



Center for Clinical and Translational Science

Pilot Funding Program Call for Applications

The UK Center for Clinical and Translational Science (CCTS) is now accepting applications for Pilot Projects. The purpose of this funding mechanism is to provide a new opportunity and resources to support innovative, collaborative research relevant to the health challenges and disparities faced by the nation and the citizens of Kentucky.

SCOPE:.....	2
PILOT AWARD TYPE	2
PARTNERSHIP WITH THE UNIVERSITY OF CINCINNATI	2
KEY DATES:	2
INSTITUTIONAL CONTACTS	3
PRIORITIES FOR FUNDING:	3
FUNDING INFORMATION:	3
SUBMISSION INSTRUCTIONS	4
NOTICE OF INTENT GUIDELINES (Due April 8th, 2024)	4
FULL APPLICATION SUBMISSION GUIDELINES (Due April 22 nd)	5
Significance.....	6
Innovation	6
Approach.....	6
Appendix.....	7
REVIEW PROCESS & CRITERIA:.....	8
AWARDEE RESPONSIBILITIES:.....	9
RELEASE OF FUNDS:.....	9
RFA APPENDIX	9

SCOPE:

Within the general guidelines outlined below, the types of projects that will be considered within these mechanisms include projects that:

- Provide support for early career investigators.
- Stimulate the development of new clinical and translational inter- and multidisciplinary teams.
- Promote community-based research.
- Develop new methodologies to leverage institutional strengths and new initiatives.
- Pursue high-risk, high reward studies.

PILOT AWARD TYPE

PARTNERSHIP WITH THE UNIVERSITY OF CINCINNATI

University of Kentucky/University of Cincinnati collaborative grant:

One award of up to **\$50,000**, in total direct cost, will be given to a meritorious project that involves collaboration between investigators at UK CCTS and the University of Cincinnati CCTST. This project will involve an equal contribution from each institution, and will require Co-PI's from each institution (\$25k/institution). Award duration is **12 months**.

The research award is designed to stimulate collaboration between the respective campuses. Specifically, this joint award aims to catalyze the development or enhance the maturation of multi-institutional research teams capable of performing highly innovative, extramurally fundable research that will continue to contribute to the health and wellbeing of Appalachia. The research topic must be related to clinical and translational science and can be any health-related topic that addresses a significant health issue identified by the community. Research activities may include but are not limited to: conducting community assessments, analyzing existing data, pilot testing data collection instruments or procedures, conducting formative research on intervention strategies or messages, and testing intervention feasibility.

KEY DATES:

Call for Applications	Notice of Intent	Full Application due date	Funding decision
March 25th, 2024	April 8th, 2024	April 22nd, 2024	Late May

INSTITUTIONAL CONTACTS

University of Kentucky
Dr. Joel Thompson
Joel.thompson@uky.edu

University of Cincinnati
Venois Peebles
peeblevj@ucmail.uc.edu

PRIORITIES FOR FUNDING:

The main priorities for funding are:

- Clear clinical and translational relevance.
- The likelihood that funding will result in a competitive application for extramural funding.
- Where appropriate, priority will be awarded based upon the strength of the research team or, for early career investigators, the mentorship team.
- Capacity for overall impact on health of Appalachia or other underserved populations in Kentucky.
- Multidisciplinary research teams representing the basic, clinical and/or applied sciences with an emphasis on bridging the divisions between basic and clinical scientists.

FUNDING INFORMATION:

Budgets for awarded pilot projects will include direct costs as well as limited PI effort, which is in addition to the \$25,000 direct cost budget. Include PI effort on the PHS 398, form page 4 budget. 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 insure that the funds being requested are relevant to the research being proposed.

