UNIVERSITY OF MIAMI
CLINICAL & TRANSLATIONAL SCIENCE INSTITUTE

Miami CTSI

Pilots and Collaborative Translational and Clinical Studies Awards

Information & Instructions for FY19 Application

PLEASE READ THE INSTRUCTIONS CAREFULLY.

Proposals that are incomplete or otherwise do not follow instructions will not be reviewed.

Table of Contents

1. MIAMI CTSI MISSION

- Improve the quality and efficacy of clinical and translational research
- Advance team science
- Culturalize health sciences

2. PURPOSE OF THE MIAMI CTSI PILOT AWARDS

The Pilot funds are meant to support highly innovative, translational (T1 to T4, see inset), interdisciplinary, and/or health disparities-oriented research proposals.

In alignment with its mission, the Miami CTSI will give priority to scientifically meritorious projects that are (1) **directly** related to health disparities and racial/ethnic minority health, or addressing challenges in health areas that disproportionately affect racial/ethnic minorities, and/or (2), **multi-disciplinary projects** where the Principal Investigator and at least one of his/her collaborators are from different fields of expertise.

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.

3. NUMBER OF AWARDS & FUNDS AVAILABLE

The CTSI Pilot Awards will provide funding of up to $40K to up to three studies (*direct research costs only)*.

These funds are intended to be flexible and can be used to fit a variety of scientific needs. Examples of allowable research costs include salaries for technical personnel, laboratory supplies, animals used to conduct the proposed research. Faculty salary is not allowable.

4. AWARD PERIOD

The award period is for one year. The start date of the Pilot awards will be contingent upon the CTSI 2.0 award start date. The research project must be completed within the award period.

No-cost extension (NCE) of support will NOT be available.

5. ELIGIBILITY

(1) Applicant Academic Status:

All **full-time faculty** from UM are eligible. Applicants from Jackson Health System, and the Miami VA are eligible if at least one of their collaborators is a full-time UM faculty.

Adjunct faculty, residents, clinical and post-doctoral fellows are not eligible.

All eligibility criteria must be met at the date of submission. Applications with pending appointments will not be considered.

(2) Only translational research proposals (**T1 to T4)** will be accepted. Basic research studies (T0) will not be considered. The definition of translational research is shown in the inset above.

(3) Type of Submission:

Only new applications and first resubmissions to **any UM internal Awards** will be accepted.

6. LETTER OF INTENT & FULL APPLICATION

Submission to the Pilots awards is a two-step process that requires a **Letter of Intent (LOI)** and a **full application**. LOIs will be screened based on the potential merits of the proposed research. Full applications will be submitted by invitation only.

7. NCATS DELAYED ONSET PRIOR APPROVAL

All Miami CTSI 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. Pilot and 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).

Is your project involving human subjects exempt from NCATS DOPA? Check here: 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.).

8. EVALUATION CRITERIA

The scientific and technical merit of the proposals will be evaluated using the NIH peer review criteria: significance, innovation, and approach.

9. REVIEW AND SELECTION PROCESS

The CTSI Pilot award review process is a two-tier process:

(1) All applications will undergo:
- Scientific and technical merit review by ad-hoc reviewers selected by the CTSI Pilot Director & Leadership.
- Biostatistics, Ethics, and/or Regulatory Review: at the discretion of the CTSI Pilot Director and/or reviewers.

(2) Applications within the funding range will undergo a programmatic review by the CTSI Alignment Committee.

All applicants will receive feedback on their proposal.

10. PROGRESS REPORTING

To allow tracking of the progress and success of each project, the funded investigators will be required to submit:
(1) an interim progress report at 6 months into the funding period, and
(2) a final report at the end of the 12-month funding period, no later than 60 days after the award period.

Detailed information on the content of the reports will be provided ahead of time to the awardees.

