Center for Clinical and Translational Science

Call for Applications

Pilot Funding that encompasses Translational Science

The UK Center for Clinical and Translational Science (CCTS) is now accepting applications for Pilot Projects. This is a new funding mechanism that is designed to provide resources to support projects that focus on translational science. The goal is to develop these translational science Pilot Projects into larger projects/programs. It is hoped that some of these projects will ultimately lead to a project that will be submitted as part of the CCTS CTSA renewal in 2025. The scope and focus of these translational science projects are described below.

Contents

SCOPE:

Within the general guidelines outlined below, the types of projects that will be considered within these mechanisms include projects that have a focus on translational science with a high likelihood to lead to future grants. Emphasis will be placed on translational science projects that align with or could be incorporated into projects such as the RC2 program or Element E (see below) for inclusion with the next UK CTSA grant submission. The next CTSA submission is projected to be in late 2025, and will include the following components:

- NCATS RC2 program alignment
- Element E: Clinical and Translational Science Research Program
- Other projects that promote Translational Science

AWARD TYPE:

Translational Science

The UK CCTS is funded through a CTSA award offered by the National Center for the Advancement of Transitional Science (NCATS). NCATS mission is to advance the science of translation, with the goal of both accelerating the process of turning observations into real world interventions as well as to break down barriers to translational research. As part of the new CTSA Funding Opportunity Announcement [PAR -21- 293], NCATS has introduced several different types of grant awards. It is anticipated that the overall CTSA application, when submitted in late 2025, will include several different types of translational science projects. This pilot award is intended to help with team building, obtaining preliminary data and other activities that will make the 2025 submission competitive.

This pilot award is expected to be a **12-month project period and $50,000 in direct costs. A second year of equal funding will be available** for projects that demonstrate sufficient progress.

There are several types of awards that can be submitted with the CTSA grant in 2025.

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 much of its funding from the National Center for Advancing Translational Sciences (NCATS). NCATS has clearly declared that CTSA's 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 good research can meet the objectives of translational science; however, 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. However, it will be important that the methodology focus on improving on 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 behavioral 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, and hence advanced translational science.

- Investigators in drug discovery routinely survey databases containing compounds, chemical data, biological outcomes. A platform was implemented that allowed investigators to easily search multiple compound data bases to find a compound that meets their specifications. This better 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 uses involving helping 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. If there are questions, please reach out to Joel Thompson, PhD, (joel.thompson@uky.edu).

Potential future grants related to translational science

As with all pilot grants, this CCTS pilot grant will be awarded with an eye towards future funding, regardless of the source of this funding. However, there are two upcoming grant opportunities that are important to the CCTS. We will be looking for pilot grants that may be eligible for the following opportunities.

RC2 Pathway Pilot Award

The NCATS RC2 funding mechanism is designed 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. These awards from NCATS have a maximum budget of $500,000 per year direct costs and are for 5 years and are typically multidisciplinary.

One of the goals of this CCTS Translational Science Pilot Award is to stimulate the development of projects/programs that will fit the goals of the NCATS RC2 funding mechanism with the ultimate goal of submitting a fully developed NCATS RC2 submission to accompany the CCTS CTSA renewal in 2025.

Element E: Clinical and Translational Science Research Program

The CTSA 2025 submission will include a UM1 grant [PAR-21-293] and Element E of this UM1 includes “Element E: Clinical and Translational Science Research Program”. These will be discrete projects that should address a significant roadblock in clinical and translational science. These projects may be disease-focused, but the project should address a question or problem that will generate generalizable innovations or insight that may increase the overall efficiency or effectiveness of translation. Although the budget of these Element E: Clinical and Translational Science Research Program is not currently

specified by NIH, these will typically be projects of 1-3 years duration with funding of $100,000 - $200,000 per year.

These “Element E: Clinical and Translational Science Research Program” projects are an essential component of the UM1 application. The current RFA for translational science Pilot Projects is intended to help UK investigators develop teams, obtain preliminary data and further develop a project that could be part of the 2025 UM1 submission.

Eligibility

- Eligibility is limited to full-time faculty (all title series including regular, research, clinical and special) of the University of Kentucky and affiliated institutions
- 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.

Please contact Dr. Joel Thompson, PhD if you have any questions regarding this new mechanism (joel.thompson@uky.edu, 859 323-7939).

Key Dates:

Call for Letter of intent	Letter of intent due date	Notice of meritorious letter of intent	Full application due date	Funding decision
November 27, 2023	**January 17, 2024**	**February 8, 2024**	**March 7, 2024**	**Mid-April, 2024**

PRIORITIES FOR FUNDING:

The main priorities for funding are:

- Clear relevance to translational science
- Likelihood of future funding
- RC2 or Element E program alignment (see above)
- The likelihood that funding will result in a competitive application for the RC2 mechanism or the Element E project.
- Where appropriate, priority will be awarded based upon the strength of the research team.
- Multidisciplinary research teams representing the basic, clinical and/or applied sciences with an emphasis on bridging the divisions between basic and clinical scientists.
- Capacity for overall impact on the health of underserved populations, including Appalachia
- Projects focused on health equity or which 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 insure 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.
- 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 approve from Dr. Joel Thompson 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.

