Center for Clinical and Translational Science

Pilot Funding for Translational Science:
Application Scope and Style Guide

The UK Center for Clinical and Translational Science (CCTS) is now accepting applications for Pilot Projects on a rolling basis with no set deadline, category, or budget. You can apply for a Pilot Project at any time, with any project that meets the criteria outlined in this guide. This is a new funding mechanism designed to provide resources for projects that focus on translational science. The goal is to develop these translational science Pilot Projects into larger projects/programs. The scope and focus of these translational science projects are described below.

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SCOPE

Within the general guidelines outlined below, the types of projects that will be considered under this funding mechanism include projects that have a focus on translational science with a high likelihood of leading to future grants, projects or Centers.

AWARD OVERVIEW

The pilot project period can be up to 36-months, distributed in three twelve-month allocations. Projects will be evaluated annually. **Only projects that demonstrate sufficient progress will receive continued funding.** Project budgets should be in line with the work proposed.

The importance of Translational Science

An important aspect of this call for applications is the incorporation of translational science into the application.

What is Translational Science?

The CCTS derives most of its funding from the NIH National Center for Advancing Translational Sciences (NCATS) under the Clinical and Translational Science Award (CTSA). NCATS has clearly declared that CTSA recipients should be focused on advancing "translational science", as opposed to "translational research." Whereas "translational research" can apply to any project that is or can be moved into humans, "translational science" is focused on understanding a scientific or operational principle underlying a step of the translational process with the goal of developing generalizable principles to accelerate translational research. A more in-depth description of translational science can be found here: https://ncats.nih.gov/training-education/translational-science-principles#scientific-principles.

Although most quality research can meet the objectives of translational science, scientists often do not think in terms of how their research can break down barriers and become more generalizable. For CCTS supported pilot studies, it will be important for the PI to describe how their project advances translational science. A project may be disease oriented (i.e. focused on something important to cancer, diabetes, heart disease, stroke, Alzheimer's, SUD, etc.) but it is important that the methodology also focus on addressing a barrier to translational research that is more widely applicable. Below are a few examples:

- A project needed to collect information from participants on their eating behavior. An app was developed that allowed the participants to input eating behavior information. Although this app was developed for a specific project, the app could be easily modified for any project that would require input from a participant in the field, hence advancing translational science by improving research tools.

- Investigators in drug discovery routinely survey databases containing compounds, chemical data, and biological outcomes. A platform was implemented that allowed

investigators to easily search multiple compound databases to find a compound that meets their specifications. The improved access to these data will accelerate the overall process of drug discovery.

- Patients with lung cancer are often reluctant to opt in to non-hospice palliative care, even though this process would benefit them. However, this is a complex issue. An investigator developed an app which helped provide education, resources, and counseling. Although this app was developed for lung cancer, it could be adapted for many other contexts to help patients navigate a complex health system.

To be competitive for this funding mechanism, a project needs to articulate how the methodology will not only address the barriers to the particular research project, but also how it could be adapted or address a translational barrier for other projects more broadly. The proposal includes a mandatory section where the candidate should describe how this project may advance translational science. We understand that this may be a new concept for some scientists.

Eligibility

- Eligibility is limited to:
    - Full-time faculty (all title series including regular, research, clinical and special) of the University of Kentucky.
    - Postdoctoral PhD fellows at UK.
- Volunteer faculty and adjunct faculty are NOT eligible to serve as PIs but may be co-investigators.
- IRB must be submitted.
- Individual principal investigators will not be allowed to hold more than one CCTS pilot research award at any one time.

If you have any questions regarding this funding mechanism, please contact Dr. Joel Thompson, PhD, CCTS Chief Scientific Officer, at joel.thompson@uky.edu or 859 323-7939.

Review Categories:

Applications requesting less than $5,000 will undergo an expedited review.

Applications requesting more than $5,000 will have a full Scientific Review Committee (SRC) review.

CRITERIA FOR FUNDING

The main priorities for funding are:

- Translational: ties findings directly to human health and/or develops insights that can improve research across settings or conditions
- Hypothesis-driven or hypothesis-generating specific research question(s)
- Pilot sized: smallest number of subjects or samples necessary to obtain preliminary data
- Involve human subjects, human tissue, human cell lines, and/or human information (e.g., medical records) and have application to human health
- Likelihood of future funding
- Capacity for overall impact on the health of underserved populations, including Appalachia
- Projects focused on health equity or that target underserved/underrepresented populations are encouraged.

