

The UK Center for Appalachian Research in Environmental Sciences and the Center for Clinical and Translational Science Call for Applications Pilot and Innovation Research Program

The UK Center for Appalachian Research in Environmental Sciences (UK-CARES) is now accepting applications for Pilot Projects. The overall goal of the UK-CARES Pilot Program is to enhance the interactions and expand the critical mass of investigators and citizen scientists with expertise and experience in transdisciplinary, translational environmental health research on the UK campus and in Appalachian communities (targeted region: Big Sandy, Cumberland Valley, Kentucky River). Information on the UK-CARES is found on the website (https://www.niehs.nih.gov/health/topics/index.cfm). The purpose of this funding mechanism is to provide a new opportunity and resources to support innovative, collaborative environmental research.

The categories of awards will be as follows:

I. INNOVATION/HIGH IMPACT AWARD

This award is for investigators at all stages of career development; junior, midlevel, and senior investigators, and is intended to stimulate innovation and to support pilot studies that will lead to extramural funding. Pilot grants will support projects that catalyze new research opportunities, expand research interactions with citizen scientists, volunteer faculty, or bring new dimensions to the Center. The total award is limited to \$50,000 which must be spent over 12 months.

- Eligibility is limited to full-time faculty (all title series including regular, research, clinical and special) at the University of Kentucky and affiliated institutions.
- o Investigators who are currently not in the area of environmental health science research are encouraged to apply.
- Investigators in training including residents, post-doctoral fellows, and clinical fellows are NOT eligible to serve as PIs but may be co-investigators.
- Volunteer faculty, adjunct faculty, and citizen scientists are NOT eligible to serve as PIs but are encouraged as co-investigators. UK-CARES partner organizations and collaborators are encouraged to serve as volunteer faculty and/or citizen scientists.

II. EARLY CAREER INVESTIGATOR AWARD

This award is intended to support pilot studies by early stage investigators to obtain preliminary data for an extramural grant submission. The maximum award will be \$25,000 which must be spent over 12 months. This award is only open to investigators in the early stage of their career, or investigators who are transitioning into a new area. Applicants must identify a mentor to assist with the investigator's training. If appropriate for the focus of the project, applicants are expected to identify at least one citizen scientist in Appalachian Kentucky to collaborate on the project.

- Eligibility is limited to full-time faculty (all title series including regular, research, clinical and special) of the University of Kentucky and affiliated institutions.
- Early career investigators who are currently not in the area of environmental health science research are encouraged to apply.
- Investigators who are PIs on other career development awards or R01-type funding are NOT eligible.
- o Investigators in training including residents, post-doctoral fellows, and clinical fellows are NOT eligible to serve as PIs but may be co-investigators.
- Volunteer faculty and adjunct faculty, and citizen scientists are NOT eligible to serve as PIs but may be co-investigators.

The UK-Center for Appalachian Research in Environmental Sciences Center will accept applications for pilot projects according to the following schedule:

- Call for Applications: January 17, 2019
- Letter of Intent due: February 15, 2019
- ❖ Invitation to submit Full Application: February 25, 2019
- ❖ Full Application due: March 22, 2019
- Funding Decision: April, 2019

GOALS:

The Goals of the UK-CARES Pilot Project Program are to:

- Expand the research mission of UK-CARES by supporting new and novel areas of investigation in promising transdisciplinary and community-engaged areas of environmental health sciences and environmental medicine.
- ➤ Provide research support, including financial, administrative, and mentoring, for early career faculty to establish competitive research programs in environmental health sciences and environmental medicine.
- ➤ Provide support for faculty to explore new and innovative directions representing a significant departure from ongoing funded research into the environmental health sciences discipline.
- ➤ Enhance the interactions with citizen scientists in Appalachian Kentucky and expand the critical mass of investigators with expertise and experience in transdisciplinary, translational environmental health and environmental medicine research on the UK campus and in the community.
- Foster opportunities that meet the goals and research interest areas relevant to NIEHS and the Environmental Health Sciences Core Centers.

