



Request for Applications

Indiana University Health Values Fund Grant Pilot & Feasibility Program - Research

a joint initiative between

INDIANA UNIVERSITY HEALTH

&

INDIANA CLINICAL AND TRANSLATIONAL SCIENCES INSTITUTE

FULL SUBMISSION DUE: Monday May 6, 2019

IF THIS FUNDING IS AWARDED to IU, IT IS CONSIDERED EXTERNAL FUNDING AND THE APPLICATION MUST BE ROUTED THROUGH ORA PRIOR TO UPLOADING

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

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

GENERAL INFORMATION

Indiana University Health will invest in the conduct of clinically relevant research that is scientifically meritorious and medically sound, and has a clear benefit to Indiana University Health and the population it serves. The research projects funded by this program must conform to and support the Values Statements of Indiana University Health. Priority areas of funding supported by Indiana University Health include the following areas:

- 1. Discovery of new knowledge and the development of new diagnostic, treatment and prevention modalities to improve patient care outcomes.
- 2. Promotion of health in the population and the provision of health care of the highest quality to its patients while also aiding the hospital to become more efficient.
- 3. Projects that demonstrate collaboration between any Indiana University Health hospital campuses including system hospitals.

Applications will be reviewed based on scientific merit as well as significance and the potential to benefit the patients in the Indiana University Health. The Pilot & Feasibility Program is funded by the Values Fund for the support of the Indiana University Health values. Those values are:

- Total patient care, including mind, body and spirit
- Excellence in education for health care providers
- Quality of care and respect for life
- Charity, equality and justice in health care
- Leadership in health promotion and wellness
- Excellence in research
- An internal community of mutual trust and respect

To be funded by this program, applications must demonstrate how the proposed research supports one or more of these values <u>AND</u> how the research benefits patients in the Indiana University Health system.

Applications to this program are **limited to \$150,000** over a three **(3) year duration**, with a \$50,000 per year maximum.

ELIGIBILITY

Applicants must be employees of Indiana University Health at any IU Health system entity (i.e. sleep labs, clinics, hospitals or physicians with medical staff privileges); other health professionals with medical staff privileges or hold a special assignment at any IU Health hospital are eligible. Post-Doctoral students are ineligible to apply to this grant program.

The Values Fund for Research is primarily directed at new and young investigators or those investigators embarking on a completely new career direction. To be eligible applicants must fit the following criteria

- 1) Are within five (5) years of their last period of training at the time of the submission.
- 2) Have held no more than one small grant (\$40,000). *It is acceptable for applicants to hold early career* training grants (e.g. NIH K08, K23, and CAP).
- 3) Hold an academic rank of Assistant Professor or lower.

GRANTEE EXPECTATIONS

Progress reports will be requested semi-annually during the funding period and then for two years annually thereafter, including reports on publications, presentations, new awards and job promotions resulting from this project will be made available to the grantor. These follow-up reports allow IU Health to evaluate the success of the Health Values program.

NIH Salary cap applies to this proposal. The 2018 salary cap is \$189,600.

Applicants must list a mentor. In many cases, the mentor will be an IU faculty member but an external mentor is allowable. Compensation for mentors is not within the scope of the budget. A letter of support from the mentor acknowledging that he/she has read the application and will assist with career development during the length of the project (3 years).

A letter of support from the department Chair is also required. It must indicate the applicant has protected time and resources specifically for the proposed project.

SUBMISSION PROCEDURES

Applicants must use the application forms provided and specified on the PULSE or CTSI website.

Application forms can be accessed:

- From the Indiana University Health <u>PULSE</u> Grants Administration website at: PULSE>Departments>Grants Administration>IU Health Funding Opportunities
- From Peter Michael at (317) 962-2373 / pmichael@iuhealth.org,
- From the CTSI website here: CTSI IU Health Values Research Link
- From Julie Driscol at the CTSI: (317) 278-2822 or icreate@iu.edu

Applications must be submitted by using the **Start a Submission** link found on the CTSI website here: CTSI IU Health Values Research Link

<u>Applicants who are IU employees</u> need to route their application through the IU Office of Research Administration (IU-ORA) before submitting it to the CTSI HUB grant system website.

