University of **Kentucky** | **Center for Appalachian Research in Environmental Sciences**

PILOT PROJECT PROGRAM
Request for Applications 2020

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https://ukcares.med.uky.edu

**REQUEST FOR APPLICATIONS
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Introduction

The UK Center for Appalachian Research in Environmental Sciences (UK-CARES) is now accepting applications for Pilot Projects. The mission of UK-CARES is to enhance research capacity focused on the major environmental health impacts (e.g., air and water contaminants, environmental disasters) that have been implicated in chronic diseases such as heart and lung disease, cancer, diabetes, and child health and early life exposures. This mission is accomplished by promoting the interactions and expanding 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 UK-CARES is found on the website (https://ukcares.med.uky.edu).

Award Type

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. This award may provide the research funds required to apply for the UK-CARES Career Development program. The maximum award will be $25,000 in direct costs which must be spent over 10 months. This award is only open to investigators in the early stage of their career (NIH definition), or investigators who are transitioning into a new area. Applicants must identify a mentor to assist with the investigator's training.

- Early career investigators who are currently not in the area of environmental health science research are encouraged to apply.

- Eligibility is limited to full-time faculty (all title series including regular, research, clinical and special) of the University of Kentucky and affiliated institutions.

- Investigators who are PIs on substantial EHS competitive NIH research grants are NOT eligible.

- 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 are NOT eligible to serve as PIs but may be co-investigators.

Innovation and High Impact Award

This award is for investigators at all stages of career development; early career, 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 in direct costs which must be spent over 10 months.

- Investigators who are currently not in the area of environmental health science research are encouraged to apply.

- Eligibility is limited to full-time faculty (all title series including regular, research, clinical and special) at the University of Kentucky and affiliated institutions.

- 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 are NOT eligible to serve as PIs but may be co-investigators.

Key Dates

03/12/2020	Call for Letter of Intent released
03/23/2020	Letter of Intent due
03/27/2020	Notice of Meritorious Letter of Intent sent
04/16/2020	College Grant Officer (CGO) in the Principal Investigator's college/department will need to initiate an e-IAF for the UK-CARES Pilot Project proposal. The e-IAF should be received in OSPA three business days before the due date of the application. ***CGO should enter this into the comment sheet:*** "Do not import the e-IAF until OSPA is notified of funding. These proposals do not go to the Research Administrator, in OSPA but go directly to the UK-CARES Pilot Project Program managers."
04/20/2020	Full Application due
04/30/2020	Notice of Award sent
05/01/2020	Project start date **NOTE:** If you do not have an approved IRB/IACUC by 05/01/20, the start date could be delayed until 7/1/2020.
03/31/2021	Project end date

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.

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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 inter- and multidisciplinary teams in 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.

- Promote community-engaged research.

- 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:

- Clear environmental health relevance for residents of Appalachian Kentucky

- The likelihood that funding will result in a competitive application for extramural funding.

- Where appropriate, priority will be given based upon the strength of the research team including citizen scientists or, for early career investigators, the mentorship team and citizen scientists.

- Scientific rigor and novelty of the proposed approach.

- Multidisciplinary research teams representing the basic, clinical and/or applied sciences with an emphasis on bridging the divisions between basic and clinical 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

Budgets for awarded pilot projects will include direct costs and indirect costs. Proposed costs should be commensurate with the work. Sufficient justification and detail should be provided to validate the need and cost of each item. The budget will be comprehensively reviewed to ensure that the funds being requested are relevant to the research being proposed.

Allowable expenses

- Salary support and fringe benefit costs for the Principal Investigator is required.

- Salary support and fringe benefit costs for staff conducting the research is optional.

- Funds are to be used for the conduct of the project, including supplies, subject payments, assays, etc.

- Travel funds needed for study execution are allowed, if essential. No funds will be provided for travel to collaborator sites or conferences.

- Facilities and Administrative (F&A) costs. Use 50.5% rate, which was in place at time of UK-CARES award from NIEHS.

Non-allowable expenses

- 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

- Mentor's time and effort.

- No funds will be provided for publication costs.

In the event that additional intra/extramural funds are secured to support the study outlined in your application you must immediately notify Amy Thomas (859-323-7395, amy.thomas17@uky.edu). **Individual principal investigators will not be allowed to hold more than one UK-CARES pilot research award at any one time.**

IRB Guidelines

Applicants will be required to submit proof of IRB/IACUC *Submission* or proof of non-human subjects research at time of Full Application Deadline. If human subjects research, applications without IRB submission prior to that deadline will be administratively disqualified. **If human subjects research, applications must have IRB approval no later than May 1, 2020**. Human subjects research projects that do not have full IRB approval by this date will not be considered for funding. All projects involving human subjects that are required to submit an IRB application are strongly encouraged to meet with UK-CARES administrative staff for consultation and planning purposes. Please note, all pilot IRB protocol titles must match the title of the UK-CARES pilot application.

Submission Guidelines

Application Style

- Margins must be no smaller than 0.5" at all points.

- Use an Arial, Calibri, Georgia, Helvetica, or Palatino Linotype 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.

Letter of Intent (LOI)

Letters of Intent will be solicited from UK faculty. The LOIs will be reviewed and a subset of meritorious LOIs will be selected and applicants will be invited to submit full applications. **Late or incomplete LOIs will be returned to the investigator and will not be considered for the funding opportunity.**

LOI submission link: https://redcap.uky.edu/redcap/surveys/?s=XTPXD89AXF

The LOI is limited to 2 pages including all the following:

- Project title (full project title required)

- Research objectives, Specific Aims

- Describe the science driving the translational effort. Provide concise, clear statements regarding anticipated outcomes of the proposed research and how it will add to existing knowledge or create value.

