

CCTS Call for Applications

Drug Discovery and Development Core

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

- Specific for Drug Discovery and Development

Applications will be accepted and reviewed according to the following schedule:

Call for Applications	Letter of Intent Deadline	Committee Decision for Full Application Request	Full Application Deadline	Funding Decision
March 24, 2017	April 24, 2017	May 15, 2017	June 15, 2017	July 15, 2017

REQUIREMENTS FOR APPLICANTS:

Eligibility is limited to full-time regular, special and clinical title faculty as well as full time research faculty of 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.

LETTER OF INTENT:

All prospective applicants must first submit a Letter of Intent and biosketch to Tonya Vance (257-5891, tonya.vance@uky.edu) by April 24, 2017. The Letter of Intent (two page maximum) should briefly summarize the significance, innovation, aims and preliminary data for the proposed pilot project. The Letter of Intent also should provide a justification for how the proposed work will advance the investigators' research towards gaining external funding, the type of extramural funding application (e.g., R21, R01, etc.) to be submitted and anticipated submission timeline. If applicable, the specific external funding announcement/opportunity should be cited.

The Therapeutic Advisory Panel will review the letters of intent by May 15, 2017, and will invite a subset of the applicants to submit a full application. Each applicant will be assigned a member of the Therapeutic Advisory Panel to help guide them through the proposal submission process. Full proposals must be submitted to Tonya Vance (257-5891, tonya.vance@uky.edu) by June 15, 2017.

PRIORITIES FOR FUNDING:

The primary objective of this RFA is to provide funding to support new drug discovery and development research with the goal of augmenting the translation of scientific discoveries to therapeutic development. Specifically, the purpose is to assist in the transition from biology and

target identification to clinical targets and to facilitate the transition of discovery through development and delivery to all phases of clinical trials and subsequent commercialization. The areas of emphasis include:

- Novel approaches in: identification and characterization of pharmacological targets, conceptualization and design of new compounds, optimization of lead compounds, delivery modalities, diagnostics and/or biologics, and the stewardship of clinical candidate(s) through pharmaceutical development and through all phases of clinical trial and commercialization.
- Pilot studies which generate critical preliminary data that will enhance the competitiveness of extramural funding for drug discovery and development.
- Pilot studies addressing an important question in translational drug discovery and development research that impacts human health.

SCOPE:

Within the general guidelines outlined above, the types of projects that might be considered within this mechanism include:

- Pilot or feasibility studies. As examples, studies may include: compound synthesis, compound structure-based modeling, analytical characterization, evaluation of biological targets and off target activity, elucidation of mechanism of action, bulk drug synthesis and characterization, evaluation of pharmacological activity in acute and chronic whole animal models, evaluation of delivery modalities, assessment of pharmacokinetics, metabolism, bioavailability, protein binding in vitro and predictive in silico toxicity, cGMP bulk synthesis, manufacturing and formulation, assistance with contracts to conduct FDA approved *in vivo* toxicology evaluation required for investigational new drug submission, assistance with investigational new drug application preparation and liaison with FDA, assistance with initiation and conduct of clinical trials, and assistance with commercialization.

FUNDING INFORMATION:

Up to \$50,000 in total direct funding may be requested for a 12-month project. With adequate progress the possibility of a renewal for a second \$50,000 in total direct and an additional 12 months will be considered contingent on available funds. Proposed costs should be commensurate with the work. A 6 month, no cost extension may be approved upon written request and evidence of adequate progress.

ALLOWABLE COSTS

- Funds are to be used for the conduct of the project, including supplies, animal costs, assays, subject payments, etc.
- Funds may be used for components of research conducted by Research Core Facilities (e.g., Center for Pharmaceutical Research and Innovation (CPRI), Center for Clinical and Translational Science, Biomedical Mass Spectrometry Core Facility, Division of Laboratory Animal Resources, Behavioral Core, Flow Cytometry Core Facility, Imaging Facility, Magnetic Resonance Imaging and Spectroscopy Center, Microarray Core Facility, Proteomics Core Facility, or Survey Research Center).

- Travel funds that are needed for study conduct are allowed, if essential.

NON-ALLOWABLE COSTS

- 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.

Funds will be held by the CCTS. Individual principal investigators will not be allowed to hold more than one CCTS-funded drug discovery and development research award at any one time.

DRUG DISCOVERY AND DEVELOPMENT RESEARCH PROTOCOL SUBMISSION PROCESS:

- Investigators are encouraged to contact Linda Dwoskin, PhD (257-4743, ldwoskin@email.uky.edu) to review the basis of your project.
- If applicable, consult with Heather Bush, PhD (218-2080 heather.bush@uky.edu) or Dick Kryscio, PhD, (257-4064, kryscio@uky.edu) for biostatistical analysis.

CCTS DRUG DISCOVERY AND DEVELOPMENT RESEARCH PROGRAM APPLICATION INSTRUCTIONS:

***If a Letter of Intent is accepted, a full application will be requested.
Applications must follow the instructions below.***

Applicants are encouraged to review the instructions provided below carefully and to contact Tonya Vance (257-5891, tonya.vance@uky.edu) with questions. Incomplete or incorrectly prepared applications may be returned without being reviewed.

