

March 14, 2023
REQUEST FOR APPLICATIONS
U OF L CENTER FOR INTEGRATIVE ENVIRONMENTAL HEALTH SCIENCES
PILOT PROJECT PROGRAM
LETTER OF INTENT DUE DATE (REQUIRED) 03/21/2023
INVITATIONS FOR FULL PROPOSAL BY 03/31/2023
FULL PROPOSAL DUE DATE 04/25/2023

Introduction: The UofL Center for Integrative Environmental Health Sciences (CIEHS) is soliciting applications for pilot projects funded through the NIEHS P30 Environmental Health Sciences Core Center grant. The Pilot Project Program was implemented to foster novel research forming the basis for new extramural grant applications. The Pilot Project Program provides resources supporting new environmental health investigators, collaborations between CIEHS members and established investigators bringing new skill sets to environmental health problems, new avenues of environmental health research by CIEHS members, and community-engaged and community-led research in collaboration with CIEHS members.

In response to the NIEHS Emerging Strategic Opportunities, priority is being given for this RFA to proposals focusing on:

- 1. Precision Environmental Health:**
 - Addresses the individual variability associated with responses to environmental exposures
 - Goal is to understand individual risk to prevent disease
 - Integrates Genetics, Epigenetics and Omics Data
- 2. Exposomics:**
 - Involves getting beyond single exposures: totality of exposures across life course
 - Requires an unprecedented integrated data infrastructure
- 3. Computational and Data Science:**
 - Proactive planning to enable interdisciplinary, collaborative, cross-cutting strategies
 - Work to ensure that grantees have access to state-of-the-art computational capabilities
 - Goal is to enable exposomics, data-driven/knowledge-driven discovery, computational toxicology, microphysiological systems, precision environmental health
- 4. Environmental Justice and Health Disparities:**
 - Environmental factors such as air and water quality are fundamental determinants of our health and well-being. Environmental factors can lead to disease and health disparities when the places where people live, work, learn, and play are burdened by social inequities.
- 5. Mechanistic and Translational Toxicology:**
 - Molecular mechanisms that underlie agent toxicity: how is gene expression impacted by exposures
 - Data generation can be translated to human biology
 - Utilizes innovative new approaches to study environmental exposures
- 6. Climate Change and Health:**
 - Direct Effects: heat-related illness; respiratory disease; heart disease; food-water-and vector-borne diseases; injury; premature death, mental health impacts, poor maternal and birth outcomes
 - Indirect Effects: chemical releases into environment, changes in air, water, food quality and quantity; population displacement; interruptions to health care; Infrastructure and supply chain disruption; economic impacts – more people living in poverty.

General Information and Types of Awards: Pilot project funds are available for the fourth budget period of the P30 award, which will be 04/01/2023-03/31/2024. The due date for pilot project applications in response to this RFA is 04/25/2023, with required Letters of Intent due on 03/21/2023. The project period will be for one year from date of award with an anticipated start date of 06/01/2023. Awardees will be required to sign an award notice committing to the terms of the award, including required post-award reporting, using the data to support a grant application to NIEHS, and to present results of the project in a CIEHS symposium at Research!Louisville in 2024. In addition, Pilot awardees with animal studies will be required to share excess tissues from animal experiments with the IHSFC's IACUC-approved biorepository. The P30 grant funds multiple types of pilot projects. This RFA solicits applications for three types of awards: Interdisciplinary Award, New Direction Award, and Community-Engaged Award (described below).