- Brief background and preliminary data (if available)

- A paragraph describing study design, methodology, statistics and outcomes

- Project milestones

- Describe how the pilot grant would facilitate a future external grant

- Priority will be given to applications with well-defined future extramural funding plans and timelines (ex. identification of the study section).

- A very limited appendix may be included at the LOI stage to list citations from the body of the proposal and relevant publications related to the proposed study. This does not count against the 2 page limit of the LOI.

- A list of key personnel is required.

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Submission Process

The full application REDCap submission survey will be provided to PIs in the email they receive acknowledging their meritorious LOI. Investigators are encouraged to contact Joel Thompson (323-7939, joel.thompson@uky.edu) to schedule a meeting to review the basis of your submission, to learn how the UK-CARES Pilot Research Program operates, to learn which UK-CARES services you might utilize for your study, and to devise a budget for your protocol. Full Application page content and page order are defined below.

We also suggest that you consult with the following as you develop your study protocol:

- 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).

Full Application Required Components

Cover Page(s)

- Title of the Project and Total Amount Requested.

- The Category of Grant you are applying for

- Applicant's information for Principal Investigators and Co-Investigators:
    - Name
    - Degree(s)
    - Rank, Title (s)
    - College
    - Department /Division
    - ERA Commons Username
    - Campus Address
    - 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

- Mentor's information (Applicable only for early career investigators): Name, Degree(s) and Rank, Campus Address, and Contact Information

- Applicant's Chair Information for each collaborator: Name, Campus Address, and Contact Information

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Budget and Budget Justification

Detailed budget and budget justification in NIH format must be provided. See NIH budget templates in the appendix, direct and indirect costs must be included.

Allowable Expenses

- Equipment essential for the conduct of the study

- Data analysis costs

- Research Subject incentive costs

- Research assistant salary support

- Project specific specimen collection/analysis or testing

- Chemistry and biological lab supplies

- Purchase of cell lines, culture reagents etc.

- Animal purchase and housing costs.

- Specimen or environmental exposure data collection/analysis or testing

Budget must be reviewed by College Grants Officer (CGO) in the applicant's college/department BEFORE submission. Applicants must account for fringe benefit costs for all personnel. 50.5% indirect cost which was the rate at the time of the parent award from NIEHS are assignable through this mechanism. The indirect cost is in addition to the awarded amount.

For NIH budget templates, please see the RFA Appendix.

Body of the Proposal

The body of the proposal is limited to 6 pages (not including the cover page) including Specific Aims and Research Strategy. 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 (limited to 5 pages)

Organize the Research Strategy in the specified order using the instructions provided below. Start each section with the appropriate section heading: Significance, Innovation, and 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).

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 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.

Innovation

- Explain how the application challenges and seeks to shift current research or clinical practice 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.

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.

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

- 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.

- Address how the completion of the pilot will lead to the development of extramural environmental science grant applications, such as R03, R21, or R01 or a Foundation application.

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).

Appendix

- Biosketch in NIH format (current [NIH Biosketch template](#)) for PI, Co-PI, and Co-I(s)

- 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 early 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 (early investigators only)

Role and qualification of mentor(s). Inclusion of a clinician (physician, 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 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.

<u>Mentor Endorsement (early investigators only)</u>

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 or other doctoral degree and must have sufficient clinical, basic science, or community-based 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. A mentor's time and effort is not an allowable expense. This letter should be included in the appendix material of the application.

<u>Letter from Supervisor/Department Chair</u>

A letter signed by the immediate supervisor (e.g. Division Chief) 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 and Criteria

Incomplete applications will not be reviewed. 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 application. 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	• What is the project's likelihood to have a sustained, powerful influence on the research field(s) involved?
Significance	• Is the study relevant to goals and the 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	• Does the investigative team have training, expertise, and experience to conduct the proposed study? As appropriate, are citizen scientists or community organizations involved in and/or supportive of the project? 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.
Environment	• Is the environment strong? • Do the investigators take advantage of available expertise? • 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 Amy Thomas, (323-7395, amy.thomas17@uky.edu) to schedule a working meeting with the UK-CARES 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 expected to submit an abstract to present at the annual UK-CARES retreat.

- Grantees will be expected to present an update of their research annually at the UK-CARES monthly Executive Committee meetings.

- UK-CARES is evaluated by the NIH on its effectiveness in stimulating new research findings and publications. **The following support acknowledgment should be included on all publications that result from UK-CARES support:**

  - "This publication or project was supported by UK-CARES through Grant P30 ES026529. The contents are solely the responsibility of the authors and do not necessarily represent the official views of the NIEHS."

Release of Funds

Funding for successful applications will be released upon receipt of 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.

RFA Appendix

- NIH budget template (detailed budget for initial budget period)
  - https://grants.nih.gov/grants/funding/phs398/fp4.pdf
- NIH budget template (budget for the entire budget period)
  - https://grants.nih.gov/grants/funding/phs398/fp5.pdf
- UK Fringe Benefit guidelines
  - https://www.research.uky.edu/office-sponsored-projects-administration/frequently-needed-information
- NIH Biosketch guidelines (Non-fellowship)
  - https://grants.nih.gov/grants/forms/biosketch.htm

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Full Application Checklist

☐ Cover Page

☐ Budget (use NIH PHS 398 Form)

☐ Budget Justification

☐ Proposal

    ☐ Specific Aims (limited to one page)

    ☐ Research Strategy (limited to five pages)

        ☐ Significance

        ☐ Innovation

        ☐ Approach

        ☐ Outreach and Dissemination Plan (if appropriate)

        ☐ Appendix

☐ Mentoring and Career Development Plan (early investigators only)

☐ Mentor Endorsement (early investigators only)

☐ Letter from Supervisor or Department Chair

Notes