ADDITIONAL REQUIREMENTS

- To be considered for funding, projects must address a specific research question.
- Applicants should clearly write and explain in the proposal how being awarded might advance their career development and how the grant study/project will specifically benefit IU Health.
- Please read the IUH Administrative Policies regarding, Conflicts of Interests,
 Misconduct in Science and Conflicts of Interest in Research to ensure you are in
 compliance with the policies. You can find these policies at:
 https://pulse.iuhealth.org/depts/PandP/policies/admin/adm1-12.pdf
- An investigator may submit only one Values Fund application to each round of competition in which he or she is the Lead PI.
- If the applicant is awarded funding from another source, IU Health Grants Administration Office should be notified at Tel: 317-962-2373.
- In general, grant funds should not be used for food or the purchase of laptop computers. Travel within the US for training needed for the research is allowable as long as it is the most cost effective way to get the training. Travel had been denied in the instructions due to past participants using extra funds to go to conferences that were not required for the project.. No international travel is allowed.
- Letters of Support (LOS) from the mentor and department chair are required. Other LOS may strengthen a proposal.
- An investigator may submit only one Research application to each round of the competition in which she or he is the Lead PI.
- Institutional Review Board (IRB), and/or Institutional Animal Control Utilization Committee (IACUC) approval, if required, must be completed prior to the project start. If you cannot obtain IRB/IACUC approval for your project prior to the release of funds you must immediately notify IU Health Grants Development & Administration Office staff Peter Michael, Tel: 317-962-2373, pmichael@iuhealth.org.

PROPOSAL FORMAT

Applications should be single spaced on 8 ½ x 11 paper with at least 0.5 inch margins and not to exceed **12 pages**, including figures and tables. Type size must be clear and readily legible and at least 11 point font.

Please Note: <u>Applications not following the formatting guidelines may be excluded from review.</u>

Applications will follow this sequence:

Face page: Specifies the title of the proposal, principal investigator and his/her institutional affiliation, where work will be performed, and the total budget. Signature of the Institutional Officer signifies approval and support of the time and effort specified by the PI on the application.

Indicate one of the following three categories that best describes your research.

- Clinical, behavioral or translational research
- Outcomes, efficiencies, quality, and adherence to evidenced based medicine.
- Laboratory or basic research

Page 2 Project Summary/Abstract: Provide a brief (one paragraph) summary of your project. The information in the summary will be used as a project description to be posted on the IU Health website should the project be selected for funding. Proprietary information should not be included in the summary, since the website posting will be publicly accessible.

Pages 3-5

<u>Budget pages</u>: Lists the direct costs for all personnel. Supplies and other costs must relate directly to performance of the project. Travel should be limited to the amount necessary to achieve the aims of the project TRAVEL TO CONFERENCES AND SEMINARS IS NOT AN ALLOWABLE EXPENSE. All costs should be specifically justified (limit justification to 1/2 page for each budget year).

Budget Restrictions:

- There is a maximum \$50,000 per year or up to a maximum of \$150,000 over three (3) years.
- The project period must have a start date of July 1, 2019 or after
- Facilities and Administrative costs, or indirect costs are not allowed.
- The Values Fund does not support infrastructure projects
- Grant funding period cannot exceed 36 months.
- No international travel is allowed. Travel beyond what is necessary for the performance of the project will require a detailed justification
- In general, grant funds should not be used for travel, food or the purchase of laptop computers.
- Supplies and other costs must relate directly to performance of the project

Page 6 Specific Aims:

State concisely the goals of the proposed research and summarize the exp ected outcome(s), including the impact that the results of the proposed res earch will exert on the research field(s) involved. List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.

Pages Research Strategy: 7-12 The Research Strate

The <u>Research Strategy</u> should *not exceed 6 pages* and should address the project period and funding requested, show the scope of the overall project and justify how the proposed project will aid in advancing IUH Values. It is to the applicant's advantage to focus and establish priorities for

the proposed project period. These priorities should be made clear in all relevant sections of the Research Strategy.

Organize the Research Strategy in the specified order and using the instructions provided below. Start each section with the appropriate section heading – **Significance**, **Innovation**, **Approach**. Cite published experimental details in the Research Strategy section and provide the full reference in the Bibliography and References Cited section.

A. <u>Significance</u>:

- Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
- Describe the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of your application.
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
- Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

B. <u>Innovation</u>:

- Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
- Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

C. Approach:

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project.
- Describe the experimental design and methods proposed and how they will achieve robust and unbiased results. Include how

the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.

- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- 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.
- Explain how relevant biological variables, such as sex, are factored into research designs and analyses for studies in vertebrate animals and humans. For example, strong justification from the scientific literature, preliminary data, or other relevant considerations, must be provided for applications proposing to study only one sex.
- If your study(s) involves human subjects, describe (a) the specific population of human subjects involved (e.g., patients referred by local cardiologists, students participating in collegiate organizations, volunteers from First Baptist Church, etc.), including the number of subjects and salient characteristics such as age range, gender, etc. (b) inclusion/exclusion criteria, and (c) how they will be recruited (e.g., by letter, oral presentation, advertising). Submit as appendices the following wherever relevant: scripts for person-to-person solicitation, and/or copies of newspaper ads, fliers, notices, etc. Include only risks of more than negligible probability and/or severity including possible delayed effects. Finally, include any precautions that will be taken to avoid such risks (including breeches of confidentiality), and actions to be taken if these risks materialize. (c) Describe any inducement or compensation for subject participation.
- Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.
- If research on Human Embryonic Stem Cells (hESCs) is proposed but an approved cell line from the NIH hESC Registry cannot be identified, provide a strong justification for why an appropriate cell line cannot be chosen from the Registry at this time.

If an applicant has multiple Specific Aims, then the applicant may address Significance, Innovation and Approach for each Specific Aim individually, or may address Significance, Innovation and Approach for all of the Specific Aims collectively. *Include preliminary studies (if available), data, and/or experience pertinent to this application in one of the above mentioned sections.

Page 13 Future Directions: Briefly describe planned next steps for the data from this project (e.g. collaboration with another PI; an R type grant; a foundation grant, etc.)

Additional Required Pages (not included in main text total)

Prior Submission (up to 1 page): If you have previously submitted this project to the IU Health Values Grand Challenge mechanism you must address how this proposal has been revised / is different from the previously submitted application.

<u>Facilities (1 page)</u>: Describe the facilities available for this project including laboratories, clinical resources, office space, animal quarters, etc. List major items of equipment available for this work.

<u>Collaborative Arrangements (1/2 page)</u>: If the proposed project requires collaboration of the PI with other investigators, describe the collaboration and provide evidence to assure the reviewers that the other collaborators agree to the arrangements (letters of support in the appendix).

References (no limit)

<u>Biographical sketches:</u> Principal investigator and any senior / key personnel in newly published NIH format (5-page maximum for each individual).

<u>Other Support:</u> Principal investigator and any key personnel that are relevant to the proposed project; 3- page maximum for each individual.

Include a letter from the mentor saying they have read and application and have advised the applicant any suggestions for craftsmanship and research design

<u>Additional Appendices</u>: Up to eight additional pages, are allowed and may contain such items as letters of agreement from collaborators, required letters of support from the mentor and departmental chair, and additional scientific materials.

REVIEW PROCESS

Application review will be completed by a peer review committee. An effort will be made to find reviewers who have expertise in the project's area of interest; however, this is not always possible in highly specialized areas.

Requests for funds will be critiqued on the following three items:

- The strength of the research.
- The alignment of the proposed project with Indiana University Health Values.

- The strength of the collaboration.
- The strength of a defined plan for future extramural support and/or IP.

After the review committee makes its recommendation, it will be submitted to the Indiana University Health Board committees on Research & Education and Values, Ethics, Social Responsibility & Pastoral Services for final review and approval. The number, size and scope of the final Grand Challenge awards will be determined by the Indiana University Health Board committees on Research & Education and Values, Ethics, Social Responsibility & Pastoral Services.

Available funding from sponsoring affiliates will allow for approximately 3-4 awards.

POST-AWARD REQUIREMENTS

- 1. All awards will be monitored for progress by the IU Health Grants Development & Administration Office as required by the grant agreement. Grant agreement will be sent out for the PI's signature after the awards are approved and must be returned no later than 30 days to IU Health Grants Administration Office (Email: GrantsAdministration@iuhealth.org Tel: (317) 962-2273) afterwards by the PI. (See Grantee Expectations section for information on progress report timeline).
- Recipients are to acknowledge Indiana University Health (IUH) and the Indiana CTSI support in any presentation or publication of work funded by an IU Health Values Fund for Research Award as follows:

This [(publication was made possible) (project was supported), or (project was funded)], in part, with support by the Board of Directors of the Indiana University Health Vales Fund for Research Award and 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."

CONTACTS

Questions regarding financial issues related to budgeting and eligibility should be directed to the IU Health Grants Administration:

Peter Michael pmichael@iuhealth.org 317.962.2373

Questions regarding scope or review of the proposal should be directed to CTSI:

Julie Driscol judrisco@iu.edu 317.278.2822