Application for

DR. CHARLES FISCH CARDIOVASCULAR RESEARCH AWARD

INDIANA UNIVERSITY SCHOOL OF MEDICINE BIOMEDICAL

RESEARCH COMMITTEE

SUBMISSION DEADLINE: May 3rd, 2021

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://indianactsi.org/researchers/services-tools/translational-research-development/open-funding-opportunities/

For WebCAMP submission questions please contact Julie Driscol @ judrisco@iu.edu / 317-278-2822

INFORMATION FOR APPLICANTS:

OBJECTIVE

The objective of the Dr. Charles Fisch Cardiovascular Research Award is to support cardiovascular research for young investigators or more senior investigators, embarking on a new research direction. Projects are funded with the expectation that they have a very strong and immediate potential to develop into larger, externally funded research programs or generate novel intellectual property. Successful proposals should include collaborations with other investigators within the Division of Cardiology or across the IU system. Successful applicants are encouraged to use the title "Suzanne B. Knoebel Young Investigator, Krannert Institute of Cardiology" during the award period.

WHO MAY APPLY

All faculty members with a primary appointment in the tenure, clinical or research tracks in the Division of Cardiology, Department of Medicine who do not have > $200,000 intramural or extramural research support are eligible to apply for *research program support*. Clinical fellows, postdoctoral researchers and students in the division of cardiology may apply for *research fellowship* to support his/her research training under a faculty member in the division of cardiology.

Extramural funding should be construed to mean grants from Federal and state agencies (e.g. NIH, NSF, VA, USDA, ISDH), National Organizations and Foundations (e.g. National Heart Association, Robert Wood Johnson Foundation, Howard Hughes Foundation), and Industry (e.g. GlaxoSmithKline, Eli Lilly Company) of $200,000 (direct costs) or greater per annum. Clinical trial contracts and salary support on career development award(s) do not count toward the $200,000 limit and grants in no-cost extensions or nearing the end of their award term may list remaining fund balances in lieu of the full awarded amounts. The amount of all extramural funding available to the applicant, if any, must be detailed. This includes any funding through program projects, centers, joint grants and any other mechanisms. If such funds are available, the relevant specific aims of that portion of the project or center grant must be provided. In listing support, the PI must specify dollar amounts for collaborative grants as well as for individual grants. If they are not the PI, the role in the project must be clearly specified, along with any resources or funding for that role.

RESTRICTIONS

1. Applications to this program are limited to a total of $60,000.

2. Faculty members who apply for *research program support* may budget up to $20,000 for salary and fringe support. All salaries will be capped at the current NIH level. Postdoctoral trainees who apply for *research fellowship support* may budget up to a total of $50,000 per year in salary and fringe benefit support.

3. Applicants who have submitted or have pending an application for extramural funding may use the same or similar proposal to apply to the Charles Fisch RFA, but this must conform to the Committee's guidelines and application format. **The applicant must address the**

Specific Aims for the single year of funding requested. It is to the applicant's advantage to focus and establish priorities for the year, and to describe how the one year of funding requested will aid in either "jump-starting" a project or strengthening a planned or pending submission. The relevant parts of an extramural proposal may be appended if desired, but the priorities for the proposed year of funding must be clearly justified.

4. Requested grant funding period cannot exceed 12 months. However, funded projects may be extended for up to one year with no additional funds if approved by the division director.

5. Frequency and number of submissions:
   - An applicant may submit a maximum of one application per deadline and maynot simultaneously receive two Dr. Charles Fisch Cardiovascular Research Awards
   - The committee will not review a proposal more than three times (original plus two revised submissions.)
   - A complete and unedited copy of reviewer's comments must be included in the appendices for all proposals previously submitted.

6. Applicants who are, or have been, associated with a senior investigator at Indiana University are strongly advised to include a letter from the senior investigator addressing the relationship of the applicant's project to the senior investigator's research.

7. Senior investigators are defined as investigators who have finished clinical training or postdoctoral research training 20 years prior to the application deadline. The application submitted by senior investigators must include a paragraph in the specific aim page of the grant application to justify the need for funding to start a new research direction. The Director of the Krannert Institute of Cardiology will review the justification and approve or disapprove the eligibility for submission.

MECHANISM FOR SUBMISSION OF APPLICATION

Applications will be considered once a year. **Submission due dates are the first regular business day in May.**

Applications will be assigned for review prior to the next scheduled meeting of the Biomedical Research Committee, which will generally meet within six weeks of the submission date. Projects should have a start date no earlier than July 1st.

Applicants are expected to review and comply with these related division research policies and procedures prior to submission:

- Clinical Trial Project Request Form
- CVI Biostats Core Policy
- Publication Policy

Applications will follow this sequence:

Page 1. Face page, which specifies the title of the proposal, principal investigator and his/her affiliation, where work will be performed, and the total budget.

Page 2. Abstract page listing all professional individuals involved in the project and an abstract of the proposed research.

