

FY19 PILOT AWARDS APPLICATION INSTRUCTION GUIDE

The goal of this document is to provide applicants with the information necessary to successfully complete an application for the FY19 Pilot Awards (letter of intent and full application).

Deadlines/Award Timeline

- Speed Review (Optional) **April 4th, 2018**
- Letter of Intent (LOI) due **April 23rd, 2018 by 5pm** (Note: Although not required, the LOI allows us to assess the responsiveness of the RFA and to help identify potential reviewers)
- Pilot Grant Applications due **May 1st, 2018 by 5pm**
- Funding decisions will be announced by May 2018

Purpose

The University of Miami Miller School of Medicine Center for AIDS Research (CFAR) Institute of AIDS and Emerging Infectious Diseases (IAEID) are now accepting applications for pilot projects in HIV/AIDS research. The purpose of this program is to stimulate new research and collaborations between basic and clinical researchers for generation of supporting preliminary data to increase competitiveness for extramural HIV/AIDS funding. Areas of interests include: AIDS-Associated Malignancies, HIV Prevention and Drug Abuse/Health Equity, HIV and Women, Cure/Reservoirs, Vaccines and Immunology, NeuroAIDS and Co-morbidities and Co-infections. Applications for translational research and emerging concepts will be accepted. In the past we have had separate RFAs but this year we are joining the CFAR and IAEID RFAs into one.

Funds Available/Award Period

Awards of approximately \$50,000 each (direct costs only) will be issued, with a 1 year project period (approximately June/July 2018-May/June 2019).

Eligibility

Investigators at the rank of Assistant Professor (in the research or clinical tracks) or above are eligible to apply. CFAR membership is not a requirement. CFAR gives priority to junior investigators, investigators new to HIV/AIDS and established investigators proposing projects representing a new area of study for them. State of Florida focuses on high impact research that can be completed in a short amount of time, regardless of senior or junior status. Collaborative projects are encouraged and defined as those involving two or more investigators from different disciplines, and/or different departments. Behavioral science investigators are encouraged to collaborate with clinical and basic scientists. Post-doctoral associates may apply if they have three or more years of experience and are working towards a transition to faculty status. Women and minorities are encouraged to apply. We strongly encourage applicants to strengthen their application by including a UM collaborator. Previous CFAR or State awardees are eligible to apply as long as there is no scientific overlap of any projects.

Speed Grant Review Program

The goal of the Speed Grant Review Program is to provide investigators applying for a CFAR/State pilot award with a critique that will increase the likelihood of obtaining funding. Attendees will receive one-on-one feedback on their Specific Aims page from up to 3 University of Miami faculty. Reviewers will be NIH funded researchers with experience as NIH/CDC/PCORI reviewers and with a background in HIV research.

The Speed Grant Review will be held on **April 4th, 2018** to enable participants to apply the critique to applications being submitted to the CFAR on **May 1st, 2018**.

- Participants should be investigators planning to apply for a pilot award.
- Participation in this program is voluntary but strongly encouraged for junior and mid-level investigators and those senior investigators new to the area of HIV research.
- Participants should submit a single page draft of their proposed specific aims prior (due to Patricia Wahl by **March 21st, 2018**) to the Speed Grant Review Program for review.
- Each applicant will have 20 minutes of feedback on their application per reviewer; following the 1st reviewer, the applicant will move to the next reviewer.

Speed Grant Review Program Duration (2 hours)

- Introduction of the CFAR mentoring program to Applicants and Reviewers (20 mins)
- Speed review (approx. 1.5 hrs)
- Summary (10 mins)

Space is limited so please contact Patricia Wahl (305-243-3345) pwahl@med.miami.edu no later than Thursday, March 15th, 2018 if you are interested in participating.

Mentoring

Mentoring is a critical component for the success of the pilot projects. Mentoring services are offered through the CFAR Mentoring Program, under the Developmental Core. Assistant professor level, post doc level and any investigator new to HIV/AIDS are required to have a mentor and are encouraged to take advantage of these services and select a mentor if they do not already have one. The Miami Clinical and Translational Science Institute (CTSI) also provides mentoring and grant writing assistance <http://miamictsi.org/>.

As part of the terms of the pilot awards, both mentors and mentees are required to participate in the activities organized by the CFAR mentoring program (i.e. speed review, mentoring seminars and workshops) and complete evaluations of the mentoring relationship as specified on the CFAR website <http://cfar.med.miami.edu/developmental-core/mentoring-program>.

