



Request for Applications

Global Health Reciprocal Innovation Demonstration Grants

A Joint Initiative Sponsored by Indiana CTSI and Indiana University Center for Global Health

DEADLINE Electronic Receipt Date

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INFORMATION FOR APPLICANTS

Please note that you will be submitting through the Indiana CTSI's grants management software WebCAMP.

I. Purpose

The Indiana Clinical and Translational Sciences Institute (CTSI), in cooperation with the IU Center for Global Health and partners at the University of Notre Dame and Purdue University, seeks to foster innovative global health research partnerships and projects to improve the health and well-being of Hoosiers and marginalized communities around the world. This effort encourages multi-disciplinary collaboration to solve the world's most critical health challenges. The Indiana CTSI has provided a platform for its partners to strengthen global health research partnerships through the concept of reciprocal innovation. In global health research, reciprocal innovation is a collaborative process to exchange lessons learned and co-develop technology and health innovations and to test health interventions with mutual benefit to partners in the United States and with at least one global partner elsewhere in the world.

This request for applications (RFA) seeks to leverage the global health research partnerships of the Indiana CTSI partner institutions (IU, Purdue, and Notre Dame) to research and demonstrate innovations with a high potential to alleviate the burden of non-communicable diseases, infant and maternal health, infectious diseases, mental health, and health systems and access to quality healthcare. Competitive applications will focus on shared health challenges faced by people in underserved settings in Indiana and at global partner sites around the world. Potential applicants working in subject areas addressing critical challenges to human health in resource-limited settings in all areas of science, environmental science, medicine, social science and other relevant fields not specifically listed, are encouraged to apply.

What is Reciprocal Innovation?

Reciprocal innovation builds on the concept of 'reverse innovation,' through which healthcare innovations and technologies are designed and tested elsewhere in the world and brought back to countries such as the United States to address important health challenges. These 'reverse innovations' are attractive because they are often cost effective; easy to replicate, scale, and sustain; require minimal infrastructure; and can be tailored to local needs. However, reverse innovation implies a unidirectional process that does not continue to engage global health stakeholder in refining and implementing these approaches. Reciprocal Innovation evolves the concept of reverse innovation in order to create a bidirectional research agenda that provides mutual benefit to both sides and identifies high quality innovations from global health partnerships for demonstration, replication, and dissemination through a statewide system.

II. Expected Outcomes

Projects funded by this RFA will seek to use reciprocal innovation to conduct demonstration projects that will develop or adapt innovative solutions that address at least one of these priority health challenges:

- Non-communicable diseases, including cancer, diabetes, and hypertension.
- Infant and maternal health
- Infectious diseases, especially HIV, malaria, and COVID-19.
- Mental health
- Health systems and access to quality health care, including health workforce capacity building, health care technologies, health financing, and community-based care.

Projects should result in high impact solutions that provide reciprocal benefit to the communities Indiana CTSI institutions serve either at home or abroad. Projects can be based either in the US/Indiana or at a global partner site, which should be located in a low or middle income country (LMIC), and eligible projects will have at least one LMIC lead partner/collaborator as part of the senior investigative

team. The lead partner is not required to be at an academic institution however they should have the relevant research qualifications to support the project. Additional partnerships are encouraged, including with nonprofit organizations, educational institutions, health systems, and/or government agencies.

Proposals should include plans to sustain and expand these efforts into either the partner country or US/Indiana after the end of support from this RFA. This should include a <u>plan for soliciting extramural funding</u> to further develop, assess, scale and integrate innovations into existing systems or models of care. Preference will be given to projects that are likely to result in written products and publications (e.g., journal manuscripts, conference abstracts and presentations, evaluation reports, etc.); result in the creation of intellectual property (IP); and lead to submissions for extramural funding. All applications must provide data and other relevant information to demonstrate why the project is likely to be successful and advance the health outcomes as described above.

Potential projects for this funding mechanism include projects that seek to utilize new technology, telecommunication, and community engagement strategies in new and innovative ways.

Examples from previous projects include:

Community Health Workers: Many LMICs are working to task shift certain aspects of healthcare delivery to community health workers. These interventions expand community access to healthcare support and education, and improve health outcomes. Researchers at IU, for example, have adapted this approach used in Kenya to help lower infant mortality in Indiana.

Point of Care Diagnostic Tools: CTSI researchers helped create very low-cost diagnostic tools to detect counterfeit drugs in LMICs. This same technology might be used to aid first responders in rapidly identifying drugs taken by an overdose patient to provide treatment that is more effective.

