

KL2 Visiting Scholars Program - Pilot Grants

The Clinical and Translational Science Awards (CTSA) program at the National Institutes of Health (NIH) supports a national consortium of medical research institutions working to transform the way biomedical research is conducted. The program is designed to help accelerate the translation of laboratory discoveries into treatments for patients, train a new generation of clinical and translational researchers, and engage communities in clinical research efforts.

The purpose of the KL2 Visiting Scholars Program is to promote cross-CTSA training, enhance KL2 scholar career development, and enhance inter-CTSA research collaboration. The associated Pilot Grants component of the program supports these objectives by funding innovative translational research projects that involve collaborations between KL2 scholars who have participated as visiting scholars and faculty at the host CTSA that they visited (multi-PIs). Funding is provided by the CTSA of the collaborating multi-PIs. It is expected that funds will be spent at the CTSA that contributes the funding (funds will not be transferred between institutions). Budget requests must not exceed \$25K per CTSA (\$50K total for direct costs only).

Eligibility Proposed multi-PI projects must involve collaboration between KL2 scholars who have participated in the Visiting Scholar Program and a faculty member at the host CTSA institution that they visited. Multi-PIs must have a full-time faculty appointment at their own CTSA institutions. KL2 scholars must have successfully graduated from their KL2 program at the time of pilot award funding. Investigators are encouraged to contact their parent institution's Administrative Contact prior to LOI submission.

Review Criteria: Letters of Intent and Full Applications will be reviewed by a study section composed of members of each participating CTSA. Review criteria will include:

- Significance of the work
- Novelty/Innovation of the research idea
- Relevance of the proposed study to translational research
- Existence of a genuine collaborative multidisciplinary team in place at both CTSA that is integral to the conduct of the research
- Evidence that the project could not be completed without the partnership between partner CTSA
- Potential for the project to lead to future external funding or to a commercialization opportunity
- Soundness of the proposed methods
- Feasibility of accomplishing the stated project goals within a 12-month project period

Application Deadline and Funding Cycle:

- **Application Release Date: July 17, 2018**
- **LOI Deadline: September 3, 2018 5:00 pm EST**
Each collaborating Principal Investigator will work together on a single combined LOI. The Lead Institution's PI will submit the combined LOI using the following online submission Redcap database: <https://redcap.uky.edu/redcap/surveys/?s=3TPJTADAL3>
- **IRB/IACUC Submission Deadline: October 15, 2018**
- **Full Application Deadline: November 1, 2018 5:00 pm EST**
Each collaborating Principal Investigator will work together on a single combined application. The Lead Institution's PI will submit the combined application within the following online submission

Redcap database: <https://redcap.uky.edu/redcap/surveys/?s=TPPKA93J9M>

- **Notice of intent to fund: December 1, 2018**
- **IRB/IACUC Approval Deadline: December 5, 2018**
- **Submission to NIH for Prior Approval: December 10, 2018**
- **Funding Cycle: February 1, 2019 through January 31, 2020**

Applications that are late or do not adhere to the instructions may be administratively denied.

LOI AND BIOSKETCH SUBMISSION GUIDELINES

Designated representatives at collaborating CTSA's will review the submission and determine whether a full application will be encouraged.

The LOI must be within a 2-page limit describing the following elements:

- Research Objectives, Specific Aims
 - Provide concise, clear statements regarding anticipated outcomes of the proposed research and how it will add to existing knowledge or create value
- Background and Preliminary Data
- Study Design, Methodology and Anticipated Outcomes
- Description of Qualifications of KL2 Scholar and host CTSA Mentor
 - Additional members of the team (co-investigators) should be included and described (Approximately 1-2 paragraphs)
- Nature of the Collaboration
- Description of a plan on how these data will be used to submit a future grant proposal (priority will be given to applications with a more specific plan and timeline, eg. identification of an NIH program announcement and proposed time line for submission).
- Total Budget Request
 - KL2 CTSA \$25K max
 - Host CTSA \$25K max
 - Brief Budget Justification:

Biosketches of the Multi-PI's must also be attached (not included in the 2-page limit).

❖ ***Note that the expectation is that each CTSA's financial contribution to the pilot will be budgeted for activities at that location.***

LOI submission link: <https://redcap.uky.edu/redcap/surveys/?s=3TPJTADAL3>

FULL RESEARCH PROTOCOL SUBMISSION PROCESS

Once all CTSA's involved have approved the specific project, the investigators will write the full proposal and submit that to their own CTSA's for review. A standard NIH-type study section assessment will be organized involving reviewers from both institutions who will determine if they are supportive of going forward with the project.

Applicants are encouraged to review the instructions provided below carefully.

- Incomplete or incorrectly prepared applications will be returned without review.
- All applications exceeding the requested page limit will be rejected and not reviewed.
- The application 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.

