECTION & FUNDING TIMELINE

The CTS pilot grant mechanism is intended to foster translational science projects or novel intellectual property (IP). Requests for funds will be critiqued on the following items (**See also review form on website**):

- The strength of the research.
- The potential translational nature of the project as it relates to translational science.
- The strength of how well it can be disseminated or implemented.
- The potential for publication describing implementation.
- How well the application addressed the expectations outlined in the RFA.

Applications will be subject to a 2-stage selection process.

Stage 1: The initial review will be completed by a joint committee with peer representatives from the six sponsoring affiliates on **October 11, 2024.**

Stage 2: Finalists will be selected by the joint committee and invited to give an oral presentation to the Indiana CTSI CTS Review Committee on **November 8, 2024.**

(NOTE: ALL APPLICANTS NEED TO HOLD THIS DATE - 12:00 PM – 5:00 PM EST)

The Indiana CTSI Review Committee will evaluate the strength and potential of the proposed project and will review and discuss with the investigators the milestones and timelines of the project. The results / comments will be collated, and recommendations forwarded to the Indiana CTSI Strategy Committee for final funding decisions.

NCATS Prior Approval: Recommendations for the number, size and scope of the CTS awards will be determined by the Indiana CTSI Strategy Committee in **December 2024**. NCATS Prior Approval must be obtained per NIH guidelines before engaging in the proposed research.

PIs with projects recommended for funding will be notified in December 2024 and will be asked to have all regulatory documents (IACUC/IRB Approval) available by January 13, 2025 for submission to NCATS. Contact Rachel Bennett (racbenne@iu.edu) with questions related to regulatory submissions and the NCATS Prior Approval process.

Projects should therefore have a start date no earlier than **May 1, 2025**

Timeline

First Review Date:	October 11, 2024
Second Review Date:	November 8, 2024
CTSI Executive Committee Review:	December 5, 2024
Funding Notices Out:	Mid-December 2024
Regulatory Documents Should be Completed:	January 13, 2025
NCATS Prior Approval Process:	January – April 2025
Funding Begins:	May 1, 2025

CTS POST AWARD REQUIREMENTS

1. The CTS Pilot Grant Award is considered federal funding and NIH funding should be indicated in regulatory submissions to the IACUC and IRB.
2. All awards will be monitored for progress by the Indiana CTSI and NIH NCATS as required by the CTSA Annual Progress Report and NIH Research Performance Progress Report (RPPR). Progress monitoring generally includes the following from all project PIs and, when appropriate, may be developed in consultation with CTSI Administration:
   a. Annual progress reports due in December that report status of milestone progress along with documentations of external grant submissions/awards, IP, publications, and/or presentations arising from the supported research.
   b. Annual follow-up reports upon request for up to 5 years after the project ends
3. It is expected that this pilot funding will lead to publications generally reported on the annual progress reports.
4. Grant recipients are required to acknowledge receipt of Indiana CTSI support in any presentation or publication of work funded by a CTS award as follows:

   This [(publication was made possible) (project was supported)] by the Indiana Clinical and Translational Sciences Institute, funded in part by grant # UM1TR004402 *from the National Institutes of Health, National Center for Advancing Translational Sciences, Clinical and Translational Science Award. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.*
5. Grant recipients are strongly encouraged to participate as reviewers for any CTSI internal grants in the future.
6. By accepting this award, grant recipients agree to have their names and project titles publicly posted on the Indiana CTSI website and/or in a publication.

Detailed Requirements for Protection of Human Subjects and/or Live Vertebrate Animals

Protection of Human Subjects

Be sure to include all required content for each section as described in the NIH Application Guide: https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#3.1

1. *Risks to Human Subjects*
   a. Human Subjects Involvement, Characteristics, and Design
   b. Study Procedures, Materials, and Potential Risks

2. *Adequacy of Protection Against Risks*
   a. Informed Consent and Assent
   b. Protections Against Risk
   c. Populations that are vulnerable to coercion or undue influence and pregnant women, fetuses and neonates, if relevant to your study

3. *Potential Benefits of the Proposed Research to Research Participants and Others*

4. *Importance of the Knowledge to be Gained*

Vertebrate Animals Section

A helpful tool to aid in completed the VAS is this NIH Worksheet and Checklist: https://ctsa.ncats.nih.gov/wp-content/uploads/2018/06/VAChecklist.pdf

1. *Description of Procedures*. Provide a concise description of the proposed procedures to be used that involve live vertebrate animals in the work outlined in the "Research Strategy" section. Identify the species, strains, ages, sex, and total numbers of animals by species, to be used in the proposed work. If dogs or cats are proposed, provide the source of the animals.

2. *Justifications*: Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g. computational, human, invertebrate, in vitro).

3. *Minimization of Pain and Distress*: Describe the interventions including analgesia, anesthesia, sedation, palliative care, and humane endpoints to minimize discomfort, distress, pain, and injury.

4. *Method of Euthanasia*: State whether the method of euthanasia is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If not, describe the method and provide a scientific justification.