Center for Clinical and Translational Science

Pilot Funding Program Call for Applications

The Neuroscience Research Priority Area and UK Center for Clinical and Translational Science (CCTS) are now accepting applications for Neuroscience related Pilot Projects. The purpose of this funding mechanism is to provide a new opportunity and resources to support innovative, collaborative research relevant to the health challenges and disparities faced by the nation and the citizens of Kentucky. There are 2 awards included in this RFA: The CCTS/NRPA Collaborative Pilot Award providing up to $50,000 in funding for clinical and translational projects and the NRPA Pilot Award supporting awards of $25,000.

SCOPE:

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

- Provide support for neuroscience research projects ranging from basic science to translational, clinical and community projects.
- Stimulate the development of new clinical and translational inter- and multidisciplinary teams.
- Develop new methodologies to leverage institutional strengths and new initiatives.
- Pursue high-risk, high reward studies.

AWARD TYPE:

NEUROSCIENCE RESEARCH PRIORITY AREA PILOT AWARD

This award is for investigators at all stages of career development (i.e., early career, midlevel, and senior investigators) and is intended to stimulate innovation and to support pilot studies that will lead to extramural funding. The anticipated award is $25,000 which must be spent over 12 months; applicants may request higher levels of funding with sufficient justification.

- This mechanism will support any neuroscience related project.
- Eligibility is limited to full-time faculty (all title series including regular, research, clinical and special) at 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.

CCTS/Neuroscience-RPA COLLABORATIVE PILOT AWARD

This clinical and translational award is for investigators at all stages of career development; (i.e., early career, midlevel, and senior investigators) and is intended to stimulate innovation and to support pilot studies that will lead to extramural funding. The total award is limited to $50,000 which must be spent over 12 months.

- Clinical and translational proposals will have the opportunity to opt-in to this mechanism during the application process.
- Eligibility is limited to full-time faculty at 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.

Key Dates:

Call for Letter of intent	Letter of intent due date	Notice of meritorious letter of intent	Full application due date	Funding decision
Mid-July, 2022	**August 25, 2022**	**Late September 2022**	**November 3, 2022**	**Mid-December 2022**

PRIORITIES FOR FUNDING:

The main priorities for funding are:

- Clear neuroscience-related basic, translational, or clinical relevance (please note, the NRPA Pilot allows for the submission of basic, translational, and clinical projects; the joint CCTS/NRPA Pilot is limited to projects that are translational and/or clinical in nature)
- The likelihood that funding will result in a competitive application for extramural support.
- As appropriate, priority will be awarded based upon the strength of the research team or, for early career investigators, the mentorship team.
- Multidisciplinary research teams representing the basic, translational, or clinical neurosciences with an emphasis on bridging the gap 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 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 required for the execution of the project and is not otherwise available. 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.
- Salary support for Principal Investigators or other investigators with faculty appointments is allowable under both the NRPA and CCTS-NRPA Pilots; however, salary support included in the joint CCTS/NRPA pilots cannot exceed $25,000. To support collaborations between basic 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 required for the execution of the project and is not otherwise available. Prior approve 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 the application the principal investigator 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, depending 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.

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.**

The LOI is limited to 2 pages including all the following:

- Project title (full project title required)
- Research objectives, Specific Aims
  - Describe the science driving the translational effort. Provide concise, clear statements regarding anticipated outcomes of the proposed research and how it will add to existing knowledge or create new research opportunities
- Brief background and preliminary data
- A paragraph describing 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 with well-defined future extramural funding plans and timelines (ex. identification of the study section).
- 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 2 page LOI limit
- Letters of support are not required but encouraged at the LOI stage

LOI submission link: https://redcap.uky.edu/redcap/surveys/?s=L48FN7XKL4D4TPHF

FULL APPLICATION SUBMISSION GUIDELINES

The full application RedCAP 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 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.

Appendix

- Biosketch in NIH format (must use the current NIH Biosketch template, effective May 25, 2021)
- 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 mission of the CCTS to promote clinical and translational science. The PI 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?**
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 notification 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. 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