



REQUEST FOR REPRODUCTIVE HEALTH  
FOR HIV–AFFECTED POPULATIONS  
RESEARCH PROPOSALS  
AUGUST 2017

<http://cfar.globalhealth.harvard.edu>

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The Harvard University Center for AIDS Research (HU CFAR) is pleased to announce a Request for Proposals in ***Reproductive Health for HIV-Affected Populations Research*** for awards beginning August 1, 2017.

The HU CFAR welcomes proposals for Developmental Awards for research in the area of reproductive health for HIV-affected men and women globally (e.g., men and women living with HIV, HIV-uninfected men and women with known-infected partners or with unknown status partners in HIV-endemic settings).

The HU CFAR is dedicated to stimulating innovative, multidisciplinary research to better understand the field of reproductive health in the context of HIV. A variety of scientific approaches can be adopted to pursue this area of investigation, including: basic science (e.g., exploring mucosal immunology and its relationship to HIV acquisition and transmission risk), clinical research (e.g., measuring clinical markers and outcomes related to contraception, conception and HIV acquisition) and behavioral science (e.g., studying feasibility acceptability of long-acting reversible contraception and/or HIV prevention technologies), which can be used together to leverage collaboration to broaden scope and enhance feasibility to answer scientific questions.

Priority areas for this request for proposals include:

- Proposals from investigators new to the HIV field with experience in reproductive health and an interest in applying that expertise to answer important questions relevant to HIV
- Proposals to use existing data from studies on reproductive health for HIV-affected populations research at Harvard to answer new questions (please contact Lynn Matthews [lmatthews@mgh.harvard.edu] or Rebecca Zash [rzash@bidmc.harvard.edu] for suggestions if you are not familiar with the resources)
- Proposals which create new collaborations across Harvard (or CFAR) institutions to address key questions relevant to reproductive health for HIV-affected populations.

## RFP Schedule

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<b>Due Date for Email Inquiries for Biostatistical Consultation:</b>	<b>March 27, 2017</b>
<b>Due Date for Email Inquiries Regarding Clinical Research Projects:</b>	<b>March 27, 2017</b>
<b>Due Date for Email Inquiries for Behavioral and Social Sciences Consultation:</b>	<b>March 27, 2017</b>
<b>Due Date for Request for Assistance Identifying a Primary Mentor</b>	<b>March 27, 2017</b>
<b>Due Date for Draft Proposal to Biostatistics:</b>	<b>April 3, 2017</b>
<b>Due Date for Developmental Award Pre-Review Materials:</b>	<b>April 3, 2017</b>
<b>Return Date for Developmental Award Pre-Review:</b>	<b>April 10, 2017</b>
<b>Last Date to Submit Applications:</b>	<b>May 1, 2017 at 4 PM</b>
<b>Application Review:</b>	<b>Mid June 2017</b>
<b>Notifications Mailed to Applicants Near:</b>	<b>June 2017</b>
<b>Earliest Possible Award Start Date:</b>	<b>August 1, 2017</b>

## DEVELOPMENTAL AWARDS

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This Developmental Award will provide both salary and research support for promising early-career investigators who are transitioning to independent funding, as well as to senior investigators who are new to HIV research. Applications will be judged on the basis of the merit of the scientific proposal.

**Eligibility for Developmental Awards:** The Developmental Award is intended to support junior investigators who are on a career path leading to an independent research program. We recognize this as an extended transition and will consider applications from candidates beginning at the time of their transition from a training grant or similar support to mentored independent research (K level) funding to the point at which they have received NIH R01 or similar level funding. This award is also intended to support senior investigators who are new to HIV research.

Thus, we will support proposals from junior faculty who have never had R01 or similar level NIH funding and who are seeking support for the development of preliminary data for an NIH R01, R21, or R34-type application, in accordance with NIH policy. We will also support junior investigators who are earlier in their career as they transition to independent mentored research programs (e.g., NIH K-level awards). This award will also provide support to senior investigators who are new to HIV research at any level of training and prior NIH funding, as long as they have not received an NIH R-01 award related to HIV research.

Applicants must hold an appointment /position at any Harvard University School (e.g., Harvard Medical School, Harvard T.H. Chan School of Public Health, Faculty of Arts & Sciences) or one of its affiliated institutions, including (but not limited to) BIDMC, BWH, CHB, DFCI, Fenway Health, IDI, MGH, Ragon Institute of MGH, MIT and Harvard, and Lemuel Shattuck.

