Request for Applications

DESIGN AND BIOSTATISTICS PROGRAM (DBP)
PILOT GRANT

INDIANA CLINICAL AND TRANSLATIONAL SCIENCE INSTITUTE

LETTER OF INTENT DUE: December 18, 2017
FULL APPLICATION ELECTRONIC RECEIPT DATE: February 5, 2018

Round 4 - 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 available under the funding announcement here: https://www.indianactsi.org/funding/all-open-rfps/
INFORMATION FOR APPLICANTS

GENERAL INFORMATION

The Design and Biostatistics Program (DBP) of the Indiana Clinical and Translational Science Institute (CTSI) is comprised of 8 units with associated expertise: 1) Department of Biostatistics, IU School of Medicine and Fairbanks School of Public Health; 2) Division of Hereditary Genomics, Department of Medical & Molecular Genetics, IU School of Medicine; 3) Computational Biology, Center for Computational Biology & Bioinformatics, IU School of Medicine; 4) Department of Epidemiology, Fairbanks School of Public Health; 5) Department of Statistics, Purdue College of Science; 6) Department of Applied & Computational Math & Statistics, Notre Dame School of Science; 7) Department of Statistics, IU Bloomington College of Arts & Sciences; 8) Department of Epidemiology and Biostatistics, IU Bloomington School of Public Health.

The objectives of the DBP are to provide investigators with easy access to: 1) comprehensive biostatistical, epidemiological, genetic, bioinformatics, and pharmacometrics research services including optimal planning and design, efficient data management, appropriate statistical analyses, and preparation of reports and manuscripts; and 2) education and training for researchers conducting clinical and translational research. Additional functions include methodology development for emerging research needs, supporting integrated functions of the Indiana CTSI, and participation in the national CTSA Committees.

To achieve its objectives and stimulate development for emerging translational research needs, the DBP will fund innovative pilot projects that support methodological research of faculty members in the eight units that comprise the DBP. The total budget for the entire RFA is $20,000, and it is expected that up to two awards will be funded at approximately $10,000 per award for a twelve month duration. The objective of this mechanism is to fund research proposals that will synergize methodological strengths and translational biomedical research of the DBP, and in particular, the following types of research proposals:

- Research projects that propose to develop novel methodology (such as biostatistical, epidemiological, genetic, and bioinformatics methods).
- Research projects that match novel methodology with translational science needs.
- Research projects that have high potential to obtain external funding.
- Preference will be given to application that support precision health research, which is defined as understanding and optimizing the prevention, onset, treatment, progression and health outcomes of human diseases through a more precise definition of the genetic, developmental, behavioral and environmental factors that contribute to an individual’s health.
- Preference will be given to investigators who have not already received extramural funding.

The reviewers will consist of selected DBP senior faculty and members of the Indiana CTSI PDT Program.
APPLICATION SUBMISSION

A brief Letter of Intent is due December 18, 2017. This letter should include:
- Names of the Principal Investigator and Co-Investigators
- A one-paragraph description of the project and methodological area
- A brief statement about how the project is translational.

The letter should be sent to the DBP director, Dr. Susan Perkins, at sperkin1@iu.edu.

Confirmation of LOI approval will be sent by January 8, 2018.

Full submission deadline is Monday, February 5, 2018.
- Applicants must use the application forms that are provided here: CTSI DBP link
- Applications may be submitted here WebCAMP DBP link or by using the Start a Submission link found here: CTSI DBP link

RESTRICTIONS

1. Facilities and Administrative costs, or indirect costs, will not be allowed.
2. Salary support is allowed.
3. Requested grant funding period cannot exceed 12 months.
4. Applicant must include a health sciences researcher as a partner/collaborator on this project. This collaborator can be from an institution outside of the Indiana CTSI. If the applicant needs assistance finding a partner, please contact the Director of the DBP, Susan Perkins (sperkin1@iu.edu), by December 1, 2017.