FUNDING INFORMATION

Budgets for awarded pilot projects will include only direct costs. 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 ensure that the funds being requested are relevant to the research being proposed.

ALLOWABLE EXPENSES

- Funds are to be used for the conduct of the project, including supplies, subject payments, assays, etc.
- Equipment can be purchased if it is absolutely necessary for the execution of the project. All equipment purchased is property of UK CCTS and will be returned to the CCTS at the completion of the project.
- Travel funds needed for study execution are allowed, if essential. No funds will be provided for travel to collaborator sites or conferences.

NON-ALLOWABLE EXPENSES

- Equipment cannot be purchased using this mechanism unless it is absolutely required for the execution of the project. Prior approval from Joel Thompson, PhD, is required. All equipment purchased using CCTS Pilot funds belongs to the CCTS and equipment will be returned to the CCTS at the completion of the project.

- Funding will not be awarded as bridge funding for ongoing projects.
- Funds **cannot be used** to support salary of the Principal Investigator or other investigators with faculty appointments.
- No funds will be provided for publication costs.
- No funds will be provided for professional memberships.
- Facilities and Administrative costs, also known as indirect costs, are not permitted.
- Funds for animal research when there is no focus on translational science 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 Amy Thomas (amy.thomas17@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.

SUBMISSION INSTRUCTIONS

APPLICATION STYLE GUIDELINES

- 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 corner.
- The application pages should be numbered consecutively in the center bottom.

APPLICATION SUBMISSION GUIDELINES

Full Application page content and page order are defined below.

Cover Page(s) - not included in the 5-page limit:

- Title of the Project
- Applicant's information for Principal Investigators and Co-Investigators including
  - Name
  - Degree(s)
  - Rank, title (s)
  - College
  - Department / division
  - Campus address

- Contact information including e-mail and telephone number
- Please indicate if you are an NIH new investigator or early-stage investigator (has not previously received an R01)
- Please indicate clinical privileges (N/Y – what clinical setting)

- Abstract
- Chair information for each principal investigator: name, campus address, and contact details

Budget:
Detailed budget and budget justification in NIH format for all services other than those that CCTS offers/will provide. Only direct costs are allowable; no indirect costs are assignable through this mechanism. See NIH budget templates (PHS 398 form pp. 4 and 5) in the appendix of this guide.

- Allowable expenses include:
  - Equipment essential for the conduct of the study
  - Participant reimbursement costs
  - Limited non-faculty personnel salary support (faculty salary support is not allowable). Applicants must account for fringe benefit costs when considering research assistant salary levels.
  - Project-specific specimen collection/analysis or testing
  - Chemistry and biological lab supplies
  - Purchase of cell lines, culture reagents etc.
  - Animal purchase and housing costs.

An initial review of the budget for allowable expenses will be done after submission. Further budget review will be done for meritorious projects.

Please contact Joel Thompson, PhD, or Chad Combs (chad.combs@uky.edu) for budget questions.

Body of Proposal:

For applications requesting less than $5,000:

The body of the proposal is limited to two pages. Please describe specific aims, significance, innovation, and approach while addressing translational science.

For applications requesting greater than $5,000:

The body of the proposal is limited to five pages, formatted according to the NIH guidelines as outlined below.

I. Specific Aims

- State concisely the goals of the proposed research. Address translational science aims 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., understanding a scientific or operational principle underlying a step of the translational process with the goal of developing generalizable principles to accelerate translational research; testing a stated hypothesis; creating a novel design; solving a specific problem; challenging an existing paradigm or clinical practice; addressing a critical barrier to progress in the field; or developing new technology.

II. Research Strategy

Organize the Research Strategy using the order and instructions provided below. Start each section with the appropriate section heading (Significance, Innovation, and Approach). Cite published experimental details in the Research Strategy section and provide the full references in the Bibliography section of the appendix. 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 address translational science to 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. Describe potential future grant submissions and note which PAR they are associated with.

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.