LETTER OF INTENT (LOI) SUBMISSION GUIDELINES

This call for Pilot Project applications focused on translational science is different from previous pilot RFAs. Please contact Dr. Joel Thompson, PhD if you have any questions regarding this new mechanism (joel.thompson@uky.edu, 859 323-7939).

Letters of Intent (LOI) and NIH-style Biosketches of all key personnel will be solicited from faculty. The LOIs will be reviewed utilizing a standard NIH-type study section assessment by subject matter experts from across UK. A subset of meritorious LOIs will be selected and applicants will be invited to submit full applications. **Late or incomplete LOIs will be returned to the investigator and will not be considered for the funding opportunity.**

The LOI is limited to 3 pages including all the following:

- Full project title (page 1)
- A statement of how the project addresses translational science and whether your project fits within the RC2 program or the Element E program (page 1)
    - Applications that address and fit within these RC2 and Element E mechanisms with a translational science focus will receive priority
- Research objectives, Specific Aims (pages 2-3)
    - 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 new research opportunities
- Brief background and preliminary data
- A paragraph describing study design, methodology, statistics and outcomes
- Project milestones
- Appendix
    - List citations from body of proposal
    - PI, Co-PI and Co-I biosketches
    - List key personnel
    - The appendix is not to be used to circumvent the 2 page LOI limit
- Letters of support are not required but encouraged at the LOI stage

LOI submission link: REDCap submission link

FULL APPLICATION SUBMISSION GUIDELINES

The full application WebCAMP submission survey will be provided to PIs in the email they receive acknowledging their meritorious LOI. Investigators are encouraged to contact Dr. Joel Thompson (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, to learn which CCTS services you might utilize for your study, and to devise a budget for your protocol. Full Application page content and page order are defined below.

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
- 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
    - Abstract, 250 word limit
- Chair Information for each principal investigator: Name, Campus Address, and Contact Information

Detailed budget and budget justification in NIH format (See NIH budget templates in the appendix), direct cost only

- Allowable expenses include:
  - Equipment essential for the conduct of the study
  - Data analysis costs
  - Participant reimbursement costs
  - Research assistant salary support
  - Non faculty personnel salary support (Faculty salary support is not allowable)
  - Project specific specimen collection/analysis or testing
  - Chemistry and biological lab supplies
  - Purchase of cell lines, culture reagents etc.
  - Animal purchase and housing costs.
  - Specimen collection/analysis or testing
  - Participant reimbursement/recruitment costs

Please review the allowable costs section and contact Dr. Joel Thompson or Amy Thomas with questions. Budgets must be approved by Amy Thomas (amy.thomas17@uky.edu) BEFORE submission. Applicants must account for fringe benefit costs when considering research assistant salary levels. No indirect costs are assignable through this mechanism.

For NIH budget templates, please see the RFA Appendix.

Body of the proposal: (limited to 6 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 and

summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved. If applicable whether your project fits within the RC2 program or the Element E program.

- 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, 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.

Research Strategy (limited to 5 pages)

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 in particular whether your project fits within the RC2 program or the Element E program.

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 (must use the current NIH Biosketch template, effective January 25, 2022)
- 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)
- The required endorsement letter from the primary mentor for early investigators (see below).
- 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.

REVIEW PROCESS & CRITERIA:

Incomplete applications will not be reviewed. The application will be sent to a minimum of two 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 application. All applications will be scored based upon the written reviews, 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. You will be notified of the outcome.

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?**
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 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 LOI or full 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/

Clinician DOE offset

Research DOE provided protected effort for a clinician scientist collaborating with a basic scientist, where both function as co-investigators. The respective roles of the basic and clinical scientist must be well described and both must be essential to performing the project. The role of the clinician scientist must be different from their standard of care clinical role. If clinician involvement in the research project does not result in a decrease in the 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.

Guidelines:

- Basic scientist and clinicians must function as Co-PIs on pilot proposal; (i.e. clinician involvement cannot be casual).
- Research DOE for a clinical scientist will be requested as an additional supplement to the pilot proposal and submitted with the full application. Please provide a separate NIH budget form with DOE justification when requesting clinician DOE.
- The clinician scientist may be physician, dentist, pharmacist, etc. but who has no available research time on DOE at the present time.
- The clinician scientist must provide a letter of support from their division chief and department chair agreeing to the arrangement. This letter should be included in the appendix of the full

application.
- CCTS to provide up to $25,000 salary plus benefits and department/division must cost share additional funding for minimum 10% effort.

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