Page 3. State the reasons for the application at the present time and specify whether these are start-up funds for a new investigator or bridge funding between periods of extramural grant support. This should not exceed one page. **If the request isa resubmission of a proposal previously reviewed by the Biomedical Research Committee, the applicant must include a detailed introduction showing what changes have been made to address the previous comments.** Changes should also be noted in the body of the proposal and prior review comments included in the appendices.

Page 4. **Use of funds for future extramural funding / IP**: Describe how the project 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 (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.

Page 5-6. Budget page listing the direct costs for all personnel and supplies. All costs should be specifically justified on page 5 (limit justification to one page).

Clinical *research program support and research fellowship support* requests must include Research Nurse support of at least sufficient effort for IRB application and patient recruitment, if any. Please consult with Krannert's clinical research manager before preparing the budget.

A 5% overhead will be added to the budget ofall research projects to pay for the administrative cost.

Page 7-10. **Biographical sketch** of the principal investigator including his/her bibliography. Use the NIH Biographical Sketch Format.

Page 11. **Other Support** of principal investigator: It is critical that the Other Support page be clear and detailed, and include funding through program projects, centers, joint grants, etc., as well as the role of the applicant in each grant and any potential overlap.

Page 12-end. Research Plan (items A-D below) should be typed on 8 ½ x 11 white paper with at least 1/2 inch margins and is **not to exceed 5 pages**. Type size should follow NIH

guidelines: Arial, Helvetica, Palatino Linotype or Georgia typeface and a font size of 11 points or larger. Type must be clear and readily legible, reasonable size and single spaced. Make every effort to write your research proposals 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 be aware that highly specialized expertise may not be available within the CTSI system.

The Research Plan should address the single year of funding requested. Relevant parts of an extramural proposal may be included, if desired, to show the scope of the overall project and to justify how the funding requested will aid in either "jump-starting" a project or strengthening a planned or pending submission. It is to the applicant's advantage to focus and establish priorities for the year. These priorities should be made clear in all relevant sections of the Research Plan.

The application narrative should be structured in accordance with the following format:

A. Specific Aims:
This section (1 page) should include objective, rationale, central hypothesis, and specific aims of the proposal.

B. Significance: (sections B-D should not exceed 4 pages)
This section should include background and importance of proposed work as well as its potential for extramural support.

- **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 it will increase the understanding of disease mechanisms, drug/device/technology developments and toxicology studies, 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 o 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.

C. Innovation:

How does the proposed project seek to challenge existing paradigms including novel concepts, approaches, methodologies, instrumentation, or inventions of current research or clinical practice? Are these innovations new to one field of research or unique in a broad sense?

D. Approach:

This section should include preliminary data and research strategy. Research strategy should include for each separate specific aim, rationale, proposed experiments and anticipate results/alternate strategies.

E. Available:

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.

F. Collaborative Arrangements:

If the proposed project requires collaboration with other investigators, describe the collaboration and provide evidence to assure the reviewers that the other collaborators agree (letters of support in the addendum).

G. Supporting Information:

Research fellowship support applications must include a support letter from a faculty sponsor. The support letter must include the following information: (1) research in progress in the sponsor's clinical service or research laboratory, (2) other related training or course work which will be required for specific technical skills or methods the applicant will expect to master, (3) the relationship of the research training plan to the applicant's career goals, (4) the role the applicant played in the development of the research proposal, (5) the sponsor's assessment of the applicant and (6) the scope and source of all funds available to the applicant to conduct his/her research, including departmental and institutional funds.

One copy of the latest approval form for recombinant DNA, human subjects, or animal protocols should be submitted *just in time* before the commencement of funding.

The Indiana CTSI offers a resource that can help strengthen submissions by providing valuable feedback and critiques. To engage with this resource, please contact Lane Coffee at rlcoffee@iu.edu to discuss meeting with one of the project development teams.

Submit your application electronically via the **'Start a submission' link: CTSI 2021 Fisch Link**

The electronic application (including addendum) should be in a single PDF file **that includes scanned signatures**.

REVIEW

The first level of review will be conducted by the Indiana University School of Medicine Biomedical Research Committee (BRC). The results will be forwarded to theKrannert Institute of Cardiology where a committee appointed by the director will perform thesecond level of review and make final funding decision.

REPORTING REQUIREMENTS FOR AWARDEES:

1. All awards will be monitored for progress.
    a. A mid-year progress report will be required by January 15th detailing progress on the project and should include documentation 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. **Note: the final 6 months of funding are contingent on satisfactory achievement of milestones.**
    b. A final progress report will be due within 60 days of the end of the grant year and should include but is 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. Requests for a no-cost extension must be submitted in writing to the Division Chief at least 30 days prior to expiration.
3. Awardees must include the following acknowledgment in all publications related to the work funded by this award: “This work is supported by the Charles Fisch Cardiovascular ResearchAward endowed by Dr Suzanne B. Knoebel of the Krannert Institute of Cardiology.”
4. In the event the PI submits official notification of departure from IUSM, spending on the account must immediately cease.