- Describe how the project advances translational science.

- 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.

- As applicable, also include the following information as part of the Research Strategy, keeping within the three sections listed above (Significance, Innovation, and Approach):

    - 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.

III. Appendix (not included in the five-page application limit)

- Biosketch in NIH format or equivalent document

- Statement of inclusion of Women and Members of Racial and/or Ethnic Minority Groups in Clinical Research (NIH Inclusion Policy)

    - Describe the planned distribution of subjects by sex, race and/or ethnicity.

    - Describe the rationale for selection of sex, racial, and ethnic group members in terms of the scientific objectives and proposed study design. The description may include, but is not limited to, information on the population characteristics of the disease or condition under study.

    - Describe proposed outreach programs for recruiting sex, racial, and ethnic group members.

    - Inclusion and Excluded Groups: Provide a reason for limiting inclusion of any group by sex, race, and/or ethnicity. In general, the cost of recruiting certain groups and/or geographic location alone are not acceptable reasons for exclusion of particular groups. See the Revised NIH Policy

and Guidelines for Inclusion of Women and Members of Racial and/or Ethnic Minority Groups in Clinical Research (NIH Inclusion Policy) for more information.

- Bibliography: 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 three pages).

- List of primary mentor(s).

- DO NOT submit published manuals, materials in the public domain, or similar materials. The appendix is not a means of extending the length of the proposal itself.

- **Trainees (Postdoctoral PhD's) should submit a mentoring plan:** To facilitate the effectiveness of the CCTS Pilot Research Program in enhancing research development on the UK campus, trainees 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 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. This letter should be included in the appendix material of the application. Inclusion of a clinician (physician, dentist, pharmacist, clinical psychologist, physical therapist, etc.) mentor is highly desirable in studies involving direct interaction with human participants.

REVIEW PROCESS & CRITERIA

Incomplete applications will not be reviewed.

Applications for more than $5,000 will be sent for a full review with the CCTS Scientific Review Committee (SRC) where a minimum of two reviewers with expertise in fields relevant to the science in the proposal will review 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 application, with particular relevance to the Priorities and Scope outlined above and the overall relevance to the mission of the CCTS to promote clinical and translational science. This feedback will be returned to

the PI. Meritorious applications will be invited to give a five-minute presentation to address the SRC's concerns. This will be followed by a ten-minute question and answer period. The PI will be asked to leave the meeting and the Scientific Review Committee will discuss the application. The PI will be notified if the proposal will be funded, will not be supported, or whether further actions such as amending the application is required.

The general criteria for review include:

Overall Impact	• Does the proposal support the underlying NCATS foundation of translational science to support high impact ideas that will lay the foundation for new fields of investigation; accelerate breakthroughs; stimulate early and applied research on cutting-edge technologies; foster new approaches to improve the interactions among multi- and interdisciplinary research teams; or advance the research enterprise in a way that could stimulate future growth and investments and advance public health and health care delivery?
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? Is there a focus on translational science?
Investigators	• Does the investigative team have training, expertise, and experience to conduct the proposed 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 Amy Thomas (amy.thomas17@uky.edu) to schedule a working meeting with the CCTS units involved with your protocol.

Successful applicants will be required to provide annual progress reports, and 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 a successful application will be released upon receipt of 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.**

RFA APPENDIX

- **Research development assistance**
  If at any point in the development of your application you need CCTS services (e.g. biostatistics, recruitment, budgets, data extraction, etc.) please fill out a Service Request Form accessed through the following link or via the UK CCTS homepage. If you are not a member of the CCTS, you'll need to complete that first—it's fast, free and available through the same link).
  https://cctsdata.uky.edu/membership/

- **UK Fringe Benefit guidelines**
- https://www.research.uky.edu/office-sponsored-projects-administration/frequently-needed-information#fringe-benefits

- **NIH Biosketch guidelines (non-fellowship)**
  https://grants.nih.gov/grants/forms/biosketch.htm

- **NIH budget template (detailed budget for initial budget period)**
  https://grants.nih.gov/grants/funding/phs398/fp4.pdf

- **NIH budget template (detailed budget for entire budget period)**
  https://grants.nih.gov/grants/funding/phs398/fp5.pdf

Version.12.25