Mentored Translational Research Scholars Program Award (KL2) Information and Instructions for Application

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Translational Research (https://ncats.nih.gov/translation/spectrum)

T1: Pre-Clinical Research connects the basic science of disease with human medicine. During this stage, scientists develop model interventions to further understand the basis of a disease or disorder and find ways to treat it. Testing is carried out using cell or animal models of disease; samples of human or animal tissues; or computer-assisted simulations of drug, device or diagnostic interactions within living systems.

T2: Clinical Research includes studies to better understand a disease in humans and relate this knowledge to findings in cell or animal models; testing and refinement of new technologies in people; testing of interventions for safety and effectiveness in those with or without disease; behavioral and observational studies; and outcomes and health services research. The goal of many clinical trials is to obtain data to support regulatory approval for an intervention.

T3: Clinical Implementation involves the adoption of interventions that have been demonstrated to be useful in a research environment into routine clinical care for the general population. This stage also includes implementation research to evaluate the results of clinical trials and to identify new clinical questions and gaps in care.

T4: Public Health: In this stage of translation, researchers study health outcomes at the population level to determine the effects of diseases and efforts to prevent, diagnose and treat them. Findings help guide scientists working to assess the effects of current interventions and to develop new ones.

Letters of Intent and applications that are not complete or otherwise do not follow the formatting requirements will not be considered for review.

A. Instructions for the Letter of Intent (LOI)

Direct entry

The LOI includes the following sections:

1. Applicant's Information & Eligibility Confirmation
2. Mentors and Collaborators
3. Proposal Information and Structured Abstract

B. Instructions for the Full Application (by invitation only)

All uploaded documents must include your name, sections title/subtitles and numbering *(e.g., Einstein A, 6B-Specific Aims, etc.)*

The full application includes all the following required components:

1. Eligibility Confirmation & Statement & Applicant's Information

Direct entry

2. Scientific Abstract

Direct entry - Limit 500 words.

3. Resubmissions

LIMIT: 1 page, Arial 11 pt. font, 0.5"margins, single-spaced for your response on the steps taken to improve the previous application.

Upload your response, the summary statements and/or reviews as ONE PDF –

This section is to be completed by applicants who have already submitted an application (mentored or Pilot-like) to the Miami CTSI or any other award mechanism, but were not funded.

Reminder: only ONE resubmission to the Miami CTSI KL2 Awards Program is allowed.

4. Introductory Cover Letter

Upload as PDF. The letter must address all the following:

A. Specific areas of health research interest
B. Statement on your career trajectory
C. Statement on how the KL2 award will enhance your research career
D. Statement on how your proposal addresses culturalized health or health disparities.

5. Proposed Research Plan

LIMIT: 6 Pages total, Arial 11 pt. font, 0.5"margins, single-spaced. The 6-page limit applies to all text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the narrative and could confer an unfair competitive advantage is not allowed and may result in administrative withdrawal of the LOI.

Applicants should prepare this section with their mentor(s).

Applicants are strongly encouraged to consult with the Biostatistics Collaboration and Consulting Core (BCCC) at least 3 weeks prior to submission.

The Research Plan must include the following sections:

A. **Preliminary work:** Summarize the research completed toward this project or accomplishments relevant to this project.

B. **Specific Aims:** State concisely the goals of the proposed research and summarize the expected outcomes, including the impact that the results of the proposed research will exert on the field involved.

C. **Significance:** Describe the importance of the problem or critical barrier to progress in the field that the proposed project addresses.

D. **Innovation:** Describe how the application challenges and seeks to shift current research or clinical practice paradigms.

E. **Approach:** Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project.

F. **Analysis Plan:** Describe how the data will be collected, analyzed, and interpreted.

G. **Translational Nature of the Research:** A brief description of the translational, clinical or public health impact of your research. Clearly state how a disease or group of diseases will be better diagnosed, treated or prevented, or how the successful completion of your research will improve human health.

For NIH definitions of Significance, Innovation, and Approach, click here.

6. Proposed Mentoring Plan

LIMIT: 2 Pages, Arial 11 pt. font, 0.5"margins, single-spaced.

This section **must be prepared in collaboration with the mentor(s)**. It must include:

A. Current and longer term research goals (5 years)

B. Proposed timeline to research independence. Provide specific benchmarks and anticipated completion of the research project.

C. Description of all planned activities, including didactic courses that will be incorporated into the career development and mentored research experience. Please outline:

1. Format of Instruction (i.e., face-to-face lectures, coursework, and/or real-time discussion groups. A plan with only on-line instruction is not acceptable). Mentors are required to provide both formal and informal instruction to their mentees.
2. Subjects of Instruction
3. Mentor and other Faculty participation
4. Duration of Instruction: The number of contact hours of instruction, taking consideration the duration of the program.
5. Frequency of Instruction

D. Plan for instructions in the Responsible Conduct of Research (RCR): this plan must be prepared in collaboration with the mentor(s). NIH policy requires that training in responsible conduct of research be an integral part of all research training, that trainees are actively involved at a level appropriate to their career stage, and that research faculty participate in training.

