Center for Clinical and Translational Science

CCTS/Alliance Pilot Funding Program Call for Applications

The UK Center for Clinical and Translational Science (CCTS) is now accepting applications for collaborative pilot projects. The purpose of this funding mechanism is to provide a new opportunity and resources to support innovative, collaborative research relevant to the mission of each Alliance with the overarching goal of addressing the health challenges and disparities faced by the nation and the citizens of Kentucky. This mechanism is open to all UK faculty eligible to submit and receive externally funded grants.

SCOPE:

Within the general guidelines outlined below, the types of projects that will be considered within these mechanisms include projects that:

- Provide support for early career investigators.
- Stimulate the development of new clinical and translational inter- and multidisciplinary teams.
- Promote community-based research.
- Develop new methodologies to leverage institutional strengths and new initiatives.
- Pursue high-risk, high reward studies.
- Promote translational science.

The CCTS derives its funding from the NIH 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. We believe that 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 addresses and/or advances translational science.

Principal Investigators may submit projects that include collaborations between multiple Alliances. A letter of support from all involved Alliance directors is required at the LOI stage for such a project to be considered. PIs are encouraged to review their project idea with the Alliance directors prior to drafting their LOI to ensure the project will fit the mission of each Alliance. ***Principal Investigators are not permitted to submit more than one application in response to this RFA.***

AWARD TYPES

UK CCTS/AI in Medicine Pilot Award

Artificial intelligence (AI) and machine learning (ML) are transforming biomedical research and health care delivery, enhancing clinical care, and speeding scientific discovery. The recent coalescence of big data, accelerated computing, and deep learning has yielded remarkable results across research discovery and translational medicine. AI has emerged as a promising tool to improve patient outcomes and reduce cost by providing insights from clinical data across medical domains, including cancer, neuroscience, aging, substance use disorder and more. Learn More

The purpose of this funding mechanism is to support development of AI research teams with the resources to compete for externally funded grant awards by providing pilot or preliminary data to support grant applications, manuscripts, and new research teams.

- The awards co-funded by CCTS, AIM and IBI will be $20,000-$25,000 which must be spent over 12 months. It is anticipated that 3-4 pilot projects will be supported.

UK CCTS/Alliance for Diabetes and Obesity Research (ADORE) Pilot Award

Kentucky's adult obesity rate has climbed dramatically over the last two decades. The state now has the fifth highest adult obesity rate in the nation – 36.6 percent, up from 21.7 percent in 2000 – and the third highest obesity rate for youth ages 10 to 17. Obesity is far more complicated than a simple accumulation of fat. The metabolic changes that occur with obesity result in an increase in cardiovascular risk factors, poor bone quality, and insulin resistance. This last complication is directly related to 13.8 percent of Kentucky's adult population having diabetes. Learn more

- Although anyone in the diabetes/obesity research area can apply, preference will be given to projects that use the ADORE tissue bank, and/or junior investigators.
- One award co-funded by the CCTS and ADORE alliance will be up to $50,000 which must be spent over 12 months

UK CCTS/COVID-19 Unified Research Experts (CURE) Pilot Award

The goals of the CURE research alliance are to support and enhance research in the area of infectious diseases with an emphasis (but not limited to) emerging and re-emerging infectious diseases. Research spanning from basic to clinical spectrum are welcomed. We also high encourage submission of research projects that are at the intersection of infectious diseases and the established UK Research Priority Areas as well as collaborations with other Alliances. Learn more

- The awards co-funded by CCTS and CURE will be up to $20,000 which must be spent over 12 months. It is anticipated that 3 projects will be supported.

UK CCTS/Kentucky Research Alliance for Lung Disease (K-RALD) Pilot Award

Lung disease is the third leading cause of death in the U.S. and a significant health problem in Kentucky, and the COVID-19 pandemic has shined a spotlight on the public vulnerability to respiratory pathogens and the need for basic and clinical research to develop new therapeutic interventions. The purpose of the Kentucky Research Alliance for Lung Disease (K-RALD) is to develop a transdisciplinary, translational platform for the investigation of lung diseases. Included within this scope are translational studies of lung diseases such as acute respiratory distress syndrome (ARDS), respiratory infections, interstitial lung diseases, pulmonary fibrosis, asthma, COPD, and cystic fibrosis. Learn more

- The awards co-funded by CCTS and K-RALD will be up to $25,000 which must be spent over 12 months. It is anticipated that 2 projects will be supported.

UK CCTS/mHealth Application modernization and Mobilization Alliance (MAMMA) Pilot Award

The overall goal of this alliance is to leverage the knowledge, experience, and skillset of the transdisciplinary alliance members to create resources that can be used by junior faculty and others new to mHealth research. Through mentorship, linkage to existing resources, and assistance with customized protocols for our existing mHealth platform, we will facilitate the development of research programs in faculty new to mHealth research. We expect that these efforts will also lead to new grant funding among these new faculty, as well as among teams of senior and junior faculty who can leverage a robust smartphone app platform to propose large-scale, collaborative grants. Learn more

- The awards co-funded by CCTS and MAMMA will be up to $30,000 which must be spent over 12 months. It is anticipated that 2 projects will be supported.

