

Request for Proposals

CFAR Scholar Grants for Faculty Development in HIV Research

Issued: June 5, 2019



I. Funding Opportunity Description

The Johns Hopkins Center for AIDS Research (CFAR) provides pilot grants to faculty in the Schools of Public Health, Medicine, and Nursing to enable and support HIV/AIDS research projects. Junior faculty in other JHU schools are eligible to apply if the proposal meets all other criteria. The primary purpose of these awards is to strengthen the individual's ability to secure independent NIH research funding with foci on R- and K-series awards. This document describes the details of these pilot awards. Please read it in its entirety.

II. RFP Schedule

Due Date for Letter of Intent (LOI)	July 15, 2019, 8:00 am
Applicant Feedback on LOI	On or before July 22, 2019
Due Date for Application	September 16, 2019, 8:00 am
Applicant Notification of Outcome	December 2, 2019

III. Award Information

Funds Available

The budget for the faculty grants is a maximum of \$50,000 in <u>direct</u> costs. The CFAR will calculate and add <u>indirect</u> costs at the time of funding. We plan to award up to six (6) <u>1-year grants</u>, with a start date of January 1, 2020.

Projects already funded through one of the other school initiatives, e.g. Faculty Innovation Fund or Global Health Faculty Grant will not be awarded a CFAR Scholar Grant.

IV. Eligibility Information

A. Eligible Applicants

Applicants must be appointed full-time Instructors; Assistant Professors in the Schools of Public Health,
Medicine, or Nursing; or Assistant Scientists or Assistant Lecturers in the School of Public Health at the
time of application. Junior faculty at other JHU schools are eligible to apply.

Postdoctoral fellows may <u>only</u> apply with a letter from their department chair confirming a pending faculty appointment. The award will not be granted until the faculty appointment is active. If a postdoc is on a T32, CFAR funds cannot pay for training and stipends that are already paid for by the T32.

Associate Professors in the field of HIV are eligible to apply <u>if</u> there is no history of an R01 award or its equivalent and the <u>criteria</u> of an NIH New and Early Stage Investigator are met.

Any Associate Professor new to HIV research is eligible to apply.

Those in other faculty titles/status are not eligible. Those in "visiting" or "adjunct" status or those pending appointment are not eligible.

A table demonstrating faculty appointment eligibility is available on our website

- Previous recipients of a CFAR Scholar award are able to apply for additional funding or funding for a
 new project <u>if</u> evidence of progress is demonstrated. Career trajectory should be evident. CFAR-funded
 awards are limited to 2 over a 5 year period (Scholar awards, supplements, etc.). Eligibility and
 assessment of need will occur during review of the Letter of Intent, so please explain the rationale for
 an additional award.
- K awardees: If you are a current recipient of an NIH K award, you are required to submit with your CFAR application NIH sponsor approval indicating that you are eligible to receive CFAR funding (an e-mail from your project officer will suffice).

K awardees can receive compensation on CFAR pilot studies for effort not directly committed to the K award, as long as the specific aims differ from those on the K award. Please see the NIH guide notice for more details. K award policies vary by specific mechanism and may have specific level of effort and salary restrictions. LINK

B. Project Information

 Applications for collaborative projects, particularly those involving faculty in different disciplines and/or schools at Hopkins are strongly encouraged.

If the proposal for the project is part of a larger grant idea, there should be an explanation of the larger idea, how this proposal fits into the larger grant and how the pilot funding will be used to help in the development of the larger grant proposal (e.g. to obtain preliminary data).

Although the Center's process borrows heavily from NIH processes, future funding targets need not be limited to the NIH alone.

The CFAR may not fund studies involving new drugs, treatments, or devices, or off-label use of a licensed drug (this includes healthy volunteer studies where drugs are administered).

The CFAR may not fund clinical trials, such as studies that include prospective assignment to one or more intervention to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes of the participants. Use this NIH TOOL to make a quick determination of a Clinical Trial.

Studies involving <u>human subjects</u> may be subject to additional NIH review prior to initiating the study, which may cause delays. Similarly, for studies with any <u>foreign</u> component, additional NIH review and approval is required prior to the initiation of any study procedures.

