OSU CCTS & UK CCTS JOINT PILOT AWARD

PURPOSE
One award of up to $50,000 in total direct cost will be given to a meritorious project that involves collaboration between investigators at UK and Ohio State University. This project will involve an equal contribution from each institution, and will require Co-PI’s from each institution. The research award is designed to stimulate collaboration between the respective campuses as well as increase community engaged research. Specifically, this joint award aims to catalyze the development or enhance the maturation of multi-institutional research teams capable of performing highly innovative, extramurally fundable research that will continue to contribute to the health and wellbeing of Appalachia.

The research topic must be related to clinical and translational science and can be any health-related topic that addresses a significant health issue associated with Appalachian Ohio and Kentucky. Research activities may include but are not limited to: conducting community assessments, analyzing existing data, pilot testing data collection instruments or procedures, conducting formative research on intervention strategies or messages, and testing intervention feasibility.

ELIGIBILITY
- Proposals must meet the first two criteria below:
  1) Proposals must be joint applications by collaborators from OSU and UK
  2) Projects must involve disease associated with Appalachian Ohio and Kentucky
- Basic scientists, clinical scientists, health services, and public health researchers are eligible to apply.
- The OSU Principal Investigator partner must be a member of the Center for Clinical and Translational Science (http://ccts.osu.edu/membership).
- The UK Principal Investigator must be a UK faculty member.

KEY DATES
Call for Applications: March 1, 2012
Letter of Intent and Biosketch Due: March 22, 2012
Letter of Intent Finalists Notified: April 6, 2012
Full Application Due: May 11, 2012
Funding Decision: July 1, 2012

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 junior investigators.
• Promote community-based research.
• Develop new methodologies to leverage institutional strengths and new initiatives.
• Pursue high-risk, high reward studies.
• Encourage collaboration across the ATRNs

PRIORITIES FOR FUNDING
The main priorities for funding are: the scientific merit of the project, clear clinical and translational relevance, and the likelihood that funding will result in submission of an application for extramural funding. Where appropriate, priority will be awarded based upon the strength of the mentorship team, the research team, or the partnership between other Universities. Other priorities for funding include:

• Multidisciplinary research teams representing the basic, clinical and/or applied sciences with an emphasis on bridging the divisions between basic and clinical scientists.
• Novel research methods in translational sciences.
• Pilot studies which generate critical preliminary data that will help to obtain extramural funding.
• Address an important question in clinical and/or translational research that impacts human health.
• Proposals focused on health promotion and disease prevention.

FUNDING INFORMATION
Individual project awards (up to $50,000 in total direct costs over an 18-month period) will be made on a competitive basis. Proposed costs should be commensurate with the work.

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 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.
• Funding is not available for thesis or dissertation projects.
• Funding will not be awarded as bridge funding for ongoing projects.
• 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 Elodie Elayi (323-7939, eel222@email.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.

LETTER OF INTENT 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 by UK, Cincinnati, Ohio State, and Marshall Reviewers. Based on the reviews, the CCTS Pilot Review Committee will select a subset of the LOIs and recommend to the CCTS Scientific Advisory Committee (SAC) who will make the final decision on the application that will be invited for development into full proposals. Full proposals will be subject to a standard NIH-type study section assessment. Each proposal will be given a primary and secondary reviewer.

Email LOI to: Elodie.elayi@uky.edu - DEADLINE DATE for LOI: Friday, March 22, 2012 by 5:00 PM (EST)
The LOI template and BIOSKETCH template can be found on the OSU CCTS website below the RFA, http://ccts.osu.edu/.

PILOT RESEARCH PROTOCOL SUBMISSION PROCESS
- Investigators are encouraged to contact Elodie Elayi (323-7939, eel222@email.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 Heather Bush, PhD (218-2080 heather.bush@uky.edu) or Dick Kryscio, PhD, Analysis Director (257-4064, kryscio@uky.edu) for biostatistical analysis and with Robert Means, MD, Research Participant Advocate (323-5079, Robert.Means@uky.edu) for help with your Data Safety Monitoring Plan during protocol development.

CCTS PILOT RESEARCH PROGRAM APPLICATION INSTRUCTIONS
Applicants are encouraged to review the instructions provided below carefully and to contact Elodie Elayi (323-7939, eel222@email.uky.edu) with questions. Incomplete or incorrectly prepared applications will be returned without review.

Follow the steps below to apply for CCTS pilot research support:
- Margins must be no smaller than .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: Junior award, Innovation award, joint UK-OSU award, joint UK- MU award, joint UK- Cincinnati award.
   3. Applicant’s information for Principal Investigators and Co-Investigators:
      o Name
      o Degree(s)
      o Rank, Title (s)
      o College
      o Department /Division
      o eRA Commons Username
      o Campus Address,
      o 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 if you are a tenure track
      • Please indicate clinical privileges
   4. Mentor’s information (Applicable only for junior 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
   • 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 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.

The budget template can be found on the OSU CCTS website below the RFA.
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 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).

Specific partnership (not included in the 250 words) and applicable to partnership with universities in the Appalachian Translational Research Network (ATRN): 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)
- Primary research questions
- Briefly describe any past or current funding for this or similar research studies, and how this study will move the work forward.
- Anticipated study design, research methods, data collection tools and protocols, and analysis plan.
- Clear description of how each partner will be engaged in the development and/or implementation of the pilot study.
- Expected outcomes and deliverables of project (both partnership development activities and pilot research study)
- Future plans for further translational studies and any potential for conducting community engaged research
- Timeline for subsequent grant submissions (must identify at least one specific funding opportunity)
- Project timeline and milestones (up to 18 months; include IRB approval process in the timeline)

V. Appendix
- Biosketch in NIH format/S
- Support for PIs from the partnering universities
- 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 new investigators (see below), as well as letters from key personnel must be included. Relevant assessment materials may be included provided 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 (new 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 (new 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. 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 could 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 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.

- **OTHER LETTERS OF SUPPORTS:**

**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 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. The CCTS pilot projects committee will review this feedback and make recommendation to the CCTS Scientific Advisory Committee (SAC). 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. All applications must receive final approval by the Scientific Advisory Committee (SAC). 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 Elodie Elayi, (323-7939, eel222@uky.edu) to schedule a working meeting with the CR-DOC or other CCTS units who will be 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 awardees must attend the Clinical and Translational Science Seminar Series. The series provides the opportunity for an informal discussion with Physician-Scientist and Clinical Scholar recipients in regard to their work where you will benefit from discussing your research with your peers and receive 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 should be included on all publications that result from CCTs support:

  University of Kentucky: “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 UL1RR033173. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.”
The Ohio State University: “The project described was supported by the National Center for Research Resources, Grant UL1RR025755, and is now at the National Center for Advancing Translational Sciences, Grant 8UL1TR000090-05. 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.

PLEASE DIRECT ALL QUESTIONS TO:
At OSU: Valerie DeGroff, Valerie.DeGroff@osumc.edu, or 614-366-7367 in Columbus, OH
At UK: Elodie Elayi, at elodie.elayi@uky.edu or 859-323-7939 in Lexington, KY.