College of Medicine, Office of Vice President for Research, and Center for Clinical and Translational Science
Call for Applications
Multidisciplinary Value Program (MVP)

The College of Medicine (COM) with support from the Office of the Vice President for Research is launching the **second** Multidisciplinary Value Program (MVP) initiative which will be coordinated by the Center for Clinical Translational Science (CCTS). The purpose of this funding mechanism is to provide a new opportunity and resources to support innovative, collaborative research projects with investigator initiated clinical studies which includes both clinical trials and observational studies* and that are developed by a multi-disciplinary team (which can be inclusive of colleges and centers across UK).

Priority will be given to (1) teams that includes at least one member with strong extramurally funded science; (2) a team that includes a translational research investigator; (3) projects with a clear plan toward future federal funding grant submissions; (4) a feasible clinical and translational study; and (5) some relevance to the health challenges and disparities faced by Kentucky.

For information about clinical trial, please visit the following link to the clinical trial.gov: *https://clinicaltrials.gov/ct2/about-studies/learn#ReasonsForConducting

Eligibility Criteria:
- *Investigators at all stages of career development, junior, middle, and senior are eligible to apply.*
- *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.*

Applications will be accepted and reviewed according to the following schedule

Call for Applications	Letter of Intent deadline	PI selected for Full Application Notification	Full Application Receipt Deadline	Funding Decision
July 20, 2016	September 15, 2016 (5:00 pm)	December 5, 2016, 2016 (5:00 pm)	January 6, 2016 (5:00 pm)	February, 2017

FUNDING INFORMATION:

Individual project awards, up to $110,000 in total direct costs over an 18-month period, will be made on a competitive basis. Proposed costs should be commensurate with the work. Opportunities for second round funding (renewal) will be considered based on progress and availability of funds.

Sufficient justification and detail should be provided to validate the need and cost of each item. The budget will be comprehensively reviewed to ensure 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 that are needed for study conduct are allowed, if essential.

To support collaborations between basic scientists and clinician scientists and to promote **clinician-scientist's** involvement in the proposed project, support for effort may be requested. The clinician-scientist may request effort included in the budget of $110K, not to exceed that amount. Any requests to cover faculty effort are subject to review and approval by the Dean. Please note that NIH cap does not apply to this funding mechanism.

In the event that additional intra/extramural funds are secured to support the study outlined in your application you must notify Elodie Elayi at Elodie.elayi@uky.edu.

Funds will be held by the CCTS for the COM and the budgets invoiced for a period of 18 months maximum, dependent on the nature and scope of the study.

FULL APPLICATION SUBMISSION

LINK TO FULL APPLICATION SUBMISSION: Multidisciplinary Value Program (MVP)-Full Application

PILOT RESEARCH PROTOCOL SUBMISSION PROCESS

Based upon review of the LOI, successful investigators will be invited to submit a full application. Invited investigators are encouraged to contact Elodie Elayi at 323-7939, elodie.elayi@uky.edu to schedule a meeting to review the basis of your 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. <u>**Cover Page(s): (not included in the 6 pages limit)**</u>

1. <u>Title of the Project and Total Amount Requested.</u>
2. <u>Applicant's information for Principal Investigators and Co- Principal Investigators :</u>
    - Name
    - Degree(s)
    - Rank, Title (s)
    - College
    - Department /Division
    - eRA Commons Username
    - Campus Address,
    - Contact Information including e-mail and telephone number

II. <u>**Detailed budget and budget justification in NIH format, direct cost only****</u>

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

To support collaborations between basic scientists and clinician scientists and to promote **clinician-scientist's** involvement in the proposed project, support for effort may be requested. The clinician-scientist may request effort included in the budget of $110K, not to exceed that amount. Any

requests to cover faculty effort are subject to review and approval by the Dean. <u>NIH cap does not apply</u> to this funding mechanism.

**Budget must be approved by Elodie Elayi <u>BEFORE</u> 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: <u>link</u>
Entire Budget Period: <u>link</u>

III. <u>Abstract and Partnership development (if applicable): (not included in the 6 pages limit)</u>.

<u>Abstract:</u> 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 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).

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. <u>Body of the proposal: (limited to 6 pages)</u>
The format of the application will follow NIH guidelines as outlined below.

<u>Specific Aims (limited to 1 page and included in the 6 pages of the body proposal)</u>

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.

<u>Research Strategy</u>

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**

- Full Clinical Trial Draft Protocol for review
- Biosketch in NIH format for PIs, Co PIs and all key personnel

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

- IRB and FDA correspondences and approval (if applicable)

- 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.

- Letter of support from all key team members.

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 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 applicants are required to attend a meeting with the Steering Committee to present an overview of their projects and address any questions from the committee. 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:

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 including a Clinical Trial feasible within time period proposed?
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 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.**