



Request for Applications

COLLABORATION IN TRANSLATIONAL RESEARCH (CTR) PILOT GRANT PROGRAM

**A JOINT INITIATIVE
SPONSORED BY INDIANA CTSI PARTNER INSTITUTIONS**

**INDIANA UNIVERSITY
AND
PURDUE UNIVERSITY
AND
UNIVERSITY OF NOTRE DAME**

**ELECTRONIC RECEIPT DATES
Application Submission: 08/01/2022**

*Please note that 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 April 2022

INFORMATION FOR APPLICANTS

GENERAL INFORMATION

The three premier research universities within the State of Indiana – Indiana University, Purdue University and the University of Notre Dame, with support from the National Institutes of Health (NIH), have formed an institute called 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 CTSI is "to increase translational biomedical research and improve the health of the people of Indiana and beyond."

The objective of the CTSI Collaboration in Translational Research (CTR) pilot grant program is to 1) foster and encourage collaborations across the CTSI partner institutions and to 2) initiate or continue translational research¹ projects that have very strong and immediate potential to develop into larger, externally funded research programs or generate novel intellectual property (IP). The application will be evaluated on the quality of the proposed science as well as the application's strength in clarifying the plan for leveraging the award toward the achievement of the two primary CTR objectives. Significant weight will be afforded in the review process for collaborative arrangements that have the potential to develop into a long-term partnership; one that uniquely positions the individuals to further their existing, or new, fields of research.

Applications to this program are limited to a total of **\$75,000** and are **24 months (2 years)** in duration. Proposed projects should have at least two (or more) principal investigators / collaborators with **equal contribution**, from at least two of the six sponsoring affiliates for this program. Sponsoring affiliates include:

IU School of Medicine (IUSM)
IUPUI (non-IUSM)
IU Bloomington
Purdue University (West Lafayette)
University of Notre Dame
Indiana Biosciences Research Institute (IBRI)

WHO MAY APPLY (ALSO SEE RESTRICTIONS SECTION BELOW)

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. *Faculty that hold the title of visiting rank must discuss eligibility with the CTSI and obtain approval. To discuss eligibility email trnslddev@iu.edu*

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

IUPUI/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.

¹ Translational Research describes the steps between a fundamental discovery and its application in clinical medicine. For purposes of grant review, the CTSI defines translational research in the broadest sense. Specifically any study which has the potential to improve health care is suitable for funding via the CTSI. This includes:

- 1) Basic science studies which seek to understand disease mechanisms, drug / device / technology development, and toxicology studies.
- 2) Early and late phase clinical studies
- 3) Studies that seek to improve health outcomes, healthcare delivery, and/or public health.

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.

IU Health: Applicants must be employees of Indiana University Health at any IU Health system entity with medical staff privileges. Residents and fellows are not eligible for this mechanism.

RESTRICTIONS

In an effort to provide a broad access to funding, teams comprised of the same co-PIs that have previously received a CTR award are ineligible to apply.

PIs that have received a CTR award in 2021 or 2022 (regardless of when the funding was available) are ineligible to be a PI/co-PI this round. PIs may have received an award prior and still be eligible (e.g. a PI that received an award in 2020 that was still ongoing during 2021 – 2022 is eligible).

We strongly encourage applicants to confirm eligibility prior to submission, if there is a question. To do so, email trnslddev@iu.edu.

APPLICATION PROCESS

Full applications are due on August 1, 2022. Submissions are via the ‘**Start a submission**’ link found here [CTSI CTR Link](#)

APPLICATIONS SEQUENCE

You must use the application forms available here [CTSI CTR Link](#)

1. Face Page

The face page specifies the title of the proposal, principal investigators 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/CO-PI.** As submission will be electronic only, facsimile or electronic signatures are appropriate.

2. Abstract & Keywords

- The abstract should be a brief (250 word maximum) abstract in layman’s terms. If an award is made, this will be published on the CTSI website.
- Provide 5 keywords that describe the research content of your project

3. **Use of funds for future extramural funding / IP:** Describe how the collaboration will lead to an extramurally funded research application / program or generate IP. Define whether this proposal will be joint between the collaborators or, if not, how the collaboration will benefit each of the collaborators individually. For extramural funding, specifically describe the agency, the program and time frame that you plan to submit an extramural proposal (see suggested outline below).

- Expected Funding Agency and/or Agency Program
- Expected Submission Date
- Expected Project Specific Aims (bullet point summary)
- Key Preliminary Data that are Needed (bullet point summary)

If this project will potentially generate IP, provide a specific timeline including short term interim deliverables toward the filing of a disclosure or patent application and discuss how this funding will help to expedite the process.

4. **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 **24 months**.

- Projects should have a start date no earlier than **May 1, 2023**.
- Proposals must reflect a sharing of budget and effort between the collaborating institutions. If a requested budget reflects a greater financial need for one of the campuses, the budget justification should indicate why and clearly indicate the project oversight on the second campus.
- No funds will be allocated for PI or co-investigator / collaborator salaries.
- Supplies and other costs must relate directly to performance of the project.
- Travel beyond that which is necessary between the institutions / campuses will require justification.
- No indirect costs may be requested.
- All costs should be specifically justified and expenditures for **each participating partner/institution** clearly denoted. Limit budget justification to ½ page per campus.

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 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. Describe the collaborative research program that exists or that will develop from the collaboration and the nature of the complimentary expertise that will promote synergism.

