Center for Clinical and Translational Science

Substance Use Disorder

Pilot Funding Program Call for Applications

The UK Center for Clinical and Translational Science (CCTS) is now accepting applications for Pilot Projects. All CCTS pilot awards are open to any faculty across all 16 colleges within the institution. In the past the CCTS has funded pilots across the translational spectrum including preclinical and clinical research, community engagement, health disparities research and dissemination and implementation research. Our pilots are intended to provide resources to support innovative, collaborative research relevant to the health challenges and disparities faced by the citizens of Kentucky and across the nation.

SCOPE

Within the general guidelines outlined below, the types of projects that will be considered within these mechanisms include projects that involve one or more of the following:

- Support research by early career investigators.
- Propose research involving new multidisciplinary teams.
- Promote community-based research.
- Develop new methodologies to leverage institutional strengths and new initiatives.
- Pursue high-risk, high reward studies.

PILOT AWARD TYPE

SUBSTANCE USE DISORDER PILOT AWARDS

Two pilots of up to $25,000 in total direct cost will be awarded with a project period of 12 months.

Areas of emphasis are:

- Identification and advancement of novel substance use disorder pharmacological treatments along the drug development continuum
- Community-engaged substance use disorder research focused on intervention development and/or implementation in community settings
- Leveraging novel technology or mHealth approaches to develop and/or deliver substance use disorder-related interventions (e.g., education, stigma reduction, support, linkage, monitoring) to patients or community members
- Development and validation of novel laboratory models relevant to substance use disorders

Key Dates:

Call for Applications	Full application due date	Funding decision
March 5, 2025	**April 18, 2025**	**Early June**

PRIORITIES FOR FUNDING:

The main priorities for funding are:

- Clear clinical and translational relevance.
- The likelihood that funding will result in a competitive application for extramural funding.
- Where appropriate, priority will be awarded based upon the strength of the research team or, for early career investigators, the mentorship team.

- Capacity for overall impact on health of Appalachia.
- Multidisciplinary research teams representing the basic, clinical and/or applied sciences with an emphasis on bridging the divisions between basic and clinical scientists.

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 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.
- To support collaborations between basic scientists and clinician scientists, a research DOE supplement of up to $25,000 for up to 10% effort may be requested for a clinician scientist. See DOE offset guidelines in the appendix.

NON-ALLOWABLE EXPENSES

- Funding is not available for thesis or dissertation projects.
- Equipment cannot be purchased using this mechanism unless it is absolutely required for the execution of the project. Prior approval from Chad Combs 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.

In the event that additional intra/extramural funds are secured to support the study outlined in your application you must immediately notify Amy Thomas (859-323-7395, 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. **Individual principal investigators will not be allowed to hold more than one CCTS pilot research award at any one time.**

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

APPLICATION SUBMISSION GUIDELINES

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

- Title of the Project and Total Amount Requested
- List SUD RFA as the Grant Category
- 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 (N/Y – what clinical setting)
- Abstract, 250-word limit
- Mentor's information (Applicable only for early career investigators): Name, Degree(s) and Rank, Campus Address, and Contact Information
- Chair Information for each principal investigator: Name, Campus Address, and Contact Information

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 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.

For NIH budget templates, please see the RFA Appendix

Body of the proposal: (limited to 5 pages)

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

Specific Aims (limited to 1 page)

- 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 develop new technology.

Research Strategy

Organize the Research Strategy in the specified order using the 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 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 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.
- 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.
- 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.

Appendix

- Biosketch in NIH format or equivalent document
- Protection of human subjects section and animal assurances (if applicable)
- Statement of inclusion of women and minorities:

  - Describe the planned distribution of subjects by sex/gender, race, and ethnicity.
  - Describe the rationale for selection of sex/gender, 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/gender, racial, and ethnic group members.
  - Inclusion and Excluded Groups: Provide a reason for limiting inclusion of any group by sex/gender, 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 Inclusion of Women and Minorities as Participants in Research Involving Human Subjects - Policy Implementation Page for more information.

- 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)
- Letters of Support from the PI's department chair and significant collaborators must be included.

  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.
- 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.

Submission Process:

Applications should be submitted via the CCTS Service Request Form; select "CCTS Pilot Submission." If you are not yet a member of the CCTS, you will be prompted to become one before applying. It's free and fast.

REVIEW PROCESS & CRITERIA:

Incomplete applications will not be reviewed.

The application 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 and questions 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, (323-7395, amy.thomas17@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 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.**

RFA APPENDIX

Research development assistance
If at any point in the development of your application you need CCTS services (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/

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

NIH budget template (budget for the entire budget period)

https://grants.nih.gov/grants/funding/phs398/fp5.pdf

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

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