Request for Applications for

Devices Advancing Surgical & Interventional Care

NOTE THAT IF THIS FUNDING IS AWARDED TO IU, IT IS CONSIDERED EXTERNAL FUNDING. FUNDING WILL BE PROVIDED BY THE SPONSOR, INDIANA UNIVERSITY HEALTH, AND THE PRIME SPONSOR, COOK MEDICAL, INC. THUS THE APPLICATION MUST BE ROUTED THROUGH ORA PRIOR TO UPLOADING

ELECTRONIC RECEIPT DATE: June 1, 2018

Please note that you will be submitting through the Indiana CTSI’s new grants management software WebCAMP. Please allow enough time to be familiar with a new system.

The WebCAMP user’s guide is also available under the funding announcement here: https://www.indianactsi.org/funding/all-open-rfps/
INFORMATION FOR APPLICANTS

GENERAL INFORMATION

The Indiana CTSI is pleased to request applications for funding to develop potential devices in the broad areas of surgery and surgical intervention. Investigators are encouraged to propose innovative ideas that can result in a device that improves human health. To this end, successful collaborations will involve at least two investigators from two different Indiana CTSI campuses representing surgical and/or interventional expertise with human patients and device expertise. Awards will be competitive and may not exceed $100,000 total for up to two (2) years.

For questions regarding scope, review of the proposal, or financial issues related to budgeting and grant submission contact Julie Driscol at the Indiana CTSI at judrisco@iu.edu or via phone at 317-278-2822.

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. Faculty that hold the title of visiting rank must discuss eligibility with the CTSI and obtain approval. Please email icreate@iu.edu to determine eligibility before submitting.

IUB/IUPUI: All tenured or tenure-track faculty at or above the Assistant Professor level; 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.

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.

MECHANISM FOR SUBMISSION OF APPLICATION

Applications for this opportunity are due on June 1, 2018. Submission of applications must be completed using the Start a Submission link found: CTSI Surgical Devices Link.

Applicants must use the application forms that are provided / specified on the Indiana CTSI website, at the web address noted above. Applications will be reviewed by a joint review committee of physicians, scientists and engineers and forwarded to the sponsor for final decision. Awards will be made in August, 2018 therefore the start date must be on or after 08/01/2018.

APPLICATION SEQUENCE:

Page 1. Face pages, which 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.

Page 2. Budget page listing all direct costs.
• Funding is provided by the sponsor, Indiana University Health, and the prime sponsor Cook Medical, Inc., through the Indiana CTSI
• Salaries are subject to the NIH cap
• Supplies and other costs must relate directly to performance of the project.
• No indirect costs may be requested.
• Travel beyond that which is necessary to complete the project is not allowed.
• No hospitality costs may be requested.
• All costs should be specifically justified (limit justification to ½ page).
• Total cost limited to $100,000 for up to two years

Page 3–5. Research Plan

• Should not exceed 3 single-spaced pages, excluding references. Margins should be at least 0.5 inch and Font must be Arial or Palatino and at least 11 point
• Structured in accordance with the format below and must address the following:

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

B. Specific Aims of the current proposal: Communicate the scientific significance and innovation of the proposed collaboration.
   a. Describe the specific aims of the proposal, the methods of procedure, and the rationale behind the chosen approach to the problem. Include a discussion of pitfalls that might be encountered and the limitations of the procedures proposed.
   b. Indicate the reason for the selection of model, if not using human or conventional animal model (or explain why this is not applicable).

C. Timetable: Provide a tentative timetable and milestones for the project.

D. Significance: What is the potential importance of the IP? 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, in its broadest definition, toward human health. Make clear the potential importance of the IP for further investigation and future research or commercialization.

E. Project Outcomes: Describe how the collaboration will lead to an extramurally funded research application / program, commercialization or further the IP development. For extramural funding, specifically describe the agency, the program and time frame that you plan to submit an extramural proposal. For commercialization, discuss the environment and the unmet need the IP will address and a simple business strategy. Address how the proposed device compares to current devices and indicate the anticipated market. If this project furthers the IP development, 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.

Additional pages (not included in page count):

References

Biographical sketch of the principal investigators (5-page maximum per investigator)

• The biosketch should be provided in the new NIH format available at http://grants.nih.gov/grants/funding/424/index.htm#biosketch. It is limited to 5 pages in length and should include positions, education/training, personal statement, contribution to
science and research support that are most relevant to the proposed project.

Appendices (not to exceed 6 pages)

- If the proposed project includes collaborators, a letter of support from each is required that states their role in the project and commitment to completion of the work.
- Other appendices as needed.

POST AWARD REQUIREMENTS

1. All awards will be monitored for progress by the Indiana CTSI as requested in the CTSA Annual Progress Report. Progress monitoring generally includes the following from all project PIs:
   a. Interim report submissions every 6 months during the life of the award demonstrating the progress and documenting external grant submissions/awards, IP, publications, and/or presentations arising from the supported research. Project support and budget management discussions may occur with CTSI representatives if adequate progress is not demonstrated.
   b. Annual follow-up status reports for 5 years after the project ends for reporting:
      i. External grant submissions and awards arising from the supported research
      ii. Intellectual property arising from the supported research including disclosures or patents filed
      iii. Publications arising from the supported research
      iv. Additional impacts of the award on your research or IP commercialization

2. Grant recipients are reminded to acknowledge receipt of Indiana CTSI support in any presentation or publication of work funded by an AIM award as follows:

   This project [or research] was made possible by Indiana University Health and the Indiana Clinical and Translational Sciences Institute, funded in part by grant #UL1 TR001108 from the National Institutes of Health, National Center for Advancing Translational Sciences, Clinical and Translational Sciences Award and The Advanced in Medicine (AIM) grant from Cook Medical. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health or Cook Medical."

Publications include: press releases, presentations, verbal reports, pamphlets, journal articles, reports, books, teaching guides posters, interviews, video clips or film.