Full Application submission link: <https://redcap.uky.edu/redcap/surveys/?s=TPPKA93J9M>

Applications should be assembled in the following order:

I. Cover Page(s): (not included in the 6 page limit)

1. Title of the Project and Total Amount Requested.
2. KL2 and host CTSA Multi-Principal Investigator Information:
 - Name
 - Degree(s)
 - Rank, Title (s)
 - College
 - Department /Division
 - Campus Address

II. Detailed budget and budget justification in NIH format, direct cost only (not included in the 6 page limit)

Each multi-PI must submit a separate NIH budget proposal (limit \$25K per institution)

Allowable requests include:

- Equipment essential for the conduct of the study
- Data analysis costs
- Participant reimbursement costs
- Research assistant salary support
- Non-faculty personnel salary support
- Project specific specimen collection/analysis or testing
- Chemistry and biological lab supplies
- Purchase of cell lines, cultures reagents etc.
- Animal purchase and housing costs.
- Specimen collection/analysis or testing
- Participant reimbursement/recruitment costs

** Budgets must be pre-approved by their parent institution's Administrative Contact prior to submission.

Budget template can be downloaded here:

http://ccts.uky.edu/ccts/sites/default/files/RFA_doc/Page4_DetailedBudget.docx

III. Abstract and Partnership development (not included in the 6 page limit).

Abstract: The abstract should provide a brief (not more than 250 word) summary of the project. Beneath the abstract, each of the key personnel and their departmental affiliation should be noted. The key personnel should minimally include multi-PIs from both CTSAs. Data analysis consultants (if included), collaborating investigators and others may be listed, if they will play a significant, active role in the conduct of the proposed work. Key personnel listed should provide a letter confirming their role (INCLUDE THESE LETTERS IN THE APPENDIX).

Explain how this partnership will provide new opportunities for the investigators, any development activities that will be conducted throughout the project, and how these activities will build a sustainable infrastructure for an ongoing partnership (not more than 250 words).

IV. 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 and included in the 6 pages of the body proposal)

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 and using the instructions provided below. Start each section with the appropriate section heading—Significance, Innovation, 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)

(a) 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.

(b) 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.

(c) 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.

(d) Preliminary Data

Discuss the multi-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.

V. References (not included in the 6 page limit).

Authors, year, title and journal information are expected for each citation. These **are not** included in the page limit and can be reported at the end of the body of the proposal.

VI. Multi-PI Plan (not included in the 6 page limit).

This section should be no longer than 2 to 3 paragraphs. For instructions/examples of multi-PI plans, please see https://grants.nih.gov/grants/multi_pi/sample_leadership_plans.pdf.

VII. Appendix (not included in the 6 page limit).

- LETTER FROM SUPERVISOR(s)/DEPARTMENT CHAIR(s)

A letter signed by the immediate supervisor(s)/(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.

- PIs and Co-PIs Biosketches in NIH format
- Protection of human-subjects section and animal assurances (if applicable)

Applicants are prohibited from using the appendix to circumvent page limits in any section of the application for which a page limit applies.

REVIEW PROCESS & CRITERIA

Full Applications will be sent to a minimum of two reviewers from each CTSA, with expertise in fields relevant to the science in the proposal. These reviewers will be asked to disclose any

relationships to the grant applicant(s). Full proposals will be subject to a standard NIH-type study section assessment. The reviewers will provide written feedback addressing the merits of the protocol. 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. Applicants will be notified of the outcome.

The general criteria for review include:

- Significance of the work
- Novelty/Innovation of the research idea
- Relevance of the proposed study to translational research
- Existence of a genuine multidisciplinary team in place that is integral to the conduct of the research
- Evidence that the project could not be completed without the partnership between UK and the partner CTSA
- Potential for the project to lead to future external funding or to a commercialization opportunity
- Soundness of the proposed methods
- Feasibility of accomplishing the stated project goals within the 18 months project period

IRB/IACUC GUIDELINES

All applicants will be required to submit proof of IRB/IACUC submission (or proof of exempt status) at the time of Pilot Application Deadline. Applications without requisite IRB/IACUC submission prior to October 15, 2018 will be administratively disqualified. IRB/IACUC approval will be required no later than December 5, 2018. Projects that do not have full IRB/IACUC approval by this date will not be considered for funding. **Please note all pilot IRB protocol titles must match the title of the CTSA pilot application.** Ongoing studies involving human subjects are eligible for pilot funding only if the project submitted for funding is a new unique project that has its own separate IRB submission and approval.

AWARDEE RESPONSIBILITIES

- Once your protocol is fully approved and funding awarded, you should contact your parent institution's Pilot Administrative Contact to schedule a working meeting with the CCTS units involved with your protocol.
- Successful applicants will be required to provide a written 6-month progress report followed by participation in a conference call with representatives from both CTSA's. A final written report describing project accomplishments must be submitted **within 60 days** of the project end date.
- The CTSA's are evaluated by the NIH on their effectiveness in stimulating new research findings and publications. **The following support acknowledgement should be included on all publications that result from support:**

"This publication was supported by the National Center for Advancing Translational Sciences, National Institutes of Health, through Grants UL1TR002529 and UL1TR001998. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH"

CTSA	Administrative Contact
 <p>Center for Clinical and Translational Science <i>Accelerating discoveries to improve health</i></p>	<p>University of Kentucky Elodie Elayi, MS (elodie.elayi@uky.edu) CTSA Grant Number: UL1TR001998 Website: http://ccts.uky.edu</p>
 <p>INDIANA CTSI <small>Clinical and Translational Sciences Institute</small></p>	<p>Indiana University Patricia C. McGuire, MS (pcmguir@iu.edu) CTSA Grant Number: UL1TR002529 Website: www.indianactsi.org</p>