SCOPE:

Within the general guidelines outlined above, the types of projects that will be considered within this mechanism include projects that:

- Stimulate the development of new translational inter- and multidisciplinary teams with a focus on environmental health sciences
- Support investigators entering into the field of environmental health sciences.
- Support investigators changing focus within the discipline of environmental health sciences. For example, investigators moving from environmental science related to diabetes to environmental science associated with cancer.
- Promote community-engaged research in collaboration with citizen scientists to solve environmental health issues in Appalachian Kentucky.
- Provide support for early career investigators.
- Develop new methodologies to leverage institutional strengths and new initiatives.
- Pursue high-risk, high reward studies.

PRIORITIES FOR FUNDING:

The main priorities for funding are: 1) the scientific merit of the project, 2) clear clinical and translational relevance for residents of Appalachian Kentucky, and 3) the likelihood that funding will result in submission of a competitive application for extramural funding. Where appropriate, priority will be awarded based upon the strength of the research team including citizen scientists or, for early career investigators, the mentorship team and citizen scientists. Other priorities for funding include:

- Significance of the clinical and/or translational work in terms of potential environmental health impact.
- Relevance of the clinical and/or translational work to the health of Appalachian Kentucky
- Scientific rigor and novelty of the proposed approach.
- Experience and productivity of the investigators.
- Multidisciplinary research teams representing the basic, clinical and/or population sciences with an emphasis on bridging the divisions between basic and population scientists.
- Pilot studies which generate critical preliminary data that will lead to subsequent external funding and/or commercial development.
- Health topics of interest to NIEHS (https://www.niehs.nih.gov/health/topics/index.cfm)

FUNDING INFORMATION:

Individual project awards (up to \$25,000 in total direct costs for early career investigators and 50,000 in total direct costs for high impact awards over a 12-month period) will be made on a competitive basis. Proposed costs should be commensurate with the work. It is anticipated that funds will be available to support 3 high impact and 2 early career investigator awards.

Sufficient justification and detail should be provided to validate the need and cost of each item. The budget will be comprehensively reviewed to insure that the funds being requested are relevant to the research being proposed.

ALLOWABLE COSTS

- Funds are to be used for the conduct of the project, including supplies, subject payments, assays, etc.
- It is expected that travel funds will be needed for study conduct and/or dissemination to the community.

NON-ALLOWABLE COSTS.

- Funding is not available for thesis or dissertation projects.
- Funding will not be awarded as bridge funding for ongoing projects.
- Travel to present at national conferences is not supported
- Faculty salary support*
- Budgets should include direct costs only

* PI effort is required but cannot be charged to the project. PI effort must be cost shared, which must be approved by the department chair, director, and assistant dean for research before funding will be made available. In the event that additional intra/extramural funds are secured to support the study outlined in your application you must immediately notify Joel Thompson (859-323-7939), joel-Thompson@uky.edu

Individual principal investigators will not be allowed to hold more than one UK-CARES pilot research award at any one time.

LOI AND BIOSKETCH SUBMISSION INSTRUCTIONS

Letters of Intent (LOI) and Biosketch (BS) in NIH format will be solicited from faculty on all the campuses. The LOIs will be reviewed and subject to a standard NIH-type study section assessment by the UK-CARES Pilot Review Committee (PRC). A subset of meritorious LOIs will be selected and applicants will be invited to submit Full applications.

Full proposals will be subject to a standard NIH-type study section assessment. Each proposal will be given a primary and two secondary reviewers.

LOI Submission Link: https://redcap.uky.edu/redcap/surveys/?s=MJCDFTA84H

Letter of Intent DEADLINE: February 15 by 5:00 PM (EST)

<u>The BIOSKETCH template</u> can be downloaded here. Note: the new format NIH biosketch is required.