- Funds must be used to support research projects in HIV/AIDS including, but not limited to, the areas of:
 - 1. Social, Prevention and Community-Based Research
 - 2. Clinical Research
 - 3. Immunology, Virology and Molecular Biology
 - 4. Epidemiology/Biostatistics
 - 5. Implementation Science

Please refer to the <u>NIH HIV/AIDS Research Priorities and Guidelines for Determining AIDS Funding</u>, as research in these areas will guide which projects the CFAR selects to fund.

C. Designation of Research Mentor

Both formal and informal mentoring processes are available to CFAR Scholar Grantees. Investigators interested in developing an application may choose a mentor or request one from CFAR in their letter of intent. Should this mentoring relationship be mutually welcome and successful, the mentor will assist the candidate through the application process, and if awarded, mentorship would continue through the completion of the award.

V. Indication of intent

Interested applicants are required to complete an online application and attach a letter of intent to apply. Applications and letters are evaluated for eligibility and those deemed likely to lead to future funding will be invited to submit a complete proposal. The letter of intent should be limited to one page and should contain:

- A. Name of applicant
- B. Title of proposal
- C. Specific Aims
- D. Abstract, including how your study will lead to future funding.
- E. Discipline of study:
 - 1. Social, Prevention and Community-based research
 - 2. Clinical research
 - 3. Immunology, Virology and Molecular Biology
 - 4. Epidemiology/Biostatistics
 - 5. Implementation Science
- F. Name of mentor or request for CFAR to assign

Please upload your Letter of Intent into our online system, which will be open by **July 1**, no later than **July 15**, **08:00 AM ET.** We will notify you by Monday, **July 22** if your project has been selected to proceed to a full application.

Submit here

VI. Application and Submission Information

A. Content and Form of Application Submission

Applications should be concise, with the <u>narrative</u> of the application being no longer than six (6) pages, single-spaced. The required components of the application are provided on the CFAR website and are as follows:

Component	Format and Notes
 Project narrative Specific Aims Research Plan: Significance [Must include how this work will lead to further grants] Innovation Approach [Note: this section should include the names and affiliations of all collaborators including those at other institutions and must clearly indicate the location of the proposed work] Timeline for implementation of the project 	Use NIH narrative format page
Proposed budget [Note #1: if your proposal includes a sub-site/subcontract, a budget page should be included for each site] [Note #2: Please consider budgeting for equipment maintenance, if appropriate]	Use NIH Budget Form
Figures and references, including letters of collaboration, especially for non-Hopkins mentors/Co-Is [This section should be used judiciously for the sake of reviewers.]	
Biosketches with Support of Principal Investigator only. You do not need to submit a biosketch for mentors or co-investigators.	Use NIH template

Note: All forms may be found on the CFAR <u>website</u>

Please follow NIH guidelines on font and margins.

The project narrative, budget, figures and references and biosketch should be merged into one PDF file for submission.

B. Submission Dates and Times

Application Receipt Date: 08:00 AM on September 16

Award Announcement Date: December 2

C. Sending an Application

Please email your full proposal to CFAR@jhmi.edu

A note regarding Office of Research Administration: This funding mechanism uses internal funding and does not require review or approval by an Office of Research Administration. Similarly, investigators should submit their application directly to the CFAR and not through ORAs.

D. Application Processing

Applications must be received no later than the date and time listed on the announcement. Applications received after that date will not be reviewed. Upon receipt, applications will be evaluated for completeness and responsiveness. Incomplete and non-responsive applications will not be reviewed.

Institutional Review Board (IRB) approval of human subjects is not required prior to review of an application. However, initiation of IRB review, if necessary or applicable, will be required prior to the release of funds or the commencement of research.

E. Funding Use and Restrictions

Funds can be requested to support the research endeavors of the faculty member, i.e., domestic travel (for dissemination of research results), technical support, lab supplies, assays, computer time, and limited research equipment. Salary to support the applicant may be requested. Additionally, although postdoctoral researchers may be involved in these pilot grants, it is not the purpose of these grants to provide substantial support for postdoctoral researchers. A letter of permission from the division chair is required for all postdocs or fellows. Application budgets will be reviewed and the Center may elect, on a case-by case basis, to deny funding if the budget appears excessive for the proposed activities.

Awards are capped at a total of \$50,000 in direct costs. Indirect costs will be added to the funding at the time of the award by the CFAR financial administrator. You do not need to concern yourself with this at the time of application. Depending on the nature of your proposal, the CFAR may choose to issue a partial award until project milestones have been met.