Home Hospice Care via Telecommunication: Palliative care is essential in the treatment of cancer and other diseases, yet many people in remote rural settings may lack adequate access to palliative care services. CTSI researchers are testing telecommunications strategies to provide remote home hospice care services in western Kenya by providing specialized training to local physicians. These same interventions might prove effective in providing care to patients in rural Indiana.

Microfinance for Health: Micro-lending groups in LMICs provide caregivers opportunities to connect patients with care for chronic diseases, such as diabetes and hypertension, while providing a vehicle to address economic factors that impact health. These community-based strategies might be applied to similar health challenges in resource-limited settings in Indiana.

The above examples are only a few of the many opportunities to apply global health lessons to local health challenges. Applicants are not limited to these examples.

III. Eligibility

This funding opportunity is open to researchers at Indiana CTSI partner institutions (IU, Purdue, and Notre Dame) including individuals with full-time, regular faculty appointments and postdoctoral research associates. Postdoctoral applicants must include their mentor on the investigator team and must provide a letter of support from said mentor included in the submission package. Eligible proposals must include a principal investigator from an Indiana CTSI partner institution. Principal investigators must have the requisite skills, knowledge, time, and resources necessary to carry out the proposed research. Eligible proposals must also be collaborative and include at least one lead global research partner from an LMIC. Additional partners may include nonprofit organizations, educational institutions, health systems, or government agencies in Indiana.

Researchers who served as a principal investigator of a CTSI-funded global health grant during the 2020-2021 or 2021-2022 funding cycles for an international project are only eligible to serve as a principal investigator/project director for this round of funding if the application is for domestic replication of a project previously piloted at an LMIC partner site.

For Notre Dame Researchers:

Notre Dame investigators must indicate their intent to submit to this opportunity by submitting the request through NDp3, Notre Dame Research's proposal intake form available on InsideND and completing the required questions in the Proposal Intake Form. This action triggers contact from your Pre-Award research administrator. This must be done **before** uploading your application into the Indiana CTSI grants site.

IV. Funding Amounts

The Indiana CTSI will grant two awards of up to \$50,000 for a period of two years.

University of Notre Dame Matching Funds: University of Notre Dame Eck Institute for Global Health will provide up to \$10,000 matching funds for successful Notre Dame faculty that are affiliated members of the Eck Institute for Global Health (EIGH) or postdoctoral applicants directly under the supervision of EIGH faculty affiliates. Researchers who meet this criteria may submit a budget inclusive of this additional funding. Please contact Nydia Morales-Soto (nsoto@nd.edu) to verify eligibility prior to submission.

V. <u>Application Technical Requirements</u>

Eligible candidates should complete a Letter of Intent and submit to the Indiana CTSI Global Health Program Manager, Rish Chauhan O'Brien (rchauhan@iu.edu) no later than February 1, 2023.

Letter of Intent should include the following criteria:

- Scope and specific aims of the research project
- Project team including US and international partners and collaborators
- The reciprocal nature of the research project

Once the letter of intent has been approved, candidates will be invited to submit a full application. Candidates should then complete, sign and upload the application using the Start a Submission link provided by the Program Manager.

Each full application will include the following sections:

1. Face Page (Template included)

2. Project Summary/Abstract

A brief summary (300-400 words) describing the project focus, its significance, expected outcomes, international partner(s), and proposed plans for the expansion of future research if funding is awarded.

- 3. Technical Narrative (No more than 6 pages single-spaced, Arial 11-point font, and 1/2 inch margins. Section page limits recommended below.)
 - a. Project Description (Recommended 4 pages, single-spaced, Arial 11-point font, and
 1/2 inch margins)
 - 1. Focus and significance of project

Describe in detail the global health challenge the proposed research will address, the potential for mutual benefit in the US and global partner site, and the potential significance of the proposed research.

2. Specific aims

Identify the specific aims and objectives of the proposed research project.

3. Innovation

Describe how the proposed research will challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches methodologies, instrumentation, or interventions.

4. Approach (Project design and methods)

Detail the project design and methods that will be used to achieve the stated project aims and objectives.

If COVID-19 guidelines and travel restrictions hinder your planning activities, please include a brief contingency plan.

5. Dissemination

Describe how research outcomes will be disseminated including a clear description of plans to produce written products and publications, and/or intellectual property.

b. Reciprocal Innovation Description (Recommended 2 pages, single-spaced, Arial 11-point font, and 1/2 inch margins)

1. Environment and collaborative partners

Provide a detailed description of the scientific environment and its probability to contribute toward the project's success. Describe all collaborating partners including details on the unique qualifications, resources, and abilities of each partner that will enable successful conduct of the proposed project. Describe how this work will support ongoing, collaborative international partnerships. Partners may include nonprofit organizations, educational institutions, government partners, health systems, and community partners. Projects may involve more than one partner.

