NIH NIGMS COBRE PHASE III PILOT PROJECT PROGRAM

REQUEST FOR APPLICATIONS

“Cardiometabolic Health and Disease”

Guidelines for Proposal Submission

Deadline for Proposal Submission: **February 15, 2020**

Award Period: July 1, 2020 – June 30, 2021

Overview of the COBRE Research Pilot Project Program

The Diabetes and Obesity Center (DOC) at the University of Louisville (https://louisville.edu/doc), funded by the NIH Center for Biomedical Research Excellence (COBRE) program, is pleased to announce that funds are available to support Pilot Projects in areas germane to Cardiometabolic Health and Disease. Projects are expected to advance understanding and management of cardiometabolic disease or to advance technology or methodology required for detecting or treating diabetes, obesity, or cardiovascular diseases. Priority will be given to applications that focus on developing a project to a level competitive for extramural funding. Additional priority will be given to applications that focus on translational research. Investigators seeking support to develop or market patentable products (e.g., devices, therapies) are also encouraged to apply. Two types of applications will be considered for funding: Science Development Grants (Type 1), and Technology Development Grants (Type 2). Renewals for Type 1 proposals must build upon the original application and progress toward the submission of a federal grant application (R01 or equivalent). This is in line with the mission of this Pilot Program, i.e., to acquire preliminary data that helps the applicant establish an outstanding research program and develop competitive NIH R01 level applications in the areas of diabetes, obesity, and cardiovascular disease. The goal of Type 2 proposals is to further develop the infrastructure, capabilities, and Cores in the Center and will only be awarded for a one-year term.

Funds available

We plan to fund two Pilot Projects per year. Projects will be funded for 12 months, with total Direct Costs limited to $75,000/yr. Applicants given priority for funding will be early career faculty (Instructor to Assistant Professor) within the Basic or Clinical Departments in the School of Medicine. Additionally, mid-career or senior level applicants that are proposing research into cardiometabolic health and disease will be considered for funding, only if the line of inquiry is a significant deviation from previous work. Projects may be considered for renewal for a second year on a case-by-case basis and contingent upon DOC and external advisory committee evaluation of an annual progress report, which will be included in the renewal submission. All awarded applications will provide opportunities to pursue innovative avenues in cardiometabolic research and will facilitate the use of the Cores.

Eligibility requirements

Applicants must be a faculty member (Instructor level or above) at the University of Louisville at the time of award. Applicants eligible for Type 1 proposals are expected to be in a full-time (12 month) term or tenure track position, with at least 50% effort devoted to research. To be considered for Type 2 applications, applicants should have significant (≥50%) effort devoted to either Research or Service. To be considered for Type 1 funding, early career applicants must not have held R01 level funding as a Principal Investigator. Mid-career/senior level applicants must not currently hold overlapping NIH funding and their applications must represent a significant deviation from previous work and focus on cardiometabolic research. For Type 2 applications, no restrictions regarding current funding applies; however, the proposed research must focus on building infrastructure,
methodological, or technological capabilities of the Diabetes and Obesity Center and its Cores. Investigators who are or have already been supported by the COBRE or IDeA Networks of Biomedical Research Excellence (INBRE) mechanisms are not eligible to apply.

Application Procedures

Applications will be solicited once per year and must be received by the deadline for submission. Applicants are encouraged to discuss Pilot Project ideas with the Pilot Program Director (Bradford G. Hill, Ph.D., bradford.hill@louisville.edu) prior to applying. The full application and NIH Biosketch should be submitted electronically (.pdf) to Dr. Hill. Applications for a COBRE Pilot Project will follow an NIH style format as outlined below. Submitted applications will be reviewed by members of the COBRE Internal Review Committee (IRC). Meritorious applications that focus on cardiometabolic health and disease will be sent, along with internal reviews to an External Advisory Committee (EAC) for recommendation of funding. Projects will be ranked based on merit and in accordance with the overall research goals of the COBRE-funded DOC.

Pilot Projects for funding fall into two categories: Scientist Development Grants (Type 1) and Technology Development Grants (Type 2).

- **Type 1 grants** will be accepted from faculty members developing an independent research program with a focus on diabetes, obesity, or cardiovascular health or disease. Projects are expected to develop basic scientific concepts and work toward developing strong R01-level applications. The PI must not have prior R01 level extramural support for cardiometabolic research.