11. DEADLINES AND AWARD TIMELINE

Request For Application	June 4, 2018	**Full applications due**	**July 30, 2018**
Letter of Intent (LOI) due	**June 25, 2018**	Funding decisions announced	September 2018
Invitations to submit full application	July 9, 2018	Start of Award *(Contingent upon CTSI start of award & Regulatory Approvals)*	October 2018

12. GENERAL INFORMATION ON AVAILABLE RESEARCH SERVICES

- **Biostatistics Consults:** Biostatistics considerations in the design and analysis of proposed investigations are critical to the procurement of funding and quality of research. The Biostatistics Collaboration and Consulting Core (BCCC), part of the Research Design and Biostatistics Component of the Miami CTSI, is available to provide support for grant proposal development. Applicants are required to schedule appointments with the BCCC at least **three weeks** before the full submission deadline. The Biostatistics Collaboration and Consulting Core request forms are available here.
  Contact Ms. Maria Jimenez-Rodriguez.
- **Regulatory Consults:** CTSI Regulatory Knowledge and Support can assist in meeting FDA and other federal regulatory requirements to establish data safety and monitoring plans and boards, and to ensure/improve the quality of research conducted particularly at the time of study development prior to grant submission.
  Contact: Jonelle Wright, PhD.
- **Clinical Translational Research Site (CTRS, previously CRC)**: For procedures required for study participants, implementation of study protocols and data collection. CTRS services/resources request forms are available here.
  Contact: Halina Kusack, PhD.
- **Other CTSI Research Services:** The CTSI supports research within a coordinated platform of research core services with the goal of advancing high quality interdisciplinary clinical and translational research that will lead to improved health in our communities, especially those of ethnic/cultural minorities and the medically underserved.
  Information on CTSI services/resources can be found below and on the CTSI website here.
- **Community Engagement and Cultural Diversity:** For consultations on conceptual, methodological and analytic issues with research with racial/ethnic minorities; strategies for recruiting research participants; establishing community research partnerships; and disseminating findings to relevant stakeholders.
  Contact: Ms. Brendaly Rodriguez.
- **Research Ethics:** For consultations on ethical considerations. Contact: Kenneth Goodman, PhD.
- **Information on additional services provided at UM** but not funded by the CTSI can be found here.

13. INSTRUCTIONS FOR APPLICATION

1. General Instructions for Letter of Intent and Full Application

Letters of Intent and full applications that are incomplete or otherwise do not follow instructions will not be considered for review.

- Adhere to all page limitations
- Follow the format requirements for all uploaded documents:
  - Font: Arial, 11 pt.
  - Margins: 0.5 inch for ALL margins
  - Single-space
- Appendices are not allowed.
- The applications are submitted electronically.
- **All uploaded files must include your name and the section # & title** *(e.g., EINSTEIN-4.2.2 References)*
- To resolve any technical issue with the electronic submission, please contact the Program Administrator during office hours and before the deadline.
- Use the templates provided within the application form and/or on the Miami CTSI website.

2. *Instructions for the Letter of Intent*

Letters of Intent are required and will be screened based on the merits of the proposed research.

The LOI consists of the following components:

1. **Applicant Information**
2. **Collaborators and Key Personnel:** Provide the name, organization, and role of all collaborators and key personnel associated with the application.
3. **Conflicts of Interest:** List all individuals other than collaborators and key personnel who may have a COI in the review of the application (including those with whom the PI has a personal or professional relationship, e.g., mentors).
4. **LOI Files:** The files include the structured LOI Narrative & Supporting Documentation.

4.1. LOI Narrative

The LOI Narrative includes all the following sections *(Direct Entry)*

4.1.1. Research Strategy and Feasibility *(LIMIT:400 words):* Concisely state the project objectives and specific aims. State the ideas and reasoning on which the proposed work is based. Explain the rationale for selecting the specific target(s) for investigation and the feasibility of the study leading to a potential therapy/solution in your research area.

4.1.2. Innovation *(LIMIT:400 words):* Describe how the project may introduce a new paradigm, challenge current paradigms, introduce novel concepts or agents, or exhibit other uniquely creative qualities that may lead to a potential therapy/solution in your research area.

4.1.3. Impact *(LIMIT:400 words):* State explicitly how the proposed work will have an impact on the development of therapy/solutions in your research area . Outline, in general terms, steps to transition the study outcomes to therapeutic application.

4.1.4. Health Disparities *(LIMIT:400 words):* Describe how the proposed work is related to health disparities, and addresses challenges in health areas that disproportionally affect racial and ethnic minorities.

4.1.5. Translational Nature of Project *(LIMIT:300 words):* Describe where the proposed project belongs on the translational T1 to T4 science spectrum (see NCATS definitions), and provide a brief justification.

4.2. LOI Supporting Documentation

The items to be included as supporting documentation for the LOI ***must be uploaded as individual files*** and are limited to the following:

4.2.1. Principal Investigator and Key Personnel Biographical Sketches *(LIMIT: 5 pages per individual). All biosketches should be uploaded as* ***one combined file:*** Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

4.2.2. References Cited *(LIMIT: one-page):* List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, reference title, and reference source, including volume, chapter, page numbers, and publisher, as appropriate).