2. Future direction & translation plan

Describe how this research project will advance reciprocal innovation. Applications should include a detailed plan for applying to extramural funding to further develop, assess, scale and integrate innovations into existing systems or models of care.

4. Proposed project timeline and milestones

Describe the timeline for all major components of the project including descriptions of key milestones.

If COVID-19 guidelines and travel restrictions hinder your timeline and milestones, please include a brief contingency plan.

5. References/works cited

List resources and references using a standard APA format which will be key to the project

and which research applicants have utilized for this application.

6. Detailed budget & budget justification

All applications require a concise, convincing, and realistic explanation of the proposed budget, which includes all planned expenditures. Submitted budgets that request the maximum without adequate explanation for that level of support, if awarded, will be reduced to a justifiable funding level based on the proposed project. If there are other resources committed to the project, please indicate these funds in the total budget. Total project costs may exceed \$50,000 when other funding entities have committed to the project.

No indirect costs or finance and administration costs are allowed. However, overhead costs necessary for the administration of the award at an LMIC partner site may be budgeted as direct costs. Overhead costs should not exceed 8% of the total budget. Overhead costs are included in the total award amount not to exceed \$50,000. Up to 15% of funds can be used to purchase critical equipment but must be clearly justified in the application's budget narrative in order to be approved. Funds cannot be used for meeting-related/hospitality expenditures (no exceptions); travel expenses are limited to those that are demonstrated to be necessary to achieve the aims of the proposed project.

Projects that provide matching funds from their home institutions, LMIC partners, or other sponsors will receive preference for funding.

Proposed project periods cannot exceed 24 months from the project start date. The required start date is July 3, 2023. (see Section IX for details).

Up to one, 12 month no-cost extension may be granted after following the CTSI's request process https://indianactsi.org/translational-research-development/no-cost-extension/

7. NIH-formatted biographical sketch

The principal investigator and co-principal investigator(s) must submit a bio-sketch. Limit 5 pages per bio sketch.

8. Letters of support (Maximum of 3)

Applicants must include at least one letter of support from collaborating partners in Indiana and one letter from a global partner setting. Letters of support should describe the activities the partner will perform if the project is funded and how these activities will fit into their own research objectives. No more than 3 letters of support may be submitted.

9. Internal Research Board (IRB) approval (if available)

Note that an application can be submitted before IRB approval, but if awarded, must provide documentation that all required IRB applications have been submitted no later than 30 days from the day a Notice of Award is received.

VI. <u>Review Criteria</u>

Proposals approved following the letter of intent review process and received by the application deadline will be reviewed by a committee, including representative global health research leaders from the Global Health Research programs of IU, Purdue and Notre Dame. After review and approval, proposal revisions may be requested prior to implementation.

Proposals will be scored using the NIH scoring system defined below:

Impact	Score	Descriptor	Additional Guidance on Strengths/Weaknesses
High	1	Exceptional	Exceptionally strong with essentially no weaknesses
	2	Outstanding	Extremely strong with negligible weaknesses
	3	Excellent	Very strong with only some minor weaknesses
Medium	4	Very Good	Strong but with numerous minor weaknesses
	5	Good	Strong but with at least one moderate weakness
	6	Satisfactory	Some strengths but also some moderate weaknesses
Low	7	Fair	Some strengths but with at least one major weakness
	8	Marginal	A few strengths and a few major weaknesses
	9	Poor	Very few strengths and numerous major weaknesses

Minor Weakness: An easily addressable weakness that does not substantially lessen impact

Moderate Weakness: A weakness that lessens impact **Major Weakness:** A weakness that severely limits impact

Scored criteria include the following:

- 1. Overall Impact: How well will the project establish a sustained reciprocal innovation program that will improve the health of underserved populations in Indiana and/or LMIC partner sites? What potential is demonstrated for significant new intellectual property, strengthening international collaboration, expanding research opportunities, and attracting future funding?
- 2. Significance: How well does the project address one of the five health priority areas identified in this RFA (non-communicable diseases, infant mortality and maternal health, infectious diseases, mental health, and health systems and access to quality healthcare) and potential impact on related policies, health systems, environment, and/or field of research?
- **3. Investigators**: How well-suited to the project are the primary researchers and international collaborators? How feasible is the proposed international collaboration and will the collaboration produce high quality results?
- **4. Innovation:** How well 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?
- **5. Approach:** Are the proposed study design and methods sound? Does the study use evidence based or best practices?
- 6. Environment and Collaborative Partners: How well will the scientific environment in which the work will be done contribute to the probability of success? How well does the proposal focus on strengthening collaborative, multidisciplinary research collaborations between Indiana CTSI and partner institutions? Do projects leverage partner expertise and resources?
- **7. Dissemination Plan:** Will this proposed innovation lead to research outcomes, including written products and publications, and/or intellectual property?
- **8. Future Direction:** Will data collected from this project be leveraged for future external funding applications? Is there a well thought out plan for next steps in the evolution of this research and next steps for accessing funding?
- 9. Reciprocal Innovation: Does the project demonstrate a reciprocal innovation approach to