Interdisciplinary Award (up to \$50,000 maximum direct costs)- A goal of the CIEHS is to foster interdisciplinary collaborative research in environmental health science. One way this will be accomplished is by funding projects on which investigators new to the field of environmental health collaborate with established investigators in this field. Interdisciplinary awards will be led by a PI who is a UofL faculty member who is either not a current CIEHS member or has not received NIH funding for a project related to environmental health sciences but will be required to collaborate on the project with an established CIEHS member to be eligible for the award. Examples of the types of researchers who could be targeted by these awards are: 1) Investigators from other fields such as biology or chemistry with environmental science background who have not previously applied their expertise to human health; 2) Researchers with novel techniques related to exposure analysis, assessment of health outcomes, data analysis techniques, etc. that could be applied toward environmental health issues; 3) Clinical researchers or epidemiologists who could apply their expertise or access to unique study populations or specimens for translational studies assessing health outcomes resulting from environmental exposures and interactions with lifestyle factors; 4) Investigators with expertise in community-engaged research who would collaborate with a CIEHS member to address impacts of pollutant exposure/lifestyle factors in the local or regional community. The Interdisciplinary Award mechanism is intended to bring talented investigators from other fields into environmental health and has the potential to produce synergistic effects on research productivity by bringing together new combinations of investigators.

New Direction Award (up to \$40,000 maximum direct costs)- An additional strategy for promoting novel science related to environmental health at UofL is to support investigators with exciting new ideas representing a departure from their current research program. New Direction awards will be led by a UofL faculty member who is a current CIEHS member, but the proposed project must be highly innovative and distinct from the applicant's currently funded research. Examples of the types of projects funded by this mechanism include: 1) Projects in which a basic researcher moves toward translating findings using human samples or subjects. The IHSFC and BIFC will assist with study design and identifying available resources for the translational component of this type of project. 2) Studies in which a researcher with a background in toxicant exposures adds a dimension of lifestyle factors such as diet, smoking, drugs of abuse, etc. Projects of this type may involve animal models or may comprise clinical or population-based research facilitated by the IHSFC. 3) Projects that involve community-engaged research. Basic or clinical researchers desiring to apply concepts or knowledge from their research programs for local or regional community impact could be funded by this type of award. These researchers would work closely with the CEC to facilitate community engagement.

Community-Engaged Award (up to \$50,000 maximum direct costs) - An overall goal of the CIEHS is to promote community engagement and community-led citizen-science research. To foster activity toward this goal, the Pilot Project Program will commit to funding projects with community-focused objectives. The research for this type of award must involve interaction with community members within the geographic focus area of P30 Center ("Louisville Regional Community," encompassing Kentuckiana and western Kentucky) and must impact an environmental problem of local or regional significance. Eligible applicants are UofL faculty members, faculty of other universities within the geographic focus area, public health professionals, and community members. Applicants from outside UofL are expected to designate a CIEHS member as collaborator. All applicants will be encouraged to utilize Facility

Cores. Projects related to the overall CIEHS theme investigating interactions between pollutant exposures and lifestyle factors are encouraged. Community-engaged research fits within many of the goals articulated in the NIEHS strategic plan (<https://www.niehs.nih.gov/about/strategicplan/index.cfm>), including understanding in community populations environmental exposures, gene-environment interactions, environmental co-exposures, and connection of exposures with health outcomes; outreach, communication, and engagement, including multidirectional communication between researchers and community stakeholders; environmental health disparities and environmental justice; evidence-based prevention and intervention; and integrating data from research findings to inform/impact public health.

Letter of Intent (2 pages maximum): A letter of intent with due date 03/21/2023 is **required** for each application. Submission of letters of intent will assist with 1) ensuring that projects are appropriate for the program before applicants invest effort in preparing a full proposal; 2) planning the review of applications; and 3) organizing interactions between the CIEHS and potential applicants during the application preparation period. Letters of intent should specify which NIEHS Emerging Strategic Opportunity you are applying for, if any, include the names of the principal investigator and key personnel, the title of the project, an abstract summarizing the proposed work, keywords related to the project, and a lay summary that describes how this project directly or indirectly affects community members within the geographic focus area of P30 Center ("Louisville Regional Community," encompassing Kentuckiana and western Kentucky). Applicants for the Interdisciplinary Award category should identify in the letter of intent the collaborating established CIEHS co-investigator(s). Letters of intent should be submitted by email to the Pilot Project Program service account (pilotprojects@louisville.edu). Lay Summary sections will undergo review by members of the Community Stakeholder Advisory Board based on the criteria of significance and community relevance, while the Letters of intent will undergo administrative review by CIEHS. Both of these will factor into selecting applicants from whom full proposals will be invited. These applicants will be informed in late September.