Biostatistics

Each applicant will be required to meet with the Biostatistics Core before their final application is submitted in order to review statistical analysis methods. In order to schedule an appointment please make your request through the following link <http://cfar.med.miami.edu/clinical-sciences-core/request-biostatistics-service> and click "CFAR Biostatistics Usage Request Form". In the section "project title" please put "Pilot Award FY19 Application" and under "category" please mark "other"

Review Criteria

Reviews will be based on scientific merit and the likelihood of attracting NIH or similar funding in the future. All applicants will receive feedback on their proposals. Specific criteria include:

- Innovation and significance to HIV/AIDS Research
- Scientific merit of proposed research
- Probability of subsequent peer review funding
- Investigator productivity

Progress Reporting Requirements

To allow tracking of the progress and success of each project, the funded investigators will be required to submit a progress report each February, whether interim or final, until the end of the project.

Additional Information

Please visit <http://cfar.med.miami.edu/> for more information on all of the CFAR services. We suggest that you contact the cores as soon as possible for assistance.

Biostatistical assistance and IRB protocol assistance is available through the CFAR Clinical Core. Information on the recruitment and retention of subjects is available through the Behavioral and Clinical Cores.

CFARs are not allowed to fund clinical research studies that include randomization to one or more low risk interventions to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. Please read over <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html> for details.

General Instructions

- The LOI and application for the Pilot Awards must be submitted electronically. REDCap from Vanderbilt University is the software used to develop the letter of intent and the application forms.
- You can find the links to both the LOI and full application at <http://cfar.med.miami.edu/developmental-core/pilot-grants>.
- You can save the information entered at any time, and return to it at a later time. Make sure to save the password provided to you as you leave the application for the first time. After you complete and submit your application, the system will generate acknowledgement of your electronic submission.

IMPORTANT! Please contact Patricia Wahl at 305-243-3345 or pwahl@med.miami.edu **before the deadline to resolve any issues.**

- Some of the fields must be completed electronically; others will require documents to be uploaded. Please ensure that each uploaded document includes your name in the header.
- All required fields are marked as “*must provide value.*” Your application cannot be processed if any required field is not completed. The software will prompt you to complete the missing fields.
- Adhere to the page limitations and format requirements for all uploaded documents: Font: Arial, 11 pt, Margins: 0.5 inch (36 pt.) for top & bottom, right & left, Single-spaced
- Appendices are not allowed.

Letter of Intent

The LOI application form requires:

1. Principal Investigator Information
2. Study Team Information: Co-PI, Co-Investigators, Mentors and Other Significant Contributors should all be identified. A Co-I is someone with a key role in the project (salary support is often provided but not required). Mentors are typically senior investigators responsible for advising the PI during the project (no salary support expected). Other significant contributors are typically investigators contributing a key element/expertise to the project but not necessarily a mentor (no salary support expected).
Note: Applications submitted by junior investigators at assistant level or new to HIV/AIDS and post-doctoral associates **require a mentor** to be listed on their project and non UM applicants are encouraged to have a UM collaborator.
3. Project Information including:
 - Project Title
 - Project Narrative: one to three sentences stating the public health significance
 - Abstract (300 words maximum) to include the objective, study design and analysis of data- Please note that this field accepts plain text input only. Special characters and formatting such as bullets, "smart quotes," bold or italic fonts, Greek letters, etc., will be lost or altered. You will need to rely on the use of capital letters, spaces, asterisks, and other standard keyboard characters. Alternatively, if necessary, you may use ASCII codes (available at <http://www.theasciicode.com.ar/>).
4. Reviewers: Consider that all UM faculty are potential reviewers. You may name any potential reviewers who you believe could not provide an impartial review and request they not review your application. The Review Committee will consider this request but is not required to accommodate it. You may include a justification for your selection (optional). In addition, if possible, please provide any recommendations for reviewers. They should not be current collaborators or mentors.

Full Application

The full application form requires:

1. Principal Investigator Information
2. Study Team Information: Co-PIs, Co-Investigators, Mentors and Other Significant Contributors should all be identified. A Co-I is someone with a key role in the project (salary support is often provided but not required). Mentors are typically senior investigators responsible for advising the PI during the project (no salary support expected). Other significant contributors are typically investigators contributing a key element/expertise to the project but not necessarily a mentor (no salary support expected).
Note: Applications submitted by junior investigators at assistant level or new to HIV/AIDS and post-doctoral associates **require a mentor to be listed on their project, and non-UM applicants are encouraged to have a UM collaborator.**
3. Project Information
4. Project Details including:
 - 4A-Project Title
 - 4B-Public Narrative: one to three sentences stating the public health significance
 - 4C-Scientific Abstract: (300 words maximum, Arial font, 11 point, single-spaced, 0.5" all margins) to include the objective, study design and analysis of data- Please note that this field accepts plain text input only. Special characters and formatting such as bullets, "smart quotes," bold or italic fonts, Greek letters, etc., will be lost or altered. You will need to rely on the use of capital letters, spaces, asterisks, and other standard keyboard characters. Alternatively, if necessary,

you may use ASCII codes (available at <http://www.theasciicode.com.ar/>). **Upload document as Last Name, 4C.**