- **Translational potential for the project:** Describe the project's potential impact on human health and/or how may it be translated to impact human health concerns in the future. Include in your description the translational stage and phase of the project at the time of implementation, at the time of completion (these might be the same) and the stage and phase for the next translational step (e.g. the project involves model development in vitro (T1) but after completion, the data would be used for an in vitro project (T1)). **See T stage / phase explanation here [Translational Stage and Phase](#)**
 - If the project is basic biomedical or behavioral research describe how will increase the understanding of disease mechanisms, drug/device / technology

developments and toxicology studies, or how it will translate discoveries into new clinical tools, assistive devices, behavioral therapies, interventions or medications.

- If the project is a clinical or implementation study describe how it will increase the understanding of disease mechanisms, drug/device/technology developments and toxicology studies and / or advance the testing and refinement of new technologies in people; the testing of interventions for safety and effectiveness in those with or without disease; or result in behavioral and observational studies that impact health services research.
- If the project focuses on population health, describe how it will assist in determining the effects of diseases and efforts to prevent, diagnose and treat them and the plan for dissemination so that the findings will inform future research

B. Description of joint research program: Briefly review the current status of research in the field and the PI / co-PI contributions to that field. Document with references. Describe any preliminary work the investigators have performed which led to this proposal, alone or in collaboration. Explain how synergism will be achieved. Consider using a table to explain roles and contributions.

Investigator	Institution	Role	Responsibilities

C. Significance and Innovation: What is the potential importance of the proposed collaboration? What is its potential impact on human health and/or how may it be translated to impact human health concerns in the future? Specifically describe its relevance and translational potential (see page 2 footnote). Discuss any novel ideas or contributions that the collaboration offers. Make clear the potential importance of the proposed collaboration for further investigation and future research on the different campuses.

D. Approach: and the 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. Recommended Content: 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. Project timeline: The following (or similar) table should be completed and inserted at the end of the research plan.

Task	Months							
	1 - 3	4 - 6	7 - 9	10 - 12	13 - 15	16 - 18	19 - 21	22 - 24
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)								
Task 4 - enter description and mark appropriate period(s)								
Task 5 - enter description and mark appropriate period(s)								
Task x – complete requisite progress reports		X		X		X		X

F. References Cited

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

8. 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>.

9. 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.

10. 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: Paul Helquist phelquis@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 / IBRI: Indiana CTSI Office (trns1dev@iu.edu)
Purdue: Michelle Pearson (pearso64@purdue.edu)
Notre Dame: David Ross (dross5@nd.edu)

REVIEW, AWARD SELECTION & FUNDING TIMELINE

The CTR Grant program is to foster collaborative research between campuses that results in new or expanded extramurally funded research programs or novel intellectual property (IP). Requests for funds will be critiqued on the following items:

- The strength of the research
- The strength of the collaboration.
- The strength of a defined plan for future extramural support and/or IP
- The potential translational nature of the project
- 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 **September 23, 2022**.

Stage 2: Approximately 10 -15 finalists will be selected by the joint committee and invited to give an oral presentation to the CTSI CTR Review Committee on **October 28, 2022**.

(NOTE: ALL APPLICANTS NEED TO HOLD THIS DATE. One of the goals of this round is to demonstrate the cohesiveness of the team)

The CTSI Review Committee will evaluate the strength and potential of the proposed collaboration, 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 CTSI Executive Committee for final funding decisions.

NCATS Approval: Recommendations for the number, size and scope of the CTR awards will be determined by the CTSI Executive Committee in **December 2022**. Final award approval must be obtained from NCATS per NIH guidelines.

PIs with projects recommended for funding will be notified in mid December and will be asked to have all regulatory documents available by February 2023 for submission to NCATS.

Projects should therefore have a start date no earlier than **May 1, 2023**

Timeline

First Review Date:	September 23, 2022
Second Review Date:	October 28, 2021
CTSI Executive Committee Review:	December 2022
Funding Notices Out:	December 2022
Regulatory Documents Should be Completed:	February 2023
NCATS Prior Approval Process:	January – April 2023
Funding Begins:	May 1, 2023

CTR POST AWARD REQUIREMENTS

1. All awards will be monitored for progress by the Indiana CTSI as required by the CTSA Annual Progress Report. 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. Project support and budget management discussions will occur if applicable.
 - b. Annual follow-up reports upon request for up to 5 years after the project ends, including but not limited to the following data:
 - i. External grant submissions and awards arising from the supported research
 - ii. Intellectual property arising from the supported research
 - iii. Publications arising from the supported research
 - iv. Additional impacts of the award on your research and the collaboration
2. It is expected that this pilot funding will lead to co-authored publications and external funding submissions, generally reported on the annual progress reports.
3. Grant recipients are required to acknowledge receipt of Indiana CTSI support in any presentation or publication of work funded by a CTR award as follows:

This [(publication was made possible) (project was supported)] by the Indiana Clinical and Translational Sciences Institute, funded in part by grant # UL1TR002529 from the National Institutes of Health, National Center for Advancing Translational Sciences, Clinical and Translational Sciences Award. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health."

4. Grant recipients are strongly encouraged to participate as reviewers for any CTSI internal grants in the future.
5. 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 Vertebrate Animals**

Human Subjects - <https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/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. Recruitment and retention
 - b. Informed consent and assent
 - c. Protection against risk
 - d. Vulnerable subjects, if relevant to your study
3. *Potential benefits of the proposed research to the participants or others*
4. *Importance of the knowledge to be gained*

Vertebrate Animals

1. *Description of Procedures*. Provide a concise description of the proposed procedures to be used that involve 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. *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.