Proposal Format: Applications for pilot projects will contain the following elements: Cover Page, Abstract, Biosketches, Detailed Budget, Budget Justification, Specific Aims, Research Strategy, Bibliography and References Cited, Vertebrate Animals (if applicable), Letters of Support (if applicable), Resource Sharing Plan(s), Authentication of Key Biological and/or Chemical Resources (if applicable), and PHS Human Subjects and Clinical Trials Information (if applicable). Submit the application as a single pdf file attachment by email to the Pilot Project Program service account (pilotprojects@louisville.edu).

Cover Page- Complete the cover page form distributed with the RFA.

Abstract- Provide a succinct description of the project including its relevance to environmental health science (limit: 400 words).

Biosketches- Provide NIH-style biosketches (<https://grants.nih.gov/grants/forms/biosketch.htm>) for all key personnel.

Detailed Budget- Provide budget information for the project period (06/01/23-05/31/2024) on NIH Form Page 4 (Detailed Budget for Initial Budget Period <https://grants.nih.gov/grants/funding/phs398/phs398.html>). The following costs will be allowable for pilot projects: supplies, core facility user fees, animal per diems, costs for human subjects research, publication costs, and salary/tuition/benefits for students, trainees, and technical personnel. Travel, major equipment, and faculty salaries are not allowed. List and provide amount of effort for all personnel, including faculty. Although faculty salaries are not allowed, it is expected that faculty involved on the projects will be spending time working on the projects (i.e. dedicating effort). Provide salary/tuition/benefits information for students, trainees, and technical personnel. For faculty, include the name of each faculty member involved in the project and the amount of effort devoted to the project, but leave the Salary Requested and Fringe Benefits columns blank and fill in the Total column with zero for all faculty personnel. Split out costs for each CIEHS core facility and list under Other

Expenses. Applicants are encouraged to consult with core facility directors (see contact list at end of document) during the application process to discuss capabilities and costs.

Budget Justification- Justify expenses and provide additional detail as needed to clarify how the requested funds will be spent.

Specific Aim(s)- Describe the overall goal of the project and the specific aim(s) that will be accomplished to achieve the goal (limit: 1 page).

Research Strategy- Describe the research strategy for the project in the format of a NIH R03/R21 application (limit 6 pages) and include all information required in NIH grant applications. Preliminary data is expected for pilot projects to demonstrate feasibility. Include Significance, Innovation, and Approach sections. In the Significance section, include a description of how the project relates to environmental health science and how it will further the goals of the CIEHS (see Introduction above and CIEHS website <https://louisville.edu/ciehs/about-us>) and/or the NIEHS strategic plan (<https://www.niehs.nih.gov/about/strategicplan/index.cfm>). Also in the Significance section, if applicable, describe how the proposed research fits within one or more of the CIEHS Research Interest Groups (RIG) (Multi-Organ Toxicology, Cancer, and Neurodevelopmental Toxicology) (<https://louisville.edu/ciehs/groups>). The Approach section should include a description of how CIEHS core facilities will be used in the proposed research if applicable. For New Direction Awards, the Innovation section must include a description of how the proposed research represents a distinct and innovative departure from the PI's current research program with potential for NIEHS funding. The ultimate success of the Pilot Project Program is the generation of new NIEHS R01 grants. Thus, the application should clearly make evident the feasibility of achieving the aim(s) and how the results will lead to an R01 application to NIEHS.

Bibliography and References Cited- No defined page limit.

Vertebrate Animals- If vertebrate animals are to be used, address the three criteria required by NIH (Description of Procedures; Justifications; Minimization of Pain and Distress): <https://grants.nih.gov/grants/olaw/VASchecklist.pdf>

Letters of Support- Letters of support may be included if applicable to assist with establishing feasibility of the project.