Applicants must be eligible to accept an award in response to this RFP on the earliest possible start date of **August 1, 2017**. Please see below for additional information for T32 and K awardees.

**Applicants can request support up to \$30,000 (direct costs) that can be used to support salary and/or research expenses as the applicant sees fit.**

- If you are a **current recipient of a T32 award**, you may use HU CFAR pilot funding to support research project costs, but you cannot use CFAR funds to pay for training and stipends that are already paid for by the T32. The following link provides information from the NIH on Institutional Research Training Grants:

[http://grants.nih.gov/grants/policy/nihgps/HTML5/section\\_11/11.3\\_institutional\\_research\\_training\\_grants.htm?Highlight=T32](http://grants.nih.gov/grants/policy/nihgps/HTML5/section_11/11.3_institutional_research_training_grants.htm?Highlight=T32)

- If you are a **current recipient of an NIH K award**, you are required to submit with your CFAR application a letter from the relevant program officer stating that you are eligible to receive CFAR funding.

Investigators are not eligible for salary support on a CFAR Developmental award if they are on a mentored K award. CFAR Developmental awards do not qualify as competing peer-reviewed research awards from NIH or any federal agency. Please refer to the NIH Grants Policy Statement for details. K award policies vary by specific mechanism and may have specific level of effort and salary restrictions:

[http://grants.nih.gov/grants/policy/nihgps/HTML5/section\\_12/12.1\\_general.htm](http://grants.nih.gov/grants/policy/nihgps/HTML5/section_12/12.1_general.htm)

**Applications from senior investigators new to HIV research will be considered for funding for this RFP.** Senior investigators applying to this RFP may have a prior NIH R-01 award, but must not have received a previous **HIV-related** R01 or R01 equivalent award. Please contact the HU CFAR prior to grant submission to clarify questions about eligibility.

**Mentorship for Early Career Investigators.** **Junior investigator** applicants must identify *at least one mentor* who will be able to provide clear support for the applicant, in the form of scientific mentorship and teaching, career guidance, and a research environment that is able to support the applicant's work. The mentor is required to write a letter of support for the applicant that includes a career development plan for the applicant and the applicant's potential for an independent research career. The letter should describe the research and training support available to the mentor and the applicant and **should explain how the research topics and/or methods and/or study designs to be used or developed by the applicant on this grant differ from the research topics and/or methods and/or study designs of the mentor (or mentors, if more than one).**

If any of the mentor's "other support sources" (current or pending) have titles or research areas that appear similar to the research proposed, please explain either: 1. how the research in the HU CFAR pilot proposal differs from that covered by the "other support source" or 2. what parts of the research aim(s) in the HU CFAR pilot proposal will be partially funded by the "other support source" (whether current or pending).

The mentor must also provide her/his Biosketch with the applicant's grant submission. Mentors must have a post-graduate degree with an appointment equivalent to an assistant professor, senior research

scientist, associate professor, principal research scientist, or professor at Harvard University. Mentors should meet the definition of Other Significant Contributors as defined by the NIH PHS 398 instructions (Rev. 03/16) and should not request salary support: (<http://grants.nih.gov/grants/funding/phs398/phs398.html>).

The Reproductive Health for HIV-Affected Populations Scientific Working Group (SWG) recognizes that finding research mentorship can be a challenge in some clinical specialties. As part of this award, the SWG leadership will provide additional mentorship to the award recipient. In the pre-application process, the SWG co-directors will be available to pre-review application materials and help to identify an appropriate mentor, if requested. During the award period, the SWG co-directors will identify a member of the SWG, whose expertise matches the applicant's needs and can serve as a co-mentor specifically for career development. The awardees will also be expected to be active members of the SWG, attend SWG meetings, and present their research findings to the group. See "Request for Assistance Identifying a Primary Mentor" below.

**International Proposals - Additional Requirements:** **Early career investigators** submitting international proposals must identify a primary mentor and a co-mentor. At least one of the two mentors must be a member of a Harvard University institution/department. For example, an International applicant might work with both a domestic mentor and a co-mentor based at the foreign site. The mentor and co-mentor must both provide a letter of support outlining the available resources and environment that will enable the successful completion of the applicant's proposed research. As noted above, the SWG directors can help to facilitate the identification of a co-mentor.

#### **Developmental Award Funding – Direct Costs:**

- You may request up to \$30,000 in salary and/or non-salary costs for one year. In addition, you may also request your institutional fringe rate on salary, calculated on top of the salary amount. Please see FAQ #13 on page 9 for an example.