PILOT RESEARCH PROTOCOL SUBMISSION PROCESS

Full Application DEADLINE: February 25, 2019 by 5:00 PM (EST)

Full Application submission link: will be provided to applicants invited to submit full applications.

Investigators are encouraged to contact Joel Thompson (859-323-7939), <u>Joel.Thompson@uky.edu</u> to schedule a meeting to review the basis of your submission, to learn how the UK-CARES Pilot Research Program operates, to learn which CCTS services you might utilize for your study, and to devise a budget for your protocol.

We also suggest that you consult with the following:

- For Community Engagement consultation and development: Ellen J. Hahn, PhD, RN, FAAN (ejhahn00@email.uky.edu)
- For consultation on Analytical Core and Analysis: Andrew Morris, PhD (a.j.morris@uky.edu)
- For guidance, assistance, and operational support for multi-directional translational and clinical research development of the pilot proposal: John Bauer, PhD (john.bauer@uky.edu).
- ➤ For Study Design Consultation: Catherine Starnes, Statistician Assistant (catherine.starnes@uky.edu)
- For help with your Data Safety Monitoring Plan during protocol development: Lisa Tannock, MD, Research Participant Advocate (<u>lisa.tannock@uky.edu</u>)
- For Biomedical Informatics Consultation: Tammy Harper, MHA, (257-9384, Tamela.Harper@uky.edu).

UK-CARES PILOT RESEARCH PROGRAM APPLICATION INSTRUCTIONS:

<u>For those LOIs selected for full application</u>, applicants are encouraged to review the instructions provided below carefully and to contact Joel Thompson (859-323-7939), <u>Joel.Thompson@uky.edu</u> with questions. Incomplete or incorrectly prepared applications will be returned without review.

Follow the steps below to apply for UK-CARES pilot research support:

- For the application, margins must be no smaller than 0.5" at all points.
- Use an Arial, Helvetica, Palatino Linotype, or Georgia typeface, a black font color, and a font size of 11 points or larger. (A Symbol font may be used to insert Greek letters or special characters; the font size requirement still applies).
- Type density, including characters and spaces, must be no more than 15 characters per inch. Type may be no more than six lines per inch.
- EACH page should provide the applicant's name in the upper right hand corner. The application should be numbered consecutively in the center bottom.

APPLICATIONS SHOULD BE ASSEMBLED IN THE FOLLOWING ORDER

I. Cover Page(s): (not included in the 6 page limit)

- 1. Title of the Project and Total Amount Requested.
- 2. The Category of Grant you are applying for: Early Career award, High Impact award.
- 3. Applicant's information for Principal Investigators and Co-Investigators:
 - o Name
 - o Degree(s)
 - o Rank, Title (s)
 - o College or Community Organization
 - o Department /Division or County of Work or Residence
 - o eRA Commons Username
 - o Campus or Organization Address
 - o Contact Information including e-mail and telephone number
- Please indicate if you are an NIH new investigator or early stage investigator (not having a previous R01)
- Please indicate clinical privileges
- 4. Mentor's information (Applicable only for early career investigators):

Name, Degree(s) and Rank, Campus Address, and Contact Information

5. <u>Applicant's Chair or Community Organization Supervisor (if appropriate) Information for each collaborator:</u>

Name, Campus or Community Address, and Contact Information

II. Detailed budget and budget justification in NIH format, direct cost only

Allowable requests include:

- Equipment essential for the conduct of the study
- Data analysis costs
- Research assistant salary support
- Non faculty personnel salary support (Faculty salary support is not allowable)
- Project specific specimen collection/analysis or testing
- Chemistry and biological lab supplies
- Purchase of cell lines, cultures reagents etc.
- Animal purchase and housing costs.
- Specimen or environmental exposure data collection/analysis or testing
- Participant reimbursement/recruitment costs
- Travel to present findings and/or collect data in the community

**Budget must be approved by Joel Thompson BEFORE submission.

Applicants must account for fringe benefit costs when considering research assistant salary levels. NO INDIRECT COSTS ARE ASSIGNABLE THROUGH THIS MECHANISM.