G. Resubmission

If you have applied in the past and wish to resubmit, please add a cover letter to your proposal indicating:

- 1. That the proposal is a resubmission
- 2. How the project has been modified
- 3. Your response to the reviewers' comments from your prior submission

VII. Application Review Information

A. Triage

Letters of intent will be triaged and reviewed for compliance with faculty status eligibility criteria, to determine if they propose eligible research projects and meet NIH HIV research priorities. Proposals not fitting eligibility criteria will not be advanced to full applications.

B. Primary Review Criteria

The primary criterion for evaluation of the application is scientific merit and the concomitant likelihood of future funding.

Please be innovative! This is an opportunity to explore new ideas and concepts. Innovation is a key review criterion.

C. Additional Review Considerations

Although scientific merit is the primary criterion, additional consideration is afforded to applications involving a collaboration of more than one Hopkins school or discipline. Specifically, this means that the proposal includes a co-investigator whose primary appointment is in a Johns Hopkins school or a discipline other than that of the applicant.

D. Review and Selection Process

Applications are evaluated by a study section (Social, Prevention and Community-based research; Clinical research; Immunology, Virology and Molecular Biology; Epidemiology/Biostatistics; or Implementation Science), similar to an NIH review. Critique information is compiled and distributed, but applicants should not expect the same extensive commentary as contained in an NIH-type review.

Review criteria:

- Does the introduction provide a clear background regarding the problem to be studied, what has been done so far, and what questions need to be answered?
- Are the aims clear, concise, and measureable? Are they feasible given the small award?
- Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well-integrated, well-reasoned, and appropriate to the aims of the project?
- Does this study address an important HIV/AIDS problem?
- Does this investigator provide a sound and convincing plan for use of the data/outcomes from this study to seek additional research funding?
- If the aims of the application are achieved, what is the likelihood that the data will contribute to a high quality application for subsequent funding?

E. Anticipated Announcement and Award Dates

Announcement of awardees is anticipated by **December 2** with award notices to follow shortly thereafter.

VIII. Award Administration Information

A. Award Notices

The Administrative Core of the Center for AIDS Research will issue award notices. The CFAR Research Service Analyst will contact you with the award IO, once the CFAR project administrator clears your study. Indirect costs are added to the award at this time.

B. Conditions of Award:

a. In the event that pending other support is funded which overlaps with or reduces your effort on this CFAR project, or you are awarded a K award, you must notify the CFAR Project Administrator. Your funding status will be reviewed, and, if it is determined that you are unable to meet the

- specific aims of your CFAR proposal or that you are ineligible for CFAR funding, you may be required to relinquish the CFAR award.
- b. **Prior to funding**, if applicable, you must forward a copy of all Institutional Biohazard, Animal Care and IRB approvals to the CFAR Project Administrator. If NIH clearance for a clinical or international study is required, funds may be withheld until these approvals are also in place.
- c. Faculty awarded funding will be required to provide annual reports of the progress of their study and a final report detailing the outcome of their project. Additionally, in order to evaluate the effectiveness of the program following the completion of your study, faculty will also be required to file brief, non-narrative annual reports indicating:
 - i. The number of subsequent grant applications
 - ii. The funding outcome of these applications
 - iii. Any publications or presentations that may have been based on the pilot grant

You are obligated to respond to CFAR requests for information for five years after your award is funded.

d. Publicity: Information about grants awarded under this program, subsequent awards, and publications will be posted on the Center for AIDS Research website. Applicants must agree to credit the Center for AIDS Research in any publication or applications that result from awards. Examples of the language required can be found on our website

IX. Core Consults

Applicants may, and are encouraged to, request consultation from any of the CFAR service cores or Scientific Working Groups to assist in the formation of proposals. <u>These consults are free</u>. You may request consultations by completing an online form here

