Center for Clinical and Translational Science (University of Kentucky) and the Clinical and Translational Science Institute (Wake forest)

Call for Applications Pilot and Innovation Research Program

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. The funding for these pilot studies is derived from the CCTS program in partnership with other UK Centers, and with other Universities in the Appalachian Translational Research Network (ATRN).

PARTNERSHIP WITH OTHER INSTITUTIONS

Within the ATRN, other universities will contribute funds to this pilot grant program, and awards will be given that involve collaborative partnership relations with investigators at these institutions. The following are the guidelines that apply to these awards.

University of Kentucky/Wake Forest University collaborative grant:

One award of up to **$50,000**, in total direct cost, will be given to a meritorious project that involves collaboration between investigators at UKCCTS and Wake Forest CTSI. This project will involve an equal contribution from each institution, and will require Co-PI's from each institution. Award duration is **12 months**.

The research award is designed to stimulate collaboration between the respective campuses. 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 identified by the community. 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.

- ***Proposals must be joint applications by collaborators from Wake Forest and UK***
- ***The research plan demonstrates that the heath issue being addressed has been defined by the community as a pressing problem.***
- ***Projects involving disease associated with Appalachian North Carolina and Kentucky are highly desirable.***
- ***The project must propose studies that not only address the identified health problem, but also include a component or approach that will provide a generalizable result that will advance translational science in fields beyond that of that disease or health issue.***
- ***The Wake Forest Principal Investigator partner must be a Wake Forest faculty member.***

- ***The UK Principal Investigator must be a UK faculty member.***
- ***Investigators in training including residents, post-doctoral fellows, and clinical fellows are NOT eligible to serve as PIs but may be co-investigators***

Please direct all questions to:

WF: Lindsay Trost, ltrost@wakehealth.edu, (336) 713-8126
UK: Joel Thompson, Joel.thompson@uky.edu, (859) 323-7939

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

Call for Applications	Letter of Intent Deadline	Invitation for Full Application	Full Application deadline	Funding Announcement
January 16	**February 17**	**March 31**	**April 28**	**June-July**

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 a competitive 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.
- Proposals that address an important question in clinical and/or

translational research that impacts human health.
- Biomedical informatics collaborative projects. Priority will be given to collaborations among biomedical (basic science, genomic, clinical, public health) researchers and informatics researchers. The goal is to fund work that can lead to publications and pilot data to help secure extramural funding.

FUNDING INFORMATION:

Individual project awards, up to **$50,000** in total direct costs over a **12-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.

To support collaborations between basic scientists and clinician scientists and to promote clinicians scientists involvement in the proposed project, a supplement of up to $25,000 for up to 10% effort may be requested for a clinician scientist. Please refer to the eligibility criteria listed below.

Research DOE for Clinician Scientists – Guidelines

- Research DOE provided for a clinician scientist collaborating with a basic scientist. The respective roles of the basic and clinical scientist must be well described and both must be essential to performing the project.
- Basic scientist and clinicians as Co-PIs on pilot proposal; (i.e. clinician involvement cannot be casual).
- Role of clinician scientist must be different from standard of care clinical role. If clinician involvement in research project does not result in decrease in 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.
- Research DOE for clinical scientist will be requested as a supplement to the pilot proposal.
- Clinician scientist may be physician, dentist, pharmacist, etc. who has no available research time on DOE at the present time.
- Clinician scientist effort to be verified in letter of support from division chief and department chair agreeing to the arrangement.
- CCTS to provide up to $25,000 salary and benefits and department/division must

cost share additional funding for minimum 10% effort.

- CCTS will fund up to 2 clinician scientist supplements per pilot RFA (2 per year).
- Final approval will be dependent upon the nature of the project, clinician scientist involvement, and availability of funds.

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 Joel Thompson (859) 323-7939, joel.thompson@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 onetime.

LOI AND BIOSKETCH SUBMISSION INSTRUCTIONS

The LOI is limited to **2 pages** describing the following elements:

- 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 and outcomes
- Project milestones
- Describe how the pilot grant would facilitate a future external grant (priority will be given to applications with a more specific plan and timeline (ex. Identification of the study section and time line planned).

*Optional attachments at the LOI stage could include key relevant publications

Letters of Intent (LOI) and Biosketch (BS) in NIH format will be solicited from faculty on all the campuses. The LOIs will be reviewed and subject to a standard NIH-type study section assessment by the CCTS Pilot Review Committee (PRC). A subset of meritorious LOIs will be selected and applicants will be invited to submit Full applications.

Letter of Intent DEADLINE: February 17, 2019 by 5:00 PM (EST)

LOI submission link: https://redcap.uky.edu/redcap/surveys/?s=3JAXXKXN4E

The BIOSKETCH template (non-fellowship) can be downloaded here.

PILOT RESEARCH PROTOCOL SUBMISSION PROCESS

Full Application DEADLINE: **April 28, 2019 by 5:00 PM (EST)**

Full Application submission link: TBD

Full Application submission link: will be provided to applicants invited to submit full applications.

Based upon review of the LOI, successful investigators will be invited to submit a full application. Invited investigators are encouraged to contact Joel Thompson at 323-7939, Joel.thompson@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.

If you need consultations related to Study Design, Data Safety Monitoring or Bioinformatics go to https://www.ccts.uky.edu and select "Request a service" in the top banner. If you have not become a member of CCTS you'll need to complete that very short process first.

CCTS PILOT RESEARCH PROGRAM FULL APPLICATION INSTRUCTIONS:

Applicants are encouraged to review the instructions provided below carefully and to contact Joel Thompson at Joel.thompson@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 should be reported in the appendix.

Please use the following formatting when completing the LOI and full application:

- Margins must be no smaller than 0.5" at allpoints.
- 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 must be assembled in the following order in the form of a pdf binder. For assistance please contact Joel Thompson at Joel.thompson@uky.edu.

1. **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: Disease Focus or ATRN partnership (i.e. UK- MU, UK- WFU or UK- WVUcollaborative award.)
- 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
- Mentor's information (Applicable only for junior investigators):
  - Name, Degree(s) and Rank, Campus Address, and Contact Information
- Applicant's Chair Information for each collaborator:
  - Name,
  - Campus Address,
  - Contact formation

2. **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.
- Recruitment costs

****Budget must be approved by Joel Thompson <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.

The NIH budget template can be downloaded here. For 12 month projects, only use the initial budget document.

Initial budget: https://grants.nih.gov/grants/funding/phs398/fp4.pdf

3. Abstract and Partnership development (if applicable): (not included in the 6 pages 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).

4. Body of the proposal: (limited to 6 pages including Specific Aims)

The format of the application will follow NIH guidelines as outlined below.

Specific Aims (limited to one page and included in the 6 pages 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 newtechnology.

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)

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.

- 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.

5. Appendix:

- Biosketch(s) in NIH format
- 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 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., 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.

- References:
    - Authors, year, title and journal information are expected for each citation.

REVIEW PROCESS & CRITERIA:

Application 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 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:

- **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 Joel Thompson, (323-7939, Joel.thompson@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 attend face to face meeting with the CCTS "Pilot Progress**

Committee" as needed. 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 must 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 applications will be released upon NCATS approval and once all assurances have been completed along with your intake meeting with the CCTS Pilot Committee.