Budget template can be downloaded here:

• Initial budget: here

• Entire Budget Period: here

III. Body of the proposal: (limited to 6 pages)

The format of the application will follow NIH guidelines as outlined below.

Specific Aims (limited to 1 page)

State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research 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.

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 section. Given the length of the application, investigators should strive to provide a relevant, although not exhaustive bibliographic review (described below)

(a) Significance

- Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
- Explain how the proposed project will improve scientific knowledge, environmental health in Appalachia, technical capability, and/or clinical/public health 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) Innovation

- Explain how the application challenges and seeks to shift current research, clinical/public health practice, or community engagement paradigms.
- Describe any novel theoretical concepts, approaches or methodologies, instrumentation, environmental exposure data collection or intervention(s) to be developed or used, and any advantage over existing methodologies, instrumentation or intervention(s).
- 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. 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 including engaging with the community.
- Clearly describe how each partner including citizen scientists will be engaged in the development and/or implementation of the pilot study.
- Address how the completion of the pilot will lead to the development of extramural environmental science grant applications, such as R03, R21, or R01.

d) Outreach and Dissemination Plan (if appropriate)

- Clearly describe how the project will facilitate new understandings of environmental factors and their community impacts.
- Include a specific communication plan for how the research team will disseminate findings to address environmental health community concerns, as appropriate. Strategies for disseminating findings may include, *but are not limited to*: community events (e.g., public presentations, forums, workshops, lunch & learn sessions, science cafes), media advocacy (e.g., radio talk shows, opinion editorials, blogs), social media (e.g., Facebook, Twitter), written materials/website (e.g., fact sheets).

As applicable, also include the following information as part of the Research Strategy, keeping within the three sections listed above: Significance, Innovation, Approach, and Dissemination Plan.

• <u>Preliminary Studies</u>. Include information on Preliminary Studies. Discuss the PI's preliminary studies, data, and/or experience pertinent to this application. Preliminary data can be an essential part of a research grant application and help to establish the likelihood of success of the proposed project.

IV. APPENDIX:

- Biosketch in NIH format (note: the new biosketch format is required!)
- Protection of human subjects section and animal assurances (if applicable)
- References- Authors, year, title and journal information is expected for each citation. Given the length of the application, investigators should strive to provide a relevant, although not exhaustive review. (Not more than 2-3 pages)
- The required endorsement letter from the primary mentor for new investigators (see below), as well as letters from key personnel and citizen scientists must be included. Relevant assessment materials may be included if they are of reasonable length and significantly enhance the review of the application. DO NOT submit published manuals, materials in the public domain or similar materials. This is NOT a means of extending the length of the proposal itself.
 - MENTORING AND CAREER DEVELOPMENT PLAN (new investigators): Role and qualification of mentor(s). Inclusion of a clinician (physician, nurse, public health professional, dentist, pharmacist, clinical psychologist, physical therapist, etc.) mentor is highly desirable in studies involving direct interaction with human participants. A career development plan must be in place to enhance clinical/public health, community engagement, and translation research capabilities. This may include didactic coursework, the UK-CARES Science Communication Workshops, Clinical and Translational Science Seminar Series, Spring Appalachian Research Day (Hazard, KY), and/or the Translational Science Spring/Fall Conference.
 - MENTOR ENDORSEMENT (new investigators): To facilitate the effectiveness of the UK-CARES Pilot Research Program in enhancing the research development of newly

appointed faculty investigators, new investigators must provide a letter of endorsement and collaboration from a senior investigator who is willing to serve as a mentor for the applicant over the course of the project. This person must possess a M.D., Ph.D., PharmD, DNP, DrPH or other doctoral degree and must have sufficient clinical research expertise to serve as a mentor to the applicant. The letter should reflect the amount of time the mentor is willing/able to direct to this role as well as the specific types of activities that will be involved. These activities should include reviewing progress on the project, reviewing initial data, helping plan for future project funding after the pilot phase, discussing relevant research articles or related activities. It is NOT required that the mentor have funded effort. This letter should be included in the appendix material of the application.

