Dear Pilot Awards Applicant,

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

The full application is due on Wednesday, March 4, 2020 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 may not be complete, and as such, cannot be reviewed.

Please contact the Program Administrator before the deadline to resolve the issue:

- CTSI: Patricia Avissar at 305-243-5085 (office hours) or at pavissar@med.miami.edu

- CFAR and IAEID: Patricia Wahl at 305-243-0810 (office hours) or at pwahl@med.miami.edu

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

Best regards,

The Miami CTSI & CFAR/IAEID Teams

Pilot Mechanism(s) Selected by the Review Committee

☐ CTSI  ☐ CFAR  ☐ IAEID

PRINCIPAL INVESTIGATOR - CONFIRMATION OF ELIGIBILITY FOR CTSI APPLICATIONS

Date UM faculty appt:

ELIGIBILITY (1): By checking ALL THREE boxes below, I confirm that, at the time of submission, I fulfill ALL the 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.
Based on NCATS Translational Science Spectrum (see Instructions document), the best way to describe this project is...

- T1: Pre-Clinical Research
- T2: Clinical Research
- T3: Clinical Implementation
- T4: Public Health

What best describes your proposal? Select all that apply:

- 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)

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**PRINCIPAL INVESTIGATOR - CONFIRMATION OF ELIGIBILITY FOR CFAR and IAEID APPLICATIONS**

What best describes your proposal? Select all that apply:

- AIDS-associated malignancies
- HIV prevention and drug-abuse/health equity
- HIV and women
- Cure/reservoirs
- Vaccines and immunology
- NeuroAIDS, co-morbidities and co-infections
- Translational research
- Emerging concepts

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**SECTION 1: PRINCIPAL INVESTIGATOR INFORMATION**

Last Name

________________________

First Name

________________________

Middle Name or Initial

________________________

Institution - Check all that apply

- UM
- JHS
- VA
- Other (for CFAR and IAEID applicants only)

If other institution, please specify

________________________
Primary Department


Division (if applicable)


Academic Rank (CTSI only)

○ Associate Professor
○ Assistant Professor

Academic Rank (CFAR & IAEID only)

○ Associate Professor
○ Assistant Professor
○ Professor
○ Assistant Scientist
○ Post-Doctoral Associate
○ Other

If other rank, please specify


Tenure Status

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

Degree(s) - Check all that apply

□ MD □ PhD □ Other

If you hold another degree, please specify


NIH eRA Username


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


Phone number(s) where you can easily be reached for clarifications
SECTION 2: PROJECT INFORMATION

Rigorously follow the instructions provided within the application form.
Follow the requested format for your uploaded files names.

2.A. Project Title

__________________________________

2.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.

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

2.D. TYPE OF APPLICATION (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.)

2.E. TOTAL BUDGET REQUESTED (Projects with budgets exceeding the limit offered will not be considered).
A detailed/itemized budget will be required in Section 4.B. of the application.

2.F. COLLABORATORS
Please list ALL your Collaborators involved in this project, and provide for each:
- Full name, Institution, Department/division, and Brief (20 words max.) description of role in your project (e.g., Scientific Mentor; e.g., Co-Investigator for Genomic analysis)

You will be required to upload your NIH BioSketch and the BioSketch of each listed Co-Investigator in Section 4.C.

[Attachment: "Collaborators Table JAN2020.xlsx"]

2.F. COLLABORATORS TABLE: please upload your Collaborators Table. Use the template in the field above.
File Name Format: YourLASTNAME_2F Collaborators

2.G. Could your research project eventually lead to commercialization?
- ☐ Yes  ☐ No  ☐ Not sure

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

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

SECTION 3: RESEARCH PLAN

To complete this section, follow the application instructions available on the Miami CTSI website.

Format requirements for ALL uploaded sections: Arial font, 11 point, single-spacing, and 0.5" for all margins.

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

3.A.1. 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.

File Name Format: YourLASTNAME_3ACritiques

3.A.3. 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.
File Name Format: YourLASTNAME_3A Response to Critiques

3.B. 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).

File Name Format: YourLASTNAME_3B Aims
3.C. Research Strategy LIMIT 6 PAGES - Arial font, 11 point, single-spacing, 0.5" all margins.