Follow the steps below to apply for CCTS Drug Discovery and Development research support:

- 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

COVER PAGE (not included in the 6 page limit)

Title of the Project: Total Amount Requested

Applicant information:

Name, Degree(s), Rank, Campus Address, and Contact Information including e-mail and telephone number

Mentor's Information (if applicable):

Name, Degree(s) and Rank, Campus Address, and Contact Information

Applicants Chair's Information:

Name, Campus Address, and Contact Information

BUDGET- Requests and justification (1 page, not included in the 6 page limit)

Allowable requests include:

- Equipment essential for the conduct of the study
- Data analysis costs
- Research assistant salary support
- 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 Elodie Elayi (elodie.elayi@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.

ABSTRACT (250 word maximum, not included in the 6 page limit)

The abstract should provide a brief 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 the PI and the designated mentor (applicable for new investigators, see below). 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).

NIH-FORMAT BIOSKETCH FOR APPLICANT AND KEY PERSONNEL

The biosketch should follow NIH format, should include other active support and be limited to 4 pages.

BODY OF THE PROPOSAL- (6 page limit)

The body of the proposal should have the following sections in the designated order: Specific Aims (one page), Significance (including a concise discussion of the clinical/translational relevance of the project), Innovation, and Approach (include preliminary data in approach). Studies involving Human Subjects must include a description and address the NIH guidelines for Human Subjects.

REFERENCES- (no page limit)

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.

APPENDIX-

The required endorsement letter from the primary mentor for new investigators (see below), as well as letters from key personnel must be included. Relevant assessment materials may be included provided 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:

Prior to proposal submission each PI must submit a Letter of Intent to Tonya Vance (257-5891, tonya.vance@uky.edu) by April 24, 2017. The Therapeutic Advisory Panel will evaluate the proposed projects. Those projects viewed as competitive will be invited to submit a full proposal (which also will be reviewed by the Therapeutic Advisory Panel). Each applicant will be assigned a member of the Therapeutic Advisory Panel to help guide them through the proposal submission process. Full proposals must be submitted to Tonya Vance (257-5891, tonya.vance@uky.edu) by June 15, 2017. Initially, full proposals will be administratively reviewed and investigators will be notified if portions of the application are missing or incomplete. All members of the Therapeutic Advisory Panel will evaluate each full proposal. A written summary of the discussion will be provided to the investigator. Applicants may be invited to the Panel meeting to present the project with the goal of addressing questions and providing additional clarity. Applications not selected for funding will be encouraged to reapply, but only after individual meetings with either Dr. Dwoskin or a Therapeutic Advisory Panel member, who will review the critique and discuss recommended improvements to the application, providing both conceptual and practical service. Applications selected for full funding by the Therapeutic Advisory Panel will be submitted to the CCTS Executive Steering Committee for final consideration of funding.

The general criteria for review include:

Overall Impact	What is the likelihood that the project will exert a sustained powerful influence on the research field(s) involved?
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	Is the proposed work hypothesis driven? Do the specific aims test the hypotheses? Are the proposed experiments feasible and likely to be completed with the available funds and within the proposed time? Are statistical considerations described and consistent with the design of the experiments? 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?
Potential	Will this proposed research generate a clinical candidate with commercial potential? Where in the general pathway of drug discovery and development does the project fit? How will the pilot funding bring the project to the next step in the process? Will the pilot study generate new knowledge that can be published? Will completion of the study lead to external funding and/or

discovery and development of a new therapeutics? Is there commercial potential?

AWARDEE RESPONSIBILITIES:

- Once funding of the application is awarded, the investigator will be expected to interact on a monthly basis with the member of Therapeutic Advisory Council assigned as liaison to the project. Also, the investigator will be required to undergo review of progress every 6 months by the Therapeutic Advisory Council. Progress will be presented as a one to two page summary and a 20-min power point overview, followed by discussion/feedback. Should the Therapeutic Advisory Panel have concerns about the viability of the project, the PI will be required to consult with a member of the Panel to discuss what is needed to make the project viable. Should the question of viability not be resolved, the Therapeutic Advisory Panel will request that the project be terminated and remaining funds returned to the CCTS.
- Contact Tonya Vance (257-5891, tonya.vance@uky.edu) to schedule a working meeting with the CPRI and/or CCTS units who will be involved with your protocol.
- A final written one to two page report describing project accomplishments must be submitted **within 60 days** of the project end date.
- The awardees are strongly encouraged to attend the monthly Clinical and Translational Science Seminar Series. The seminar series provides an opportunity for an informal discussion of their work with Physician-Scientist and Clinical Scholar recipients and obtain feedback on research grants, publication, etc.
- The UK CCTS is evaluated by the NIH on its effectiveness in stimulating new research findings and publications. **The following support acknowledgement must be included on all publications that result from CCTS support :**

*“The project described was supported by the National Center for Advancing Translational Sciences, **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.**

NOTE: In the event that additional intra/extramural funds are secured to support the study outlined in your application you must immediately notify Tonya Vance (257-5891, tonya.vance@uky.edu)