



# 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.*

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## **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.

## **AWARD TYPE**

### **EARLY CAREER INVESTIGATOR AWARD**

This award is intended to support pilot studies by early stage investigators (NIH definition) 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.

- Eligibility is limited to full-time faculty (all title series including regular, research, clinical and special) of the University of Kentucky and affiliated institutions that are still considered Early Career in accordance with NIH policy (*NIH definition: A Program Director / Principal Investigator (PD/PI) who has completed their terminal research degree or end of post-graduate clinical training, whichever date is later, within the past 10 years and who has not previously competed successfully as PD/PI for a substantial NIH independent research award*).
- Investigators who are PIs on 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 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.
- 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	Letter of intent due date	Notice of meritorious letter of intent	Full application due date	Funding decision
August 3, 2020	August 31, 2020	October 2, 2020	November 2, 2020	Mid December, 2020

## 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.
- 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 only direct 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 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 UK CCTS 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.

## NON-ALLOWABLE EXPENSES

- Funding is not available for thesis or dissertation projects.
- Equipment cannot be purchased using this mechanism unless it is absolutely required for the execution of the project. Prior approval from Ryan Bentley is required. All equipment purchased using CCTS Pilot funds belongs to the CCTS and will be returned to the CCTS at the completion of the project.
- 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.
- 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](mailto:amy.thomas17@uky.edu)). Funds will be held by the CCTS and the budgets invoiced for a period of 12 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.**

## 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.

## LOI SUBMISSION GUIDELINES

Letters of Intent (LOI) and NIH-style Biosketches of all key personnel will be solicited from faculty. The LOIs will be reviewed utilizing a standard NIH-type study section assessment by subject matter experts from across UK. 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.**

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
- 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).
- An appendix should be included at the LOI stage to list citations from the body of the proposal, PI and Co-I biosketches and a list of key personnel. This does not count against the 2 page limit of the LOI. However the appendix should not be used to circumvent the 2 page LOI limit.
- Letters of support are not required, but are strongly encouraged at the LOI stage.
- **If you are proposing to recruit human subjects, please include a TriNetX/i2b2 cohort assessment based on your inclusion/exclusion criteria as a separate document in the appendix. Please contact Joel Thompson ([joel.thompson@uky.edu](mailto:joel.thompson@uky.edu)) with any questions**

## FULL APPLICATION SUBMISSION GUIDELINES

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](mailto:joel.thompson@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. 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
- 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
- Abstract, 250 word limit
- 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

Detailed budget and budget justification in NIH format (See NIH budget templates in the appendix), direct cost only

- 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 contact Joel Thompson or Ryan Bentley with questions. Budgets must be approved by Ryan Bentley ([ryan.bentley@uky.edu](mailto:ryan.bentley@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.

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

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.

### **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 (must use the current NIH Biosketch template)
- 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),
- Letters of Support from the PI's department chair and significant collaborators 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., PharmD 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:

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. You will be notified of the outcome.

The general criteria for review include:

<b>Overall Impact</b>	<ul style="list-style-type: none"><li>• <b>What is the project's likelihood to have a sustained, powerful influence on the research field(s) involved?</b></li></ul>
<b>Clinical Significance</b>	<ul style="list-style-type: none"><li>• <b>Is the study relevant to human health and the health of Kentucky citizens?</b></li></ul>
<b>Innovation</b>	<ul style="list-style-type: none"><li>• <b>Are the aims original and concepts novel? Are novel methodologies proposed?</b></li></ul>
<b>Approach</b>	<ul style="list-style-type: none"><li>• <b>Do the specific aims test the hypotheses? Are statistical considerations provided? Is the risk/benefit ratio acceptable?</b></li></ul>
<b>Investigators</b>	<ul style="list-style-type: none"><li>• <b>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. Does the investigative team have training, expertise, and experience to conduct the proposed study?</b></li></ul>
<b>Environment</b>	<ul style="list-style-type: none"><li>• <b>Is the environment strong?</b></li><li>• <b>Do the investigators take advantage of available expertise?</b></li><li>• <b>Is there a transdisciplinary team involved in the study?</b></li></ul>
<b>Feasibility</b>	<ul style="list-style-type: none"><li>• <b>Is the study feasible from the perspective of recruitment and availability of resources?</b></li></ul>
<b>Potential</b>	<ul style="list-style-type: none"><li>• <b>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?</b></li></ul>

## AWARDEE RESPONSIBILITIES:

Once your protocol is fully approved and funding awarded, you should contact Amy Thomas, (323-7395, [amy.thomas17@uky.edu](mailto: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-annual 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.**

## **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://cctsdata.uky.edu/membership/>

### Clinician DOE offset

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>