

Center for Clinical and Translational Science Call for Applications Pilot and Innovation Research Program

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.

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 18 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.

- *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 other career development awards or R01-type funding 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. The total award is limited to \$50,000 which must be spent over 18 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.*
- *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

- **Call for Letter of Intent: September 17, 2018**
- **Letter of Intent Due: October 12, 2018**
- **Letter of Intent Finalists Notified: November 9, 2018**
- **Full Application Due: December 7, 2018**
- **Funding Decision: January 2019**

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 clinical and translational inter- and multidisciplinary teams.
- Provide support for early career investigators.
- Promote community-based 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: 1) the scientific merit of the project, 2) clear clinical and translational relevance, 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 or, for early career investigators, the mentorship team. Other priorities for funding include:

- Significance of the clinical and/or translational work in terms of potential health impact.
- Capacity for overall impact on health of Appalachian Kentucky, Ohio and West Virginia.
- Scientific rigor and novelty of the proposed approach.
- Experience and productivity of the investigators.
- 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.
- Biomedical informatics collaborative projects. Priority will be given to collaborations among biomedical (basic science, genomic, clinical, public health) researchers and informatics researchers. The goal is to fund work that can lead to publications and pilot data to help secure extramural funding.

FUNDING INFORMATION:

Individual project awards (up to \$25,000 for Early Career category of award and up to \$50,000 for Innovative and High Impact category of award, in total direct costs-over an 18-month period) will be made on a competitive basis. 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 COSTS

- Funds are to be used for the conduct of the project, including supplies, subject payments, assays, etc.
- Travel funds needed for study conduct are allowed, if essential.

To support collaborations between basic scientists and clinician scientists and to promote clinician scientists involvement in the proposed project, a research DOE supplement of up to \$25,000 for up to 10% effort may be requested for a clinician scientist associated with the Early Career Investigator or High Impact Awards.

- **Research DOE for Clinician Scientists – Guidelines**
 1. Research DOE provided for clinician scientist collaborating with basic scientist. The respective roles of the basic and clinical scientist must be well described and both must be essential to performing the project.

2. Basic scientist and clinicians as Co-PIs on pilot proposal; (i.e. clinician involvement cannot be casual).
3. Role of clinician scientist must be different from standard of care clinical role. If clinician involvement in the research project does not result in decrease in 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.
4. Research DOE for clinical scientist will be requested as an additional supplement to the pilot proposal.
5. Clinician scientist may be physician, dentist, pharmacist, etc. but who has no available research time on DOE at the present time.
6. Clinician scientist effort to be verified in letter of support from division chief and department chair agreeing to the arrangement.
7. CCTS to provide up to \$25,000 salary plus benefits and department/division must cost share additional funding for minimum 10% effort.
8. CCTS will fund up to 2 clinician scientist supplements per pilot RFA.

NON-ALLOWABLE COSTS.

- Funding is not available for thesis or dissertation projects.
- Funding will not be awarded as bridge funding for ongoing projects.
- Funds **cannot be used** to support salary of the Principal Investigator or other investigators with faculty appointments.
- 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)

Funds will be held by the CCTS and the budgets invoiced for a period of 18 months maximum, dependent on the nature and scope of the study. Individual principal investigators will not be allowed to hold more than one CCTS 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 CCTS Pilot Review Committee (PRC). A subset of meritorious LOIs will be selected and applicants will be invited to submit Full applications.

LOI SUBMISSION GUIDELINES

The LOI must be within a 2 page-limit describing the following elements:

1. PROJECT TITLE (Full Project Title required)
2. 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
3. BRIEF BACKGROUND AND PRELIMINARY DATA
4. A PARAGRAPH DESCRIBING STUDY DESIGN, METHODOLOGY AND OUTCOMES

5. PROJECT MILESTONES

6. DESCRIBE HOW THE PILOT GRANT WOULD FACILITATE A FUTURE EXTERNAL GRANT (priority will be given to applications with a more specific plan and timeline (ex. Identification of the study section and time line planned).

** Optional attachments at the LOI stage could include key relevant publications

DEADLINE DATE for LOI: October 12, 2018 by 5:00 PM (EST)

LOI submission link: <https://redcap.uky.edu/redcap/surveys/?s=KW7NTJFCR4>

Biosketch Template can be downloaded [here](#).

FULL APPLICATION SUBMISSION INSTRUCTIONS

Full Application DEADLINE: December 7, 2018 by 5:00 PM (EST)

The link to the full submissions will be provided to the LOI finalists at the time of notification.

Investigators are encouraged to contact Amy Thomas (323-7395, amy.thomas17@uky.edu) to schedule a meeting to review the basis of your submission, to learn how the CCTS 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:

- To set up a consultation with a biostatistician, please send an email to berd@uky.edu.
- For help with your Data Safety Monitoring Plan during protocol development: Lisa Tannock, MD, Research Participant Advocate (lisa.tannock@uky.edu)
- For Biomedical Informatics Consultation: Tammy Harper, MHA, (257-9384, Tamela.Harper@uky.edu).

CCTS PILOT RESEARCH PROGRAM APPLICATION INSTRUCTIONS:

Applicants are encouraged to carefully review the instructions provided below and to contact Amy Thomas at amy.thomas17@uky.edu with questions.

- Incomplete or incorrectly prepared applications will be returned without review.
- All applications exceeding the requested page limit will be rejected and not reviewed.
- **References- Authors, year, title and journal information are expected for each citation. These are not included in the page limit and should be reported in the appendix.**

Follow the steps below to apply for CCTS 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 :
 - 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
4. Mentor's information (Applicable only for early career investigators):
Name, Degree(s) and Rank, Campus Address, and Contact Information
5. Applicant's Chair Information for each collaborator: Name, Campus 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
- 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, cultures reagents etc.
- Animal purchase and housing costs.
- Specimen collection/analysis or testing
- Participant reimbursement/recruitment costs

**Budget must be approved by Judy Evans-Pack (859-588-0147 or judy.evans-pack@uky.edu) BEFORE submission.

Applicants must account for fringe benefit costs when considering research assistant salary levels.

NO INDIRECT COSTS ARE ASSIGNABLE THROUGH THIS MECHANISM.

Initial budget: [Download](#)

Entire Budget Period: [Download](#)

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, 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.

(b) 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.

(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.
- 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.
- **Preliminary Studies.** 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 early investigators (see below), as well as letters from key personnel 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): Role and qualification of mentor(s). Inclusion of a clinician (physician, 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 Clinical and Translational Science Seminar Series, and/or the Translational Science Spring/Fall Conference.
 - **MENTOR ENDORSEMENT** (early investigators): To facilitate the effectiveness of the CCTS 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., Pharm 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) 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 the CCTS. You will be notified of the outcome. The general criteria for review include:

Overall Impact

Clinical Significance	Is the study relevant to human health and the health of Kentucky citizens?
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?
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. 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? Is there a transdisciplinary team 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?

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 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.
- The UK CCTS 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 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.**