5. Research Plan-all documents need to be uploaded into the electronic application and include the following sections:

- **5A-Specific Aims:** Limited to 1 page (Arial font, 11 point, single-spacing, 0.5" top, bottom, left & right 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.
- **5B-Research Strategy, Career Goals and Resources:** Limited to 5 pages (Arial font, 11 point, single-spacing, 0.5" top, bottom, left & right margins). *Research Strategy:* Significance, Innovation and Approach (**include a timeline for the project and also how the results will lay the groundwork for an application to an external funding source**). *Career Goals:* explain how this project is important to your career goals. *Resources:* List the CFAR cores and UM resources to be utilized for this project (every project is required to utilize one or more CFAR Cores). Please visit the CFAR website <http://cfar.med.miami.edu> to familiarize yourself with these cores. **Upload 5A and 5B together as Last Name, 5AB.**
- **5C-Bibliography and References Cited:** Limited to 1 page. **Upload document as Last Name, 5C.**
- **5D-Budget and Budget Justification:** Use the budget template provided on the CFAR website under Pilot Awards. Each award is limited to \$50,000 for direct costs only, for a one-year project period (estimated June 2018 to May 2019). Expenses should be restricted to personnel, laboratory supplies, cost for subject participation, travel, test supplies and technical support. **Equipment and indirect costs are not allowed. Junior investigator and post-doctoral salary up to 10% may be included in the budget.** Senior investigators should not have salary support on pilot awards. Provide a budget justification for each person and item listed in the budget. A sample budget justification can be found at the end of this document. **Please note:** *the fringe rate for CFAR (federal) and State of Florida (non-federal) are different. For purposes of this application, please use the federal fringe rates (link to rates at end of this document) and we will adjust the budget at award time if necessary.* 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 an individual is being listed on your grant with effort but no salary support, they typically should be listed as mentor or other significant contributor. If the individual has not yet been hired, please list as "TBD." **Upload document as Last Name, 5D.**
- **5E-Current biosketches for the principal investigator(s) and each co-investigator:** Biosketches are required for the PI and Co-Investigators, however they are not required for collaborators, mentors, or other significant contributors. **Upload document as Last Name, 5E.** Please use the NIH template <http://grants.nih.gov/grants/funding/424/index.htm#format>.
- **5F-Regulatory documents:** IRB, IBC, IACUC, CITI training certifications for Human Subjects Research, etc. If you do not yet have your approval, please upload a document explaining what approvals will be needed for you to conduct your research and provide a status update (example: submitted and pending, or no approvals needed, etc.). **Please note:** *IRB, IACUC and IBC approvals need to be received by time of award start (June 2018) so make sure you act in a timely manner to receive all required approvals.* **Upload document as Last Name, 5F.**
IMPORTANT! Funding cannot be released until copies of the official approvals are provided.
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 may not 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, please 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.
- **5G-Letter of support from Mentor(s):** If you have included a mentor in your application, a letter of support is required (junior faculty, post docs and any investigator new to HIV/AIDS) in regards to

their support of this project. The letter needs to detail exactly how the mentor intends to support the pilot awardee. **Upload document as Last Name, 5G.** If you do not require a mentor as per the RFA, please upload a document with N/A.

Submitting your application

The system will acknowledge your electronic submission of your LOI and Application and will generate a pop up message to notify you that each submission was received.

Useful Tips & Links

- How to merge multiple files into one PDF:
<https://www.adobe.com/content/dam/Adobe/en/feature-details/acrobatpro/pdfs/combine-multiple-documents-into-one-pdf-file.pdf>
- Fringe & Composite Fringe Benefit Rates:
<https://www.ora.miami.edu/forms-and-rates/fringe-benefit-rates/index.html>
- Miami CFAR website: <http://cfar.med.miami.edu>
- Institute of AIDS and Emerging Infectious Diseases website: <http://hivaidsinstitute.med.miami.edu/>

Sample budget justification

Personnel

John Smith, PI. 10% salary support. Dr. Smith will be responsible for the overall project... (elaborate on role and responsibilities.)

Karen Roberts, Technician. 5% Karen will be performing lab experiments to support this project.

Tom Jones, Mentor. No salary support. Dr. Jones is the mentor of Dr. Smith for this project and will provide guidance in... (elaborate on role).

Supplies

Lab supplies: \$5000 is requested for lab supplies such as pipettes, gloves, etc... to perform the experiments outlined in the proposal.

Other direct costs

Lab Core services: \$5000 is requested to use the CFAR lab core for services (describe service) as outlined in the proposal.