1. All trainees conducting research on human subjects are required to complete the web-based CITI Program training course "Human subjects research (HSR) series" training course.
2. Trainees conducting animal research are required to complete the University's web-based "Animal care and use (ACU) series" training course.
3. All trainees are required to take the face-to-face Responsible Conduct of Research (RCR) course offered by the Ethics Program at the University of Miami (CTI 603, or equivalent), and complete all the on-line modules that best fit their disciplinary background or area of research.
4. As deemed applicable to their line of research by their mentors, trainees must attend clinical research-related training modules provided by the UM Office of Clinical Research Operations & Regulatory Support (CRORS), and/or research compliance related training modules provided by the Office of Research Compliance and Quality Assurance (RCQA). Registration to these classes is done via ULearn. Mentors may require their trainees to take modules refreshers yearly.

IMPORTANT NOTES:

– Trainees must keep their certifications current throughout the period award.

– Trainees and mentors must document all training activities, and be able to provide documentation upon request.

7. Proposed Education Plan

Upload as a PDF - LIMIT 1 Page, Arial 11 pt. font, 0.5"margins, single-spaced.

Describe the training to be completed during the two years of the KL2 award. This training plan might include special training in research techniques, courses which will enhance research capabilities, such as biostatistics or epidemiology, attendance at specific conferences, enrollment in a Master's Degree or Ph.D. program, etc. The lists of required and recommended courses and training are provided in the Individual Research Career Enhancement Plan available on the CTSI website.

8. Budget and budget justification for $30K for research costs

Upload as a PDF - LIMIT 1 Page, Arial 11 pt. font, 0.5"margins, single-spaced.

A detailed budget and budget justification will be required if the proposal is awarded.
List in this section how the yearly $30K will be allocated for research costs:

A. Supplies needed for the conduct of the research project
B. Clinical training and education during the award period
C. Travel to expert labs or scientific meetings during the award period.

9. Information on Human Subjects (If applicable)

Upload as a PDF

Download PHS 398 form "Planned Enrollment" Table available at
http://grants.nih.gov/grants/funding/phs398/phs398.html.

10. Biosketch (NIH Format) AND CV (UM format)

Upload both documents as ONE PDF
Both the Biosketch and the CV are required.

11. Letters of Support and Commitment

Upload all 3 letters as ONE PDF

1. Letter from the scientific/primary mentor
2. Letter from the candidate's chairperson: this letter must include agreement to assure that the candidate will be hired into his/her department for the duration of the award, AND will have 75% protected research time for research.
3. Additional letter of recommendation

12. Regulatory Approvals

Upload as a PDF

If the proposal is awarded, and if your research project requires regulatory approval(s), you will be asked to provide all approval documentation before receiving funding. Research will not start until all the appropriate regulatory approvals are in place:

– Institutional Review Board (IRB) for research involving Human Subjects
– Institutional Animal Care & Use Committee (IACUC) for research involving the use of animals
– Institutional Biosafety Committee (IBC) for research involving the use of recombinant DNA
– Embryonic Stem Cell Research Oversight Committee (ESCRO) for research involving the use of Embryonic Stem Cells or Somatic Cell Nuclear Transfer.

IMPORTANT NOTE: Additional Approval Required: NCATS Delayed Onset Prior Approval

All Miami CTSI KL2 (and Pilots) projects involving human subjects and/or live vertebrate animals **must receive approval from NCATS prior to the involvement of human subjects and/or live**

vertebrate animals.

Why this new requirement? The Miami CTSA grant was submitted to NIH/NCATS with the knowledge that human subjects and/or live vertebrate animals projects may be supported by the grant, but definite plans for these projects could not be described in the application. KL2 projects must be reviewed and approved by NCATS to ensure protection of human subjects and/or live vertebrate animals, appropriate data and safety monitoring, and scientific integrity. This process is called NCATS Delayed Onset Prior Approval (DOPA).

To check if your project involving human subjects is exempt from NCATS DOPA, go to Decision Tree Exemption 4.

The request for approval must be submitted at least 30 days before the involvement of human subjects and/or live vertebrate animals. NCATS prior approval will not be obtained without valid IRB/IACUC approval documentation. Funding will not be released and human subject and/or live vertebrate animals research will not start until NCATS approval is obtained.

For more information on NCATS DOPA, click here.

Applicants invited to submit their full application will be asked to immediately start the NCATS DOPA process (IRB approval, IACUC approval, gathering of required documentation, etc.).

The Miami CTSI staff is committed to providing guidance and support to complete the DOPA process.