Address ALL the sections below:

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.

File Name Format: YourLASTNAME_3C Strategy

3.D. Long-term Goals (CTSI application) 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

File Name Format: YourLASTNAME_3D Goals CTSI

3.D. Long-term Goals (CFAR or IAEID application) 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

File Name Format: YourLASTNAME_3D Goals

3.E. 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.

File Name Format: YourLASTNAME_3E Biblio
All CFAR and IAEID-funded projects are required to use relevant CFAR Cores. Please visit the CFAR website to identify these cores and services.
Resources: List the cores and services you will be using in this project.

SECTION 4: SUPPORTING DOCUMENTATION; BUDGET & BIOSKETCHES

4.A. BUDGET
Follow the instructions provided in the RFA & Instructions document.
Use the budget template provided on CTSI webpage, under "Forms".
File Name Format: YourLASTNAME_4 Budget

4.B. RESOURCES & BUDGET JUSTIFICATION
Use the budget justification and resources template provided on CTSI webpage, under "Forms".
File Name Format: YourLASTNAME_4 Justification

4.C. 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.
File Name Format: YourLASTNAME_4CBiosketches

SECTION 5: LETTERS OF SUPPORT AND COMMITMENT

5. LETTERS OF SUPPORT AND COMMITMENT
Upload all the letters in ONE PDF
- 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.
- Collaborators: Letters of commitment from your collaborators should clearly spell out their roles in the project. 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.
- Consultants: letters should include rate/charge for consulting services.
File Name Format: YourLASTNAME_5LOS
SECTION 6: 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 (see below). These processes might take several weeks. Initiate them as early as possible.

<table>
<thead>
<tr>
<th>IRB - Institutional Review Board- for research involving HUMAN SUBJECTS</th>
<th>Approval is already obtained for this project</th>
<th>Submission process is initiated</th>
<th>Submission process is not initiated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Applicable</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IACUC - Institutional Animal Care and Use Committee- for research involving animals</th>
<th>Approval is already obtained for this project</th>
<th>Submission process is initiated</th>
<th>Submission process is not initiated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Applicable</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ESCRO - Embryonic Stem Cell Research Oversight Committee- for research using Stem Cells</th>
<th>Approval is already obtained for this project</th>
<th>Submission process is initiated</th>
<th>Submission process is not initiated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Applicable</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IBC - Institutional Biosafety Committee- for research using recombinant DNA</th>
<th>Approval is already obtained for this project</th>
<th>Submission process is initiated</th>
<th>Submission process is not initiated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Applicable</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>

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.

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

CTSI Applications: NCATS Delayed Onset Prior Approval
All 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 use of live vertebrate animals. 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 be obtained only with 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 Delayed Approval, click here.

Applicants invited to submit their full application are recommended to familiarize themselves with the NCATS Delayed Onset process (IRB approval, IACUC approval, gathering of required documentation, etc.).

Prior Approval requests that involve human subjects research, including studies that may be considered exempt, will be submitted via the new NIH Human Subjects System (HSS). The HSS is active and submission via the HSS will be required starting Jan. 1, 2019.

For studies that require the use of live vertebrate animals, further information will be provided when made available by NCATS.
CFAR Applications: NIH Clearance
Should your project be awarded and considered greater than minimal risk by the IRB, involves vulnerable populations and/or has an international component, it will need additional clearance from NIH and funds cannot be expended from the CFAR account until this clearance has been obtained.

The process to request additional NIH clearance will start if your project is awarded. For more information on this requirement, visit http://www.niaid.nih.gov/LabsAndResources/resources/cfar/Pages/guidelines.aspx. The NIH considers children as under age 18 and thus, as a vulnerable population and will need NIH clearance.

SECTION 7: INVESTIGATOR PERSONAL DATA

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  ☐ Not Hispanic or Latino  ☐ Do not wish to provide

IMPORTANT NOTE about External Reviewers:
Due to the challenges posed by conflicts of interest, we may consider to involve external reviewers. Would you agree to have your proposal reviewed by external reviewers?

☐ Yes  ☐ No