4.2.3. List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols used in the LOI Narrative.

3. *Instructions for the Full Application (by invitation only)*

The full application includes the following sections:

- Section 1: Principal Investigator Information
- Section 2: Project Information

- Section 3: Research Plan
- Section 4: Supporting Documentation
- Section 5: Letters of Commitment and Support
- Section 6: Regulatory Approvals

SECTION 1: PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Please note that an **eRA NIH Commons username** will be required not only for the Awardees, but also for their collaborators, and all students working on this project. The process of registration may take a few weeks. If eRA accounts need to be created, please make sure to initiate this process as soon as possible[1].

Demographics: If you do not wish to provide information, check the *"Do not wish to provide"* answer.

SECTION 2: PROJECT INFORMATION

2.A. Project Title

2.B. Public Health Relevance Statement *(LIMIT: 5 sentences):* The purpose of this statement is to clearly articulate the project's potential to improve public health. The public health relevance statement should be written in plain language that can be understood by a general, lay audience, reviewers and colleagues.

2.C. Scientific Abstract: *(LIMIT: 300 words)*

2.D. Type of Application (new application, resubmission)

For resubmissions, a copy of the reviewers' critiques and your response addressing the critiques will be required in Section 3A.

Only **one** resubmission to the Miami CTSI Pilot Awards for any given project is allowed.

2.E. Total budget requested- Enter here only the estimated budget total. Budget details will be required in Section 4 of the application

2.F. Co-Investigators: List the names of your Co-Investigators in this project, their role, their institution, and their department/division.

2.G. Potential Commercialization of the Project: Will your research eventually lead to commercialization? What is your estimated timeframe? If you would you like to discuss the project's potential to commercialization, please contact Dr. Bin Yan, Office of Transfer Technology Director.

SECTION 3: RESEARCH PLAN

The Research Plan will be uploaded into the on-line application. It includes the following sections:

3.A. INTRODUCTION TO APPLICATION (FOR RESUBMISSIONS ONLY)

LIMIT: 1 PAGE, Arial font, 11 point, single-spacing, 0.5" all margins

If this application is a resubmission to any earlier UM internal grant application, you are required to complete this section, and address the specific critique(s) raised by the reviewers. Summarize the substantial additions, deletions, and changes to the application. Explain any significant changes to the specific aims and new directions.

The review panel will consider your response, however resubmission does not guarantee funding.

You will also be asked to upload a copy of the critiques.

[1] To create an eRA account, click here.

3.B. SPECIFIC AIMS

LIMIT: 1 PAGE, Arial font, 11 point, single-space, 0.5" all margins

- 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.
- List succinctly the specific aims of the proposed research (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).

3.C. RESEARCH STRATEGY

LIMIT: 6 PAGES, Arial font, 11 point, single-space, 0.5" all margins

Organize the Research Strategy in the order specified below. Start each section with the appropriate section heading (i.e., 3.C.1. Significance; 3.C.2. Innovation; 3.C.3. Approach).

Cite published experimental details in the Research Strategy section and provide the full reference in the Bibliography and References Cited section (Section 3E).

3.C.1. 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.
- **IMPORTANT:** Describe how your project addresses **health disparities.**

3.C.2. 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 interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

3.C.3. 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, and any resource sharing plans as appropriate.
- If the project is in the early stages of development, describe any strategy to establish feasibility.
- Discuss anticipated results (including benchmark for assessing success to achieve the proposed aims), and potential problems. Provide a timeline for project completion within one year.

3.D. LONG-TERM GOALS (LIMIT: 500 words, Arial font, 11 point, single-space, 0.5" all margins)

- Describe the future direction of your research, your long-term goals, and the project timeline for submitting extramural grant application(s).
- Specify which type of grant you expect to submit.
- Describe how the goals of the submitted proposal and future extramural grant(s) may promote the overarching goal of the CTSI, which is to incorporate ideas and approaches from multiple

disciplines and/or propose innovative translational research initiatives to help reduce health disparities in our community.

3.E. BIBLIOGRAPHY AND REFERENCES CITED *(Not included in the 6-PAGES LIMIT)*

Include at least the first three authors, full title of the article, journal, volume and page numbers.