Resource Sharing Plan(s)- Include a data sharing plan and, if applicable, plans for sharing model organisms and genomic data (https://grants.nih.gov/grants/policy/data_sharing/).

Authentication of Key Biological and/or Chemical Resources- Include this section if applicable based on NIH instructions: <https://grants.nih.gov/grants/funding/phs398/phs398.pdf>

PHS Human Subjects and Clinical Trials Information- If applicable, complete the PHS Human Subjects and Clinical Trials Information form (pdf version available here: <https://www.grants.gov/web/grants/forms/r-r-family.html>)

Review Process: An administrative review of pilot project applications will be performed, and those that meet the requirements specified in this RFA will be reviewed for scientific merit and programmatic relevance. Each application will be assigned to two external reviewers and will be scored for scientific merit on the 9-point NIH rating scale. NIH review criteria of Significance, Investigator, Innovation, Approach, and Environment will be scored, and an overall impact score will be given. A component of the overall impact score will be the likelihood that completion of the proposed research would lead to submission of a competitive R01 application. Programmatic review will be performed by an internal CIEHS committee to rate applications regarding the extent to which the proposed research 1) complements existing environmental health research ongoing within the CIEHS (i.e. aligns with one or more RIGs); 2) contributes to the overall goals of the CIEHS (<https://louisville.edu/ciehs/about-us>) or the NIEHS strategic plan (<https://www.niehs.nih.gov/about/strategicplan/index.cfm>) (examples: foster

collaborative research in current and new environmental health science areas, promote translation of science findings into knowledge to inform health outcomes, recruit new and established investigators to environmental health science research, promote community-based research); and 3) utilizes CIEHS core facilities.

Post-Award Administration of Pilot Projects:

Reporting- Awardees will be required to submit 6-month progress reports during the project period and the subsequent year, and annual reports for the following 3 years. The 6-month reports will contain a brief summary of scientific progress, spending, core facility usage, CIEHS collaborations, presentations, publications, data sharing, grant applications submitted, and grants awarded. The subsequent annual reports will contain information on presentations, publications, grant applications submitted, and grants awarded. The information gathered in this way will be used to measure success of the program, which will be necessary for a renewal of the P30 center.

Research!Louisville Symposium- Pilot project awardees agree to participate in a CIEHS symposium as part of Research!Louisville.

Strategies for New Grant Funding- A central goal of the Pilot Project Program is to expand environmental health research at UofL by facilitating the procurement of new external funding with an emphasis on NIEHS funding. Pilot project awardees will be expected to submit a proposal for external funding to continue the project within a year after the original end date of the award. Pilot project awardees will be encouraged to interact with the CIEHS to facilitate procurement of new external funding; the CIEHS can provide assistance with identification of collaborators, use of core facilities, and pre-submission internal grant review.

Program Contacts

For general information about the CIEHS Pilot Project Program and the application process, contact:

Amanda Jo LeBlanc, PhD
Director, Pilot Project Program
amanda.leblanc@louisville.edu
502-854-0560

For information related to P30 Center cores, see the CIEHS website or contact the individual core directors:

Integrated Health Science Facility Core (IHSFC)

<https://louisville.edu/ciehs/cores/ihsfc/ihsfc>

Matthew Cave, MD

m0cave01@louisville.edu

Community Engagement Core (CEC)

<https://louisville.edu/ciehs/cores/cec/cec>

Luz Huntington-Moskos, PhD, RN, CPN

luz.huntingtonmoskos@louisville.edu

Biostatistics and Informatics Facility Core (BIFC)

<https://louisville.edu/ciehs/cores/bifc/bifc>

bifc@louisville.edu

Omics and Exposure Facility Core (OEFC, formerly the ITEMFC)

<https://louisville.edu/ciehs/cores/itemfc/itemfc>

Michael Merchant, PhD

oeffc@louisville.edu