

CTSI PILOT AWARDS - FY2022- FULL APPLICATION

Dear Pilot Awards Applicant,

Thank you for your interest in the CTSI Pilot funding opportunity.

The full application is due on Wednesday, April 28, 2021 at 11:59 PM. Late applications will not be accepted. No exceptions.

After your application is submitted, the system will generate an automated message to notify you that your electronic submission was received.

Important! If you do not receive the automated message, your application will be considered incomplete, and will not be reviewed.

Contact Patricia Avissar before the deadline to resolve the issue (305-243-5085 (office hours) or at pavissar@med.miami.edu)

Proposals that are incomplete or otherwise do not follow instructions will not be considered for review.

Best regards,

The Miami CTSI Team

SECTION 1: PRINCIPAL INVESTIGATOR & PROJECT ELIGIBILITY

ELIGIBILITY (1): By checking ALL THREE boxes below, I confirm that, at the time of submission, I fulfill ALL THREE eligibility criteria of the Miami CTSI Pilot Awards:

- I am a FULL-TIME Assistant Professor or Associate Professor at UM, JHS or the Miami VA.,
- This proposal is a TRANSLATIONAL research project (T1, T2, T3, or T4).
- This proposal is a NEW submission, or a FIRST RE-SUBMISSION to a UM internal award.

Date UM faculty appt:

Based on the definition of NCATS Translational Science Spectrum, the best way to describe this project is...

- Pre-Clinical Research
- Clinical Research
- Clinical Implementation
- Public Health

What best describes your proposal? Select only what applies to you

- The proposal directly addresses health disparities and minority populations health
- The proposal addresses health issues across the lifespan (aging, pediatrics, etc.)
- The proposal offers novel informatics, diagnostics, or data capture tools; or patient-reported data methods
- The proposal offers novel methods to engage and recruit underserved populations of all ages
- The proposal studies barriers to translating research knowledge to care and policies
- The proposal involves collaborators from more than one field of expertise, i.e., from two different schools or departments.
- The Principal Investigator is from an under-represented minority in sciences and medicine (Note: Women are NOT an under-represented minority in sciences and medicine; Asian and White/Caucasian individuals are NOT an under-represented minority in sciences and medicine)

SECTION 2: PRINCIPAL INVESTIGATOR - INFORMATION

Last Name

First Name

Middle Name or Initial

Institution - Check all that apply

- UM
 JHS
 VA

Primary Department

Division (if applicable)

Academic Rank (CTSI only)

- Full-Time Associate Professor
 Full-Time Assistant Professor

Tenure Status

- Tenured On tenure-track Not on tenure-track / Research

Degrees (Newest on top) Name (e.g. MD, PhD, etc.) Date Received (e.g. 2018)

Degree 1 _____

Degree 2 _____

Degree 3 _____

Email Address (UM, JHS or VA email address only, NO gmail, hotmail, etc.)

Phone number(s) where you can easily be reached for clarifications

Gender

Female Male Do not wish to provide

Race (Check all that apply)

- American Indian/Alaska Native
 Asian
 Black/African American
 Native Hawaiian/Other Pacific Islander
 White/ Caucasian
 Unknown
 Other
 Do not wish to provide
-

Ethnicity

Hispanic or Latino/a Not Hispanic or Latino/a Do not wish to provide

SECTION 3: MENTORS AND COLLABORATORS

MENTOR TABLE Name Dept/Div (Institution if not UM) Mentoring Role

Mentor 1 (If not applicable, enter N/A) _____
Mentor 2 (If not applicable, enter N/A) _____
Mentor 3 (If not applicable, enter N/A) _____

COLLABORATOR TABLE Name Dept/Div (Institution if not UM) Role in Project (MAX 20 words) e.g. Co-I, genomics services, etc.

Collaborator 1 (If not applicable, enter N/A) _____
Collaborator 2 (If not applicable, enter N/A) _____
Collaborator 3 (If not applicable, enter N/A) _____

SECTION 4- SUBMISSION TYPE (New or 1st re-submission)

4.A SUBMISSION VERSION (Note: Only first submission and first re-submission are allowable)

This proposal is:

- New application (was never submitted to any UM internal grant mechanism (e.g., CTSI, CFAR, Cancer Center, etc.)
 FIRST re-submission from a UM internal grant mechanism (e.g., CTSI, CFAR, Cancer Center, etc.). NOTE: Re-submitted proposals are not guaranteed to be selected for this round of award, as they are competing with all new proposals.
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4.B. Since this proposal is a re-submission to any UM internal award mechanism, provide the following information:

- (1) under which title the project was originally submitted,
(2) to which mechanism, and
(3) when the proposal was submitted.
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4.C. FOR RE-SUBMISSIONS ONLY: Upload the FULL Summary Statement/Critiques/Reviews of your previous submission.

4.D. FOR RE-SUBMISSIONS ONLY- LIMIT 1 PAGE - Arial font, 11 point, single-spacing, 0.5" all margins.

Respond to the specific critique raised by the reviewers at the first submission.

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.

SECTION 5: RESEARCH PROPOSAL - Outline

5.A. Project Title

5.B. Public Health Relevance Statement or Public Narrative (LIMIT: 100 WORDS)

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

5.C. SCIENTIFIC ABSTRACT (LIMIT: 300 WORDS) - Include the objective, study design and data analysis.