SECTION 4: SUPPORTING DOCUMENTATION: Resources, Budget and Biosketches

4.A. RESOURCES AND BUDGET

The budget details and justification will be carefully reviewed by the CTSI fiscal manager.
Use the templates provided on the Miami CTSI website, or within the application.

4.A.1. Resources: This information is used to assess the capability of the organizational resources available to perform the effort proposed. Identify the facilities to be used (Laboratory, Animal, Computer, Office, Clinical and Other). If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Describe only those resources that are directly applicable to the proposed work.

4.A.2. Budget Details: This is a *modified* NIH template: it includes direct costs only, and outlines which items are "not allowable".

Each award is limited to **$40,000** for direct costs only, for a **one-year** project period.

Since this one-year award period spans over two fiscal years, please provide a **quarterly breakdown** of the budget, as displayed in the template.

The Miami CTSI expects budgets to be realistic estimates. The Pilot Awards funds are intended to be flexible and can be used to fit a variety of scientific needs, including salaries for technical personnel, supplies and other miscellaneous items required to conduct the proposed research.

Only allowable direct costs may be charged.

Faculty salary is not an allowable expense within the budget.

Patient care is not an allowable expense within the budget.

Equipment and Travel: Requests for equipment and travel are not encouraged, but may be considered on a special needs basis, contingent upon appropriate written justification. Travel for awardees is restricted to (i) attendance at conferences where the awardee will present findings from this study, (ii) workshops and trainings associated with the research, and/or (iii) the travel is required for the performance of the study.

4.A.3. Budget Justification: Provide a justification for each item listed in the budget. Use the provided template:

- Senior/Key Personnel & Other Personnel:
  - Names and positions of all personnel must be individually listed and the percentage of time to be devoted to the project by each person should be noted even when no salary is being requested. If the individual has not yet been selected, please list as "TBD."
  - Justify the need for each person listed.
  - Information regarding UM-Approved Composite Fringe Benefit Rates for FY 2018 is available here.
- Reagents, Supplies, Animals, Expenses related to Study Participants
- Core services (not CTSI cores)

4.B. CURRENT BIOSKETCHES FOR THE PRINCIPAL INVESTIGATOR AND EACH CO-INVESTIGATOR

Upload your current biosketch and the biosketches of all Co-Investigators as ONE PDF.

Each biosketch will include:

4.B.1.Positions and Honors.

4.B.2. Selected Peer-Reviewed Publications: Provide a bibliography of any references cited in the Research Plan. Each reference must include the names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. Make sure that only bibliographic citations are included.

4.B.3. Research Support:

- Include (i) ongoing research support and (ii) completed research support.
- Include both institutional and extramural support and indicate any potential scientific overlap.

SECTION 5: LETTERS OF SUPPORT AND COMMITMENT

*Upload all Letters of Support as **ONE** PDF.*

- Letters of commitment in your application should clearly spell out the roles of your collaborators. The award application should contain a **signed and dated letter from each collaborator** that lists the contribution he/she intends to make and his/her commitment to the work. These letters are often the primary assurance to the reviewers that this work can/ will in fact be done.
- For New Investigators, a letter from the Department Chair is **highly recommended**. The letter should state whether the applicant has independent laboratory space and has established an independent research project/program, or if she/he is on the path of becoming independent. If it is the latter, the letter should state how the CTSI Award will help achieve the independent status for the applicant, and which arrangements (provide specifics) can be made to ensure the applicant's path of independence if the grant is funded.
- For consultants, letters should include rate/charge for consulting services.

SECTION 6: REGULATORY APPROVALS

- **REGULATORY APPROVALS:** If your research involves Human Subjects, animals, embryonic stem cells, and/or recombinant DNA, you must obtain regulatory approval from the IRB, IACUC, ESCRO and/or IBC, respectively.

  IMPORTANT: Funds cannot be released until all the appropriate regulatory approval are in place. These include the NCATS Prior Approval for human subjects research and live vertebrate research. All these processes may take weeks. Initiate them as early as possible.

- **ENVIRONMENT SAFETY** (if applicable): Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.

14. SUBMITTING YOUR APPLICATION

After you complete and submit your LOI and later your application, you will receive acknowledgement of your electronic submission.

IMPORTANT! If you have not received a confirmation of receipt, your application may not have gone through. Please contact the Program Administrator (Patricia Avissar at 305-243-5085 or at pavissar@med.miami.edu) during office hours and before the deadline to resolve the issue.