Clinical Core Core Director: Richard Moore Co-Directors: Shruti Mehta, David Thomas, Jason Farley Sr. Manager: Lois Eldred (leldred1@jhmi.edu) Research Coordinators: Sarah Morris, Crystal Stone, Laura Clark	 Provides assistance in the design and conduct of clinical research. Offers support for Institutional Review Board submissions. Links investigators to a range of experts in HIV clinical & translational research. Provides venues for investigators to present research in progress with a team of experts. Provides access to resources that support grant writing and project implementation. Works with investigators to enhance recruitment in clinical trials.
Prevention Core Core Director: David Celentano Co-Directors: Carl Latkin, Kathleen Page, Erica Sibinga Sr. Manager: Rupali Limaye (rlimaye@jhu.edu)	 Supports junior and senior faculty in the processes of grant development and implementation. Manages the online CFAR Grant Development and Implementation Toolkit (toolkit.hopkinscfar.org). Develops and plans targeted events to collaborate and engage in existing research programs. Provides mentoring for junior faculty engaged in prevention science. Supports training in existing & emerging methodologies and technologies.
Clinical Laboratory and Biomarkers Core Core Director: Craig Hendrix Program Manager: Curt Reynolds (cjreyn@jhmi.edu)	 Facilitates access to research labs, clinical labs, and core labs across the Johns Hopkins Enterprise. Provides discounted research pricing for the performance of laboratory assays. Offers consultation, training and technical support in laboratory practices. Provides guidance in meeting regulatory requirements. Offers biospecimen storage and potential access to samples banked by other researchers.

Biostatistics and Epidemiology Methodology Core Co-Directors: Larry Moulton, Bryan Lau Program Manager: Parastu Kasaie Contact: jhucfarbem@jhu.edu

• Provides leadership and collaborative support for educational and research initiatives.

- Links investigators with BEM Core members who can contribute their expertise in HIV/AIDS
- epidemiology and methodology, including the construction of protocols and study design, constructing inclusion/exclusion criteria, constructing dynamic and stochastic models of HIV/AIDS, working with statistical programmers and data management staff, developing and executing statistical analysis plans, writing research reports and manuscripts and contributing to scientific presentations.
- Provides support for data management through the JHBC Data Informatics Services Core.

Baltimore HIV Collaboratory

Co-Directors: Susan Sherman, Kathleen Page Program Manager: Jordan White (jwhite@jhmi.edu)

- Promotes community linkages between JHU researchers and HIV focused NGOs, the Baltimore City Health Department, and people affected with HIV/AIDS
- Identifies, recruits and trains under-represented minority undergraduates, graduate students and fellows in community-based HIV/AIDS research in Baltimore.
- Facilitates an annual conference focused on HIV/AIDS in Baltimore City.

Adolescent and Young Adult (AYA) SWG

Co-Directors: Allison Agwu, Julie Denison and Renata Sanders Contact: Eileen Martin (emarti77@jhmi.edu)

Aims to:

- Address critical scientific gaps for AYA who are living with, affected by, or at risk for HIV in domestic & international settings;
- Build interdisciplinary bridges across Johns Hopkins institutions to foster collaborative scholarship & mentorship to junior investigators at JHU;
- Promote translation of research-informed policies & practices impacting AYA populations by fostering partnerships with policy makers and practitioners.

HIV Cure SWG

Co-Directors: Christine Durand, Ashwin Balagopal and Kelly Pate Contact: Eileen Martin (emarti77@jhmi.edu)

Aims to:

- Bring together investigators in the JHU HIV/AIDS research community who are interested in HIV eradication, including those interested in immunologic and virologic approaches;
- Engage JHU investigators who are not currently doing AIDS research but whose expertise bears on the problem;
- Facilitate the sharing of scientific expertise in the measurement of viral reservoirs;
- Promote the design and execution of clinical trials of potential eradication strategies.

Central Nervous System Dysfunction SWG

Co-directors: Leah Rubin, Jennifer Coughlin, Dionna Williams

Contact: Eileen Martin (emarti77@jhmi.edu)

Aims to:

- Promote the growth of our diverse team through provision of resources and mentorship to young clinician and non-clinician investigators who have new interest in HIV research. Facilitate practical application of IS for JHU HIV researchers;
- Facilitate the development and success of new protocols that generate new data(e.g., clinical, neuroimaging, biospecimens) or use existing and prospective clinical datasets such as the electronic health record (EHR), multi-domain neuropsychological and mental health data, biospecimen characteristics, and neuroimaging toward characterizing people with HIV with CNS dysfunction and comorbidities

Also, the CFAR Website offers an online Toolkit to assist in the development and implementation of a grant.

X. Additional Information and Questions

Please direct requests for additional information and questions to:

Anne R. Efron, MSN, MPH

Project Administrator, Center for AIDS Research

CRB II, 1M.02

aefron@jhmi.edu

cfar@jhmi.edu

410-502-2803