ALLOWABLE EXPENSES

- Funds are to be used for the conduct of the project, including supplies, subject payments, assays, etc.
- Equipment can be purchased if it is absolutely necessary for the execution of the project. All equipment purchased is property of the purchasing institution and will be returned at the completion of the project.
- Travel funds needed for study execution are allowed, if essential. No funds will be provided for travel to collaborator sites or conferences.
- To support collaborations between basic scientists and clinician scientists a research DOE supplement of up to \$25,000 for up to 10% effort may be requested for a clinician scientist. See DOE offset guidelines in the appendix (UK only)

NON-ALLOWABLE EXPENSES

- Funding is not available for thesis or dissertation projects. Graduate assistants can be paid an hourly wage plus fridge benefits.

- Equipment cannot be purchased using this mechanism unless it is absolutely required for the execution of the project. Prior approval from your institutional contact is required. All equipment purchased using Pilot funds belongs to the purchasing institution and equipment will be returned to the institution at the completion of the project.
- Funding will not be awarded as bridge funding for ongoing projects.
- **No funds will be provided for publication costs.**
- No funds will be provided for professional memberships.
- Facilities and Administrative costs, also known as indirect costs are not permitted.

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). Budgets will be invoiced for a period of 12 months maximum. **UK investigators will not be allowed to hold more than one CCTS pilot research award at any one time.**

SUBMISSION INSTRUCTIONS

APPLICATION STYLE GUIDELINES

- 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.

NOTICE OF INTENT GUIDELINES (Due April 8th, 2024)

The application process will start with a Notice of Intent. The NOI can be emailed to your institutional contact. It must include the following elements:

- Study PI name
- Study Title
- Brief Description of proposed pilot
- Key Personnel List

No applications will be accepted if the NOI is not received by April 8th. The NOI is not a binding agreement to submit a full application. You will receive additional instructions after April 8th to complete your full application submission.

FULL APPLICATION SUBMISSION GUIDELINES (Due April 22nd)

The full application WebCAMP submission survey will be provided to PIs after receipt of their NOI. Investigators are encouraged to schedule a meeting with their institutional contact to review the basis of your submission, to learn how the Pilot Research Program operates, to learn which 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.

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

- Title of the Project and Total Amount Requested
- 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
- Abstract, 250 word limit
- Mentor's information (Applicable only for early career investigators):
Name, Degree(s) and Rank, Campus Address, and Contact Information
- Chair Information for each principal investigator: Name, Campus Address, and Contact Information

Detailed budget and budget justification in NIH format (See NIH budget templates in the appendix).

- Allowable expenses include:
 - Equipment essential for the conduct of the study
 - Data analysis costs
 - Participant reimbursement 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, culture reagents etc.
 - Animal purchase and housing costs.
 - Specimen collection/analysis or testing
 - Participant reimbursement/recruitment costs

Please review the allowable costs section and meet with your institutional contact with questions. Budgets must be approved by your institutional contact BEFORE submission. Applicants must account for fringe benefit costs when considering research assistant salary levels. No indirect costs are assignable through this mechanism.

For NIH budget templates, please see the RFA

Appendix 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 (five 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, 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.
- For health disparity pilots, please indicate how the study has the potential to generate knowledge relevant to health equity.

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 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.
- Clearly describe how each partner will be engaged in the development and/or implementation of the pilot study. (Applicable for partnership applications)
- 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.

Appendix

- Biosketch in NIH format or equivalent
- Protection of human subjects section and animal assurances (if applicable)
- Statement of inclusion of women and minorities (if applicable)
 - Describe the planned distribution of subjects by sex/gender, race, and ethnicity.
 - Describe the rationale for selection of sex/gender, racial, and ethnic group members in terms of the scientific objectives and proposed study design. The description may include, but is not limited to, information on the population characteristics of the disease or condition under study.
 - Describe proposed outreach programs for recruiting sex/gender, racial, and ethnic group members.
 - Inclusion and Excluded Groups: Provide a reason for limiting inclusion of any group by sex/gender, race, and/or ethnicity. In general, the cost of recruiting certain groups and/or geographic location alone are not acceptable reasons for exclusion of particular groups. See the [Inclusion of Women and Minorities as Participants in Research Involving Human Subjects - Policy Implementation Page](#) for more information.
- 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).
- Letters of Support from the PI's department chair and significant collaborators must be included.

