University of Kentucky CCTS
"CTSA Consortium Multi-Institutional Collaborative Translational Research Pilot Grants"
Award Program

The Clinical and Translational Science Awards (CTSA) program at the National Institutes of Health (NIH) supports a national consortium of medical research institutions working to transform the way biomedical research is conducted. The program is designed to help accelerate the translation of laboratory discoveries into treatments for patients, train a new generation of clinical and translational researchers, and engage communities in clinical research efforts

UK CCTS is interested in promoting inter-institutional collaborations among the 62 CTSAs and has made pilot matching funds available for eligible teams of researchers using the guidelines below. The purpose of this program is to fund innovative translational research projects that involve at least two or more CTSAs. Funding is provided by the CTSAs of the investigators on the team and it is expected funds will be spent at the CTSA that contributes (funds will not be transferred between institutions). It is anticipated that budget requests will range from $10K-$25K direct cost, per CTSA.

Eligibility: Proposed projects must involve investigators at two or more CTSA institutions. Applicants must have a full-time faculty appointment at their own CTSA institution.

Review criteria: Letters of Intent and Full Applications will be reviewed by UK CCTS and the applicants CTSA Study Section. Review criteria will include:

1) Significance of the work
2) Novelty/Innovation of the research idea
3) Relevance of the proposed study to translational research
4) Existence of a genuine multidisciplinary team in place that is integral to the conduct of the research
5) Evidence that the project could not be completed without the partnership between UK and the partner CTSA
6) Potential for the project to lead to future external funding or to a commercialization opportunity
7) Soundness of the proposed methods
8) Feasibility of accomplishing the stated project goals within the 18 months project period

LOI SUBMISSION GUIDELINES
There are no set deadlines. Complete following link to LOI submission:
https://redcap.uky.edu/redcap/surveys/?s=EKRNTPHJ9W

UK and the designated representative at your Co-PI's CTSA institution will review the submission and inform both PIs if supportive of inviting the applicants to submit a Full Application.

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

- RESEARCH OBJECTIVES, SPECIFIC AIMS:
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 AND OUTCOMES

- DESCRIPTION OF QUALIFICATION OF EACH TEAM MEMBER (UK PI and CTSA CO-PI)
  Additional members of the team (co-investigators) can be included and should be described
  (Approximately 1-2 paragraphs)

- BRIEFLY DESCRIBE THE NATURE OF THE COLLABORATION WITH THE OTHER
  CTSA RESEARCHERS (including whether this is a new collaboration)

- DESCRIPTION OF A PLAN ON HOW THESE DATA WILL BE USED TO SUBMIT A
  FUTURE GRANT PROPOSAL (priority will be given to applications with a more specific plan
  and timeline, ex. Identification of the study section and time line planned).

- TOTAL BUDGET AMOUNT REQUESTED:$
  UK CCTS $
  Other CTSA (s) $
  Brief Budget Justification:

Note that the expectation is that each CTSA's financial contribution to the pilot will be budgeted for activities at that location.

PILOT FULL RESEARCH PROTOCOL SUBMISSION PROCESS

Once all CTSAs involved have approved the specific project, the investigators will write the full proposal and submit that to their own CTSAs for review. A standard NIH-type study section assessment will be organized involving reviewers from both institutions who will determine if they are supportive of going forward with the project.   Invited investigators at UK are encouraged to contact Elodie Elayi at elodie.elayi@uky.edu to schedule a meeting to review the basis of their submission, to learn how the CCTS Pilot Research Program operates, and to learn which CCTS services you might utilize for your study.

We also suggest that you consult with the following:

- For Study Design Consultation: Kristen McQuerry, MS, Project Manager,
  (kristen.mcquerry@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, (Tamela.Harper@uky.edu).

CCTS PILOT RESEARCH PROGRAM APPLICATION INSTRUCTIONS:

Applicants are encouraged to review the instructions provided below carefully and to contact Elodie Elayi at elodie.elayi@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 can be reported at the end of the body of the proposal.

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.

If invited for full application, 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. UK Principal Investigators and CTSA Co- Principal Investigators information :
    o   Name
    o   Degree(s)
    o   Rank, Title (s)
    o   College
    o   Department /Division
    o   Campus Address

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

Each institution must submit a separate NIH budget proposal

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
- 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

** UK Budget must be approved by Elodie Elayi BEFORE submission.

Applicants must account for fringe benefit costs when considering research assistant salary levels. NO INDIRECT COSTS ARE ASSIGNABLE THROUGH THIS MECHANISM.
Budget template can be downloaded here:

Initial budget: http://ccts.uky.edu/ccts/sites/default/files/RFA_doc/Page4_DetailedBudget.docx
Entire Budget Period: http://ccts.uky.edu/ccts/sites/default/files/RFA_doc/Page%205_BudgetforEntireProjectPeriod.docx

III.   Abstract and Partnership development (not included in the 6 page limit).

Abstract: The abstract should provide a brief (not more than 250 word) summary of the project. Beneath the abstract, each of the key personnel and their departmental affiliation should be noted. The key personnel should minimally include PIs from both institutions and the designated mentor (s) (applicable for new investigators). Data analysis consultants (if included), collaborating investigators and others may be listed, if they will play a significant, active role in the conduct of the proposed work. Key personnel listed should provide a letter confirming their role (INCLUDE THESE LETTERS IN THE APPENDIX).

Explain how this partnership will provide new opportunities for the investigators, any development activities that will be conducted throughout the project, and how these activities will build a sustainable infrastructure for an ongoing partnership (not more than 250 words).

IV.   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 and included in the 6 pages of the body proposal)

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.

V.   **Appendix**

- LETTER FROM SUPERVISOR(s)/DEPARTMENT CHAIR(s) (*applicable for both UK and Participating CTSA applicants)*: A letter signed by the immediate supervisor(s)/ (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.

- UK PIs and CTSA Co-PIs Biosketches in NIH format

- Protection of human subjects section and animal assurances (if applicable)

Applicants are prohibited from using the appendix to circumvent page limits in any section of the application for which a page limit applies.

REVIEW PROCESS & CRITERIA:

Full Applications will be sent to a minimum of two UK and two external reviewers representing the partner CTSA(s), with expertise in fields relevant to the science in the proposal. These reviewers will be asked to disclose any relationships to the grant applicant(s). 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. Applicants will be notified of the outcome.

The general criteria for review include:

- Significance of the work

- Novelty/Innovation of the research idea

- Relevance of the proposed study to translational research

- Existence of a genuine multidisciplinary team in place that is integral to the conduct of the research

- Evidence that the project could not be completed without the partnership between UK and the partner CTSA

- Potential for the project to lead to future external funding or to a commercialization opportunity

- Soundness of the proposed methods

- Feasibility of accomplishing the stated project goals within the 18 months project period

UK AWARDEE RESPONSIBILITIES:

- Once your protocol is fully approved and funding awarded, you should contact Elodie Elayi, (323-7939, elodie.elayi@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 attend face to face meeting with the CCTS "Pilot Progress Committee". 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.**