WHO MAY APPLY

All full-time faculty, regardless of tenure status, having a primary appointment within one of the units in the DBP as detailed above. This includes those faculty appointed as part-time Assistant Professor or above, if they are located in the State of Indiana full-time. Faculty in visiting ranks or on sabbatical are not eligible for funding.

PEER REVIEW AND AWARD SELECTION

Applications will be subject to a one stage selection process. Numeric scores will be created based on strength of the research, match with translational science needs, and potential for external funding. The review will be completed by a joint committee of selected DBP senior faculty from each campus plus 2-4 health sciences researchers from the PDT program. Health sciences experts will be chosen based on scientific areas reflected by the pool of applications.

The number, size and scope of the final awards will be determined by the DBP Director, based upon recommendations from the review team. Awards will be announced on April 1, 2018. Projects should have a start date no earlier than May 1, 2018.

CONTACT INFORMATION

Please contact the Director of DBP, Dr. Susan Perkins (sperkin1@iu.edu), with questions.
APPLICATION SEQUENCE

Applications must follow the sequence below and be single spaced in at least 11 point Arial, Helvetica, Palatino Linotype, or Georgia typeface using 0.5 in margins. Application forms can be obtained on-line at CTSI DBP link.

Page 1-2. 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. Department / School support must be indicated by completion of all signatures on the face page(s). As submission will be electronic only, facsimile or electronic signatures are appropriate.

Page 3. Project Summary - Provide a brief 3-4 sentence general description of the research and its relevance to biomedical research.

Page 4. If this application is a resubmission of a previous proposal to this mechanism, a one-page response to reviewers is required.


Requests for funds will be critiqued on the following three items:
- The strength of how the project will meet an existing translational science need
- The strength of the research.
- The strength of a defined plan for future extramural support and/or IP.

The Research Plan narrative 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. **Significance:** 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.

C. **Specific Aims and methods of the current proposal:** Communicate the specific aims and the proposed methods of the proposed collaboration. Include a discussion of pitfalls that might be encountered and the limitations of the procedures proposed.

D. **Use of Funds for Future Extramural funding / IP:** Describe how the research will lead to an extramurally funded research application / program or generate IP. For extramural funding, specifically describe the agency, the program and time frame that you plan to submit an extramural proposal.

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

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<th>Task</th>
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<td>Task 1 – enter description and mark appropriate period(s)</td>
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<td>Task x – complete requisite progress reports</td>
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Page 9-13. Biographical sketch of the principal investigator (5-page maximum). The biosketch should be provided in the new NIH format and a copy is available in the
application for. It is limited to 5 pages in length and should include positions, honors, publications and selected research projects that are most relevant to the proposed project.

Page 14. Budget page listing all direct costs. An Excel budget template is provided with in the application form. Projects should have a start date no earlier than May 1, 2018. Facilities and Administrative costs, or indirect costs, will not be allowed. Salary support is allowed.


POST AWARD REQUIREMENTS

1. Awards cannot be given with proof of any applicable regulatory documentation. It is, therefore, important that applicants be ready to submit any necessary IACUC/IRB documents at the time of award notification.

2. 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. A milestone driven budget management plan developed cooperatively with the CTSI. This includes interim report submissions according to the budget management plan demonstrating status of milestone progress and documenting 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. Final report submission electronically to the administrative office of the Indiana CTSI upon request or within 90 days of the termination date.

3. Expectations
   a. Annual follow-up reports upon request for up to 2 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 including disclosures or patents filed
      iii. Publications arising from the supported research
      iv. Additional impacts of the award on your research and the collaboration
   b. Notification must be provided to Dr. Perkins (sperkin1@iu.edu) in writing if you leave your institution before the project is complete and/or if the project is transferred to another PI.
   c. No-cost extensions must also be requested in writing to Dr. Perkins (sperkin1@iu.edu).
   d. Grant recipients are reminded 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 # UL1 TR001108 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.