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.

- 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.

REVIEW PROCESS & CRITERIA:

Incomplete applications will not be reviewed. The application will be sent to a minimum of two 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 the CCTS to promote clinical and translational science. You will be notified of the outcome.

The general criteria for review include:

Overall Impact	<ul style="list-style-type: none"> • What is the project’s likelihood to have a sustained, powerful influence on the research field(s) involved?
Significance	<ul style="list-style-type: none"> • Is the study relevant to human health and the health of Kentucky and Ohio citizens? • For health equity pilots, does the study have the potential to generate knowledge relevant to health equity?
Innovation	<ul style="list-style-type: none"> • Are the aims original and concepts novel? Are novel methodologies proposed?
Approach	<ul style="list-style-type: none"> • Do the specific aims test the hypotheses? Are statistical considerations provided? Is the risk/benefit ratio acceptable?
Investigators	<ul style="list-style-type: none"> • Does the investigative team have training, expertise, and experience to conduct the proposed study? Is this an early career investigator? If so, a mentorship team must be identified. The qualification and experience of the mentor, and their plan for career development for the early career investigator, will be an important aspect of review.
Environment	<ul style="list-style-type: none"> • Is the environment strong? • Do the investigators take advantage of available expertise? • Is there a transdisciplinary team involved in the study?
Feasibility	<ul style="list-style-type: none"> • Is the study feasible from the perspective of recruitment and availability of resources?

<p>Potential</p>	<ul style="list-style-type: none"> • 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? For health equity pilots, does the proposed research show clear evidence of potential for future funding in health equity research?
-------------------------	--

AWARDEE RESPONSIBILITIES:

Successful applicants will be required to provide semi-annual progress reports and a final written report describing project accomplishments must be submitted **within 60 days** of the project end date.

Both institutions are CTSA funded and 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 CCTs support:**

“This publication was supported by the National Center for Research Resources and the National Center for Advancing Translational Sciences, National Institutes of Health, through Grant UL1TR001998. 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.**

RFA APPENDIX

Research development assistance

If at any point in the development of your LOI or full application you need CCTS services (Biostatistics, recruitment, budgets, data extraction, etc.) please fill out a Service Request Form accessed through the following link or via the UK CCTS homepage. If you are not a member of the CCTS, you'll need to complete that first (It's fast, free and available through the same link).

<https://cctsdta.uky.edu/membership/>

Clinician DOE offset (University of Kentucky only)

Research DOE provided protected effort for a clinician scientist collaborating with a basic scientist, where both function as co-investigators. The respective roles of the basic and clinical scientist must be well described and both must be essential to

performing the project. Role of the clinician scientist must be different from their standard of care clinical role. If clinician involvement in the research project does not result in a decrease in the generation of RVUs, then no additional research DOE should be requested for clinician scientist. For example, if a clinician provides discarded tissue samples from a procedure that does not require any additional time/effort, the clinician's involvement would not qualify for research DOE.

Guidelines:

- Basic scientist and clinicians must function as Co-PIs on pilot proposal; (i.e. clinician involvement cannot be casual).
- Research DOE for a clinical scientist will be requested as an additional supplement to the pilot proposal and submitted with the full application. Please provide a separate NIH budget form with DOE justification when requesting clinician DOE.
- The clinician scientist may be physician, dentist, pharmacist, etc. but who has no available research time on DOE at the present time.
- The clinician scientist must provide a letter of support from their division chief and department chair agreeing to the arrangement. This letter should be included in the appendix of the full application.
- CCTS to provide up to \$25,000 salary plus benefits and department/division must cost share additional funding for minimum 10% effort.

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>