UK CCTS/Maternal and Pediatric Research Alliance (MaPRA) Pilot Award

The Maternal & Pediatric Research Alliance (MaPRA) is inviting applications for pilot proposals that are in alignment with the stated goals and purpose of the Alliance. Specific areas of funding interest include projects that involve multiple departments (including the 3 founding MaPRA departments, Pediatrics, Obstetrics/MFM, Immunology), and collaborative involvement of clinicians and/or clinician scientists. Potential for project development leading to new and fundable teams is also encouraged. Learn more

- The awards co-funded by CCTS and MaPRA will be up to $25,000 which must be spent over 12 months. It is anticipated that 2 projects will be supported.

UK CCTS/T Cells to Induce Liver Tolerance (TILT) Pilot Award

Manufacturing Optimization of Regulatory T cells for Clinical Application in Solid Organ Transplantation

TILT alliance is working in the development of projects related to tolerance induction in solid organ transplantation (SOT) with special focus on the use of adoptive Treg cell immunotherapy. This is a high risk/high yield therapeutic approach that can reduce drug-related toxicity in SOT patients by enabling immunosuppression minimization or even withdrawal while sustaining allograft survival. The UK Transplant Center is one of the only 7 active programs in the US approved by the FDA to use this therapeutic modality in SOT. This approach may have implications beyond the field of transplantation as it is being tested in other immuno-related conditions such as autoimmune diseases, graft versus host disease (GVHD) and type I diabetes. Learn more

Funds will be available for 1 project up to $20,000 to enhance the manufacturing process of primary human Treg cells and improve consistency and quality of the final cell product. The

areas of interest include but are not limited to the assessment of phenotypic, molecular and metabolic signatures (single or combinatory markers) linked to expansion rates, suppressor activity and lineage stability.

- One award co-funded by CCTS and TILT will be up to $20,000 which must be spent over 12 months.

Key Dates:

Call for Letter of intent	Letter of intent due date	Notice of meritorious letter of intent	Full application due date	Funding decision
April 17, 2023	**May 17, 2023**	**Mid-June**	**Mid July**	**Mid-August**

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 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

- 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.
- Equipment cannot be purchased using this mechanism unless it is absolutely required for the execution of the project. Prior approval from Ryan Bentley(Ryan.Bentley@uky.edu) 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.
- 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. Principal Investigators are not permitted to submit more than one application in response to this RFA.

SUBMISSION INSTRUCTIONS

APPLICATION STYLE GUIDELINES

Applications must be submitted as a single PDF binder. Applications submitted as word docs or with multiple files will not be considered for funding.

- 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.

LOI SUBMISSION GUIDELINES

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.**

- This award is open to investigators in the UK faculty eligible to submit and receive externally funded grants.

The LOI must include all the following:

- **Cover page** including:
  - Project title (full project title required)
  - PI name(s)
  - Abstract
  - Key word (up to 5 MeSH headings)
- **Research Description** including the following**: Limited to 2 pages**
  - Brief background and preliminary data
  - A description of study design, methodology, statistics and outcomes
  - Project milestones
  - Describe how the pilot grant would facilitate a future external grant
  - Priority will be given to applications that address translational science (see above).
  - Priority will be given to applications with well-defined

future extramural funding plans and timelines (ex. identification of the study section).

- **Appendix** (not counted in the 2-page LOI limit)
  - List citations from body of proposal
  - PI, Co-PI and Co-I biosketches
  - List of key personnel
  - The appendix is not to be used to circumvent 2-page LOI limit

- Letters of support are not required but encouraged at the LOI stage. **If you are submitting a project that involves collaboration between more than one Alliance, a letter of support is required from all Alliance directors involved.** If you are only submitting to a single Alliance you do not need a letter of support from the Alliance Director.

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. **Applications must be submitted as a single PDF binder. Applications submitted as word documents or with multiple files will not be considered for funding.**

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
- 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

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
  - Specimen collection/analysis or testing
  - Participant reimbursement/recruitment costs

Please review the allowable costs section and contact Dr. Joel Thompson or Ryan Bentley with questions. Budgets must be approved by Ryan Bentley (ryan.bentley@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 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 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 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.
- 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.
- Priority will be given to applications that address translational science (see above).

Appendix

- Biosketch in NIH format (must use the current NIH Biosketch template, effective 10/202, Approved Through 09/30/2024)
- 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, relevance to the Priorities and Scope outlined above, and the overall relevance to the long term goals of the CCTS to promote clinical and translational science. You will be notified of the outcome.

The general criteria for review include:

Overall Impact	• **What is the project's likelihood to have a sustained, powerful influence on the research field(s) involved?**
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? Does the project address translational science (see above)?**
Investigators	• **Does the investigative team have training, expertise, and experience to conduct the proposed study? Is this an early career investigator? If so, a mentorship team must be identified. The qualification and experience of the mentor, and their plan for career development for the early career investigator, will be an important aspect of review.**
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/

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