SECTION 6: RESEARCH PLAN

The Research Plan will include all the following sections, merged into ONE PDF.

All sections must be written in Arial font, 11 point, single-spacing, 0.5" all margins and follow the PAGE LIMIT restrictions.

Each new section must start on a new page and must include the section title (Specific Aims, Research Strategy, etc.) at the top of the page.

6.A SPECIFIC AIMS

6.B RESEARCH STRATEGY

6.C LONG-TERM GOALS

6.D REFERENCES CITED

Proposals that are incomplete or otherwise do not follow instructions will not be considered for review.

Section 6: RESEARCH PROPOSAL - INSTRUCTIONS - READ CAREFULLY**6.A. Specific Aims - LIMIT 1 PAGE - Arial font, 11 point, single-spacing, 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 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).

6.B. Research Strategy LIMIT 6 PAGES - Arial font, 11 point, single-spacing, 0.5" all margins.

Address ALL the sections 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.
- **IMPORTANT:** Describe how your project addresses health disparities.

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.

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.

6.C. Long-term Goals LIMIT 400 WORDS - Arial font, 11 point, single-spacing, 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).
- Explain how this project is important to your career goals
- 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.

6.D. Bibliography & References Cited - No page limit- Arial font, 11 point, single-spacing, 0.5" all margins

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

DO NOT INCLUDE ANY VISUALS OR ANY INFORMATION THAT IS NOT A CITED REFERENCE.

INCLUDE ONLY THE REFERENCES CITED IN YOUR NARRATIVES. YOUR OWN PUBLICATIONS WILL BE LISTED IN YOUR BIOSKETCH.

6- RESEARCH PROPOSAL UPLOAD

MAKE SURE THIS SECTION INCLUDES ALL THE REQUIRED SECTIONS, AND THAT PAGE LIMITS ARE RESPECTED

Proposals that are incomplete or otherwise do not follow instructions will not be considered for review.

SECTION 7 - BUDGET & BUDGET JUSTIFICATION

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This section will include the 2 following sections, merged into ONE PDF.

7.A Budget (Use the template provided here and/or on CTSI website)

7.B Budget justification (Use the template provided on CTSI website)

Proposals that are incomplete or otherwise do not follow instructions will not be considered for review.

NOTE: the merging of these two documents might take time because of the Excel spreadsheet. Make sure the merged PDF is complete and readable.

[Attachment: "Miami_CTSI_Pilot_Awards-FY2022-Budget Template2.xlsx"]

7.A. BUDGET UPLOAD

Please make sure that the merged PDF includes the 2 required sections

SECTION 8 - LETTERS OF SUPPORT AND BIOSKETCHES

8.A. SUPPORTING DOCUMENTATION: BIOSKETCHES

Upload YOUR Biosketch and the Biosketch of each Co-Investigator, as ONE PDF.

Each biosketch will include the following sections:

- Positions and Honors

- Selected Peer-Reviewed Publications

- Research Support:

Include (i) ongoing research support and (ii) completed research support.

Include both institutional and extramural support and indicate any potential scientific overlap.

8.B. LETTERS OF SUPPORT AND COMMITMENT

Upload all the letters AS ONE PDF

- Collaborators: Letters of commitment from your collaborators should clearly spell out their roles in the project. The application should contain a signed and dated letter from each listed collaborator that outlines the contribution he/she intends to make and his/her commitment to the project.

- Department chair: For Junior 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.

- Consultants: letters should include rate/charge for consulting services.

SECTION 9 - REGULATORY APPROVALS

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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 (see below).

These processes might take several weeks. Initiate them as early as possible.

	Not Applicable	Approval is already obtained for this project	Submission process is initiated	Submission process is not initiated
IRB - Institutional Review Board- for research involving HUMAN SUBJECTS	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
IACUC - Institutional Animal Care and Use Committee- for research involving animals	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
ESCRO - Embryonic Stem Cell Research Oversight Committee- for research using Stem Cells	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
IBC - Institutional Biosafety Committee- for research using recombinant DNA	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Provide a copy of approval letters for IRB, IACUC, ESCRO, or IBC, as appropriate. If you have two or more approval letters, please merge them into ONE PDF.

CTSI Applications: NCATS Delayed Onset Prior Approval

All CTSI Pilots projects involving human subjects and/or live vertebrate animals must receive approval from NCATS in addition to the IRB and IACUC approvals.

For more information on NCATS Delayed Approval, [click here](#).

ENVIRONMENT SAFETY

Does your research involve any procedures, situations, or materials that may be hazardous to personnel?

Yes No

If yes, specify what are these procedures, situations, or materials, and which precautions will be exercised

10- MISCELLANEOUS

Could your research project eventually lead to commercialization?

Yes No Not sure

If you would you like to discuss the project's potential to commercialization, please contact Dr. Bin Yan (byan@miami.edu), Office of Transfer Technology Director.

If yes, what is your estimated timeframe?

IMPORTANT NOTE about External Reviewers:

Due to the challenges posed by conflicts of interest, we may consider to involve external reviewers. Do you agree to have your proposal reviewed by external reviewers if necessary?

Yes No

Provide up to 4 keywords that best describe your research project.