global health research, including a project that seeks to clearly identify or address a shared health challenge and/or health solution through their research?

VII. Funding Decisions

The review committee will submit final rankings and scores to the Indiana CTSI Global Health Research chair for review. The chair will make final funding recommendations to the Indiana CTSI executive committee. All applicants will be notified by e-mail of the funding decisions on or before June 22, 2023. Specific feedback will be provided as part of funding decisions.

VIII. Post-Award Requirements

Projects selected for funding will be expected to comply with the following requirements:

- Responsible Conduct of Research Documentation that all personnel in the project have completed a course in the responsible conduct of research such as CITI or an equivalent training.
- Conflict of Interest Disclosure All personnel must have an up-to-date conflict of interest disclosure form on file with Indiana University. Non-IU affiliated personnel should submit a non-IU affiliate conflict of interest disclosure form available online: http://researchcompliance.iu.edu/coi/coi/disclosure.html.
- Institutional Review Board (IRB) Approval The project must provide documentation that all
 required IRB applications have been submitted no later than 30 days from the day a Notice of
 Award is received. Documentation of IRB approval must be provided before award funds will be
 released. This is only required for projects proposing to utilize human subjects.

Once all regulatory documentation is on file, the Indiana CTSI finance office will facilitate the release of funds to the academic partner.

Funded recipients will be required to:

- Submit progress reports annually during the life of the award including a complete description of the work accomplished and related budget expenditures.
- Attend a required face-to-face meeting with the Program Manager of the Indiana CTSI Global Health Platform. Subsequent meetings will be either face-to-face or via teleconference.
- Present their project results to the Indiana CTSI Global Health Platform leadership committee.
- Present their project at an Indiana CTSI or IU Center for Global Health-sponsored event, if requested.
- Allow project findings to be shared on the Reciprocal Innovation Online Repository. Please
 inform Rish Chauhan O'Brien (rchauhan@iu.edu) of any intellectual property or
 confidential information that may not be appropriate to share.

If necessary and deemed appropriate, a 12-month no-cost extension (NCE) may be granted to grant awardees. Note that only <u>one</u> NCE may be granted to each awardee according to current CTSI procedure. Awardees are encouraged to carefully calculate the estimated time needed to complete the project and to request the maximum amount of time required.

The closeout report will be due during the first annual progress report. All recipients must:

- Summarize the project and primary findings for dissemination to the public (1 page).
- Submit a final project summary report which will include project results; lessons learned; any publications and extramural funding applications applied for and/or received; and plans for sustainability, dissemination, and other next steps (up to 5 pages).
- Every year for up to five years after completion of the project, the IU Center for Global Health
 will contact recipients to complete a status report on the project; confirm on-going
 regulatory approvals (IRB); and gather data on publications, extramural funding, or IP that
 resulted from the project.
- The project is required to acknowledge Indiana CTSI support in all presentations, publications, and reports. Citation guidelines can be found here.

IX. RFA Timeline

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RFA Release Date	December 9, 2022
Letter of Intent Deadline	February 1, 2023
Proposal Application Deadline	March 30, 2023
Notification of Award Decisions	June 22, 2023
Grant Start Date	July 3, 2023
Annual Progress Report Due	December 30, 2023; December 30, 2024
Initial Project Period Ends	June 2, 2025
Closeout Report Due (unless NCE is approved)	December 2025
Status Reports	December 2026-2029

X. <u>Contact Information</u>

Questions regarding this opportunity should be sent to Rish Chauhan O'Brien, program manager of Indiana CTSI Global Health Research at rchauhan@iu.edu.

XI. Consultations

Applicants who are interested in individual consultation sessions with a member of the CTSI Global Health Leadership team should reach out to Rish Chauhan O'Brien (rchauhan@iu.edu) to schedule a meeting. The 30-minute, individual meetings are available for specific questions, feedback, or discussion on a proposal or concept.