• LETTER FROM SUPERVISOR/DEPARTMENT CHAIR: A letter signed by the immediate supervisor (e.g. Division Chief, Public Health Director) and/or Department Chair that includes acknowledgement of their support for the project and providing assurance that sufficient protected time to complete the research will be available. No specific amount of protected time is required, but the review committee will consider the distribution of effort and other activities of the applicant.

REVIEW PROCESS & CRITERIA:

Your submission will initially be administratively reviewed. You will be notified if portions are missing or incomplete. The application will be sent to a minimum of two internal or external reviewers with expertise in fields relevant to the science in the proposal. These reviewers will be asked to disclose any relationships to the grant applicant. Full proposals will be subject to a standard NIH-type study section assessment. The reviewers will then provide written feedback addressing the merits of the protocol. All applications will be scored based upon the written reviews, relevance to the Priorities and Scope outlined above, and the overall relevance to the long term goals of UK-CARES. You will be notified of the outcome. The general criteria for review include:

Overall Impact

Significance	Is the st	tudy relevant to	goals and	research	mission	of the	UK-CARES

program? Does the study support new and novel areas of investigation in promising transdisciplinary and community-engaged areas of

environmental health sciences and environmental medicine?

Innovation Are the aims original and concepts novel? Are novel methodologies

proposed?

Approach Do the specific aims test the hypotheses? Are statistical considerations

provided? Is the risk/benefit ratio acceptable? If the project is community focused, is the outreach and dissemination plan appropriate to the aims and

feasible given the scope of the project?

Investigators Is this a new investigator? If so, a mentorship team must be identified. The

qualification and experience of the mentor, and their plan for career development for the new investigator, will be an important aspect of review. As appropriate, are citizen scientists or community organizations involved in and/or supportive of the project? Does the investigative team have training, expertise, and experience to conduct the proposed study?

Environment Is the environment strong? Do the investigators take advantage of

available expertise at UK and in the community? Is there a transdisciplinary team including citizen scientists, as appropriate, involved

in the study?

Feasibility Is the study feasible from the perspective of recruitment and availability

of resources?

Potential

Will the pilot study generate new knowledge that can be published? Will completion of the study lead to external funding or development of a novel or translational methodology? Is there commercial potential? Is there potential to grow community engagement in environmental science? Importantly, will the completion of the pilot lead to the development of an extramural environmental science grant application, such as R03, R21, or R01?

AWARDEE RESPONSIBILITIES:

- Once your protocol is fully approved and funding awarded, you should contact Joel Thompson (859-323-7939), Joel.Thompson@uky.edu to schedule a working meeting with the CARES and CCTS units involved with your protocol.
- Successful applicants will be required to provide semi-annually progress reports and a final
 written report describing project accomplishments must be submitted within 60 days of the
 project end date.
- Grantees will be required to complete the Community Engagement Core REDCap survey quarterly to ensure that new publications in scientific journals and emerging findings are 'in queue' for community dissemination.
- Grantees will be expected to submit an abstract to present at the annual UK-CARES retreat.
- The UK-CARES is evaluated by the NIH on its effectiveness in stimulating new research findings and publications. The following support acknowledgement should be included on all publications that result from UK-CARES support:

"This publication was supported by the National Institues of Envionmental Health and Sciences, National Institutes of Health, through Grant P30 ES026529. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH"

RELEASE OF FUNDS:

- Funding for successful application will be released upon receipt of applicable IRB/IACUC approval, if applicable.
- If required IRB/IACUC approval is not provided within a period of 90 days after the announcement of the award, **THE FUNDS WILL BE SUBJECT TO CANCELLATION.**