- **Type 2 grants** will provide support to applicants proposing to develop novel methodological or technological applications relevant to the mission of the DOC. Type 2 grants are non-renewable.

Application guidelines and format

Applicants are encouraged to discuss Pilot Project ideas with Dr. Hill prior to applying. This will help ensure that the proposal is appropriate for this Pilot Project Program and will additionally help identify potential mentors. Applications for a COBRE Pilot Project will follow an NIH style format. Applications for Year 1 funding will be an abbreviated format, as detailed below, formatted similar to NIH Parent R21 proposals (as indicated in PA-18-489; https://grants.nih.gov/grants/guide/pa-files/PA-18-489.html).

Initial Applications must include the following components:

1) Title Page, including Descriptive Title, PI’s name, Department and position title.

2) Description of Project (Abstract)

3) Specific Aims (1 page) – Containing a brief background, testable hypothesis, and aims.

4) Research Strategy (6 pages maximum, excluding references)
   a. Significance (0.5 page) – The importance of the scientific question should be addressed. The applicant should expound on how the project will improve knowledge in the area.
   b. Innovation (0.5 page) – Applicants should discuss the novelty of the hypothesis, approach, technology, and/or interventions.
   c. Approach (~4 pages), including:
      i. Rationale for each Aim: If available, present data that support the rationale for moving in this research direction and testing the hypothesis proposed for each aim.
      ii. Experimental Methods: Describe the overall strategy and methodology used to accomplish the Specific Aims. Applicants should state clearly how the COBRE Core Facilities will be used in the project.
      iii. Anticipated Results: Describe results anticipated from the experiments.
      iv. Alternative Strategies: The applicant should state what strategies will be taken should he/she arrive at the null hypothesis or encounter obstacles during the course of research.
d. Statistical Considerations (~0.5 pages) – When possible, the applicant should identify a statistician to help with the research design and prepare an appropriately powered study.

e. Plans and timeline for submission of an R01 level application (~0.5 pages).

5) Literature Cited (Not included in the page limits)

6) PI biographical sketch. Include NIH style biosketch prepared using NCBI format (see https://grants.nih.gov/grants/forms/biosketch.htm). All current research support, pending applications, and completed funding (within the last five years) must be included.

7) Budget: Use NIH format, including budget justification. Applicants may request funds for technical support (research technician salary), research supplies/consumables, animal models, and other costs for conducting the study; however, pilot funds may not be used for the following: PI salary, graduate student stipends, postdoctoral trainee salary, laboratory renovations, equipment costing more than $5,000, computers, administrative support, or subscriptions/memberships to societies or journals.

To be competitive for Renewal Applications, applicants must develop a full proposal, identical to the NIH R01 format (e.g., as indicated in PA-18-484; https://grants.nih.gov/grants/guide/pa-files/PA-18-484.html https://grants.nih.gov/grants/guide/pa-files/PA-16-160.html). The Research Strategy should be expanded to 12 pages, with appropriate addition to the Significance, Innovation and Approach sections. A progress report, in the form of a 2-page Introduction to the proposal, should be included in the application. Progress reports should include: major findings, publications occurring during the funding period, presentations at scientific conferences, new findings that affect the scope of the investigation significantly, and future directions.

Animal and human welfare issues

Applicant must have IACUC, IBC, and/or IRB approval before project commences.

Criteria for application review

Overall Impact: Similar to NIH-style reviews, reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to develop into an R01-level project or to contribute significantly to methodology/technology that will contribute to the DOC Core’s ability to address issues in cardiometabolic health and disease.

Scored review criteria: IRC reviewers will give a separate score for each review criteria below. An application does not need to be strong in all categories to be judged likely to have major scientific impact.

- **Significance**: Does the project address an important problem or a critical barrier to progress in the field? Is there a strong scientific premise for the project? If the aims of the project are achieved, will the applicant’s ability to obtain R01 level funding be improved significantly?

- **Investigator**: Does the PI show evidence of productivity? Is the investigative team qualified to lead this project?

- **Innovation**: 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? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

- **Approach**: Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex?
- **Core usage**: How will the DOC Cores be leveraged to address the goals of the project? How does the project influence Core applications?

**Contact Details**: For additional information, contact Bradford G. Hill, Ph.D. (bradford.hill@louisville.edu; 502-852-1015).