#### **Developmental Award Funding – Indirect (Overhead) Costs:**

- The HU CFAR will award indirect costs at the rate of 25 percent for the domestic portion of the budget.
- The HU CFAR will award indirect costs at the rate of 8 percent for the international portion of the budget, if any.
- Please note that proposals are frequently selected to be supported with Harvard University institutional funding, in which case indirect costs will not be awarded.

### **APPLICATION SUBMISSION PROCESS**

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**You should submit the application only after you have reviewed the final version of your application. Changes cannot be accepted after the deadline.**

**Applications Due Date:** Applications are due no later than **4 p.m. on Monday, May 1, 2017**. After 4 p.m., no applications will be accepted.

**Provost Approval:** If you are submitting your application through a Harvard University department and/or school, you may be required to obtain Provost approval prior to your application submission. You should discuss this potential requirement with your Sponsored Programs Office. For more information, see "Provost Criteria" at the following link: <http://vpr.harvard.edu/pages/provost-criteria-review>

**Application Format:** Your application must be submitted as a single PDF document.

**Application Contents:** This award has unique application contents. A checklist is provided at the end of this RFP. Missing materials will not be accepted after the submission deadline.

**New Application Requirement:** Applicants must submit a cover letter (front page of the application) that is no longer than one page in length describing, if applicable, how their proposed research differs from their Mentor's or Mentors' research topics and/or methods and/or study designs and how the award will help on the path to independence and future funding opportunities.

**Application Form:** Applications must be submitted using NIH PHS 398 forms dated 3/2016. The text must be Arial, Garamond, Georgia, Helvetica, Palatino Linotype, Times New Roman, or Verdana typeface in a font size of 11 points or larger with at least one-half inch page margins. **Proposals that are submitted using incorrect PHS 398 forms will not be reviewed.** The most recent forms and instructions are available at:

<http://grants.nih.gov/grants/funding/phs398/phs398.html>

#### **Application Delivery:**

➔ Pop-Up Blocker Must Be Turned **OFF**

Go to <https://www.hightail.com/>

Enter the following:

- 1) Sign into your existing Hightail account or sign up to create a free account.
- 2) Click "Send" at top of screen.
- 3) To: Enter [cfar@harvard.edu](mailto:cfar@harvard.edu).
- 4) Subject: Enter HU CFAR RFP application.
- 5) Click "UPLOAD FROM DESKTOP" to choose your application file.
- 6) Please **do not** check the box "Verify recipient identity".
- 7) Click "Send It". Do not exit from the screen until you are notified that your file was sent.

If you have any questions regarding the [www.hightail.com](http://www.hightail.com) process, please contact Bethany Booth at [bethany\\_booth@harvard.edu](mailto:bethany_booth@harvard.edu) or 617-495-8236. You will receive email confirmation of your sent application from [www.hightail.com](http://www.hightail.com). You will also receive email confirmation from the CFAR Financial and Developmental Core Program Manager that your application was received and downloaded within 24 hours of the application deadline.

#### **The following cannot be accepted:**

- Emailed applications.
- Paper applications.
- Multiple files for a single application.

#### **IMPORTANT REQUIREMENT OF THE APPLICATION PROCESS:**

The HU CFAR RFP process requires institutional approval on all submitted applications. Prior to submission of your final application, it is required that you submit your application to your respective institution's Research Administration department for review and signature within the required time frame dictated by your school or institution. It is recommended that you become familiar with your institution's/school's review requirements and contact the Sponsored Programs Office/Research Administration Department at the earliest possible date. Applications will not be accepted without a face page signed by an authorized signatory of your Research Administration department.

Please direct questions related to the application submission process to either of the following individuals:

Bethany Booth  
Financial and Developmental Core Program Manager  
[bethany\\_booth@harvard.edu](mailto:bethany_booth@harvard.edu)  
617-495-8236

Mark Ingaciola  
Administrative Director  
[mark\\_ingaciola@harvard.edu](mailto:mark_ingaciola@harvard.edu)  
617-384-9039

## Developmental Application Pre-Review

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Developmental applicants may request a preliminary review and unofficial critique by submitting a draft of the Research Plan by **April 3, 2017** to bethany\_booth@harvard.edu (up to three pages in length). Applicants must indicate that a pre-review is being requested. If this option is taken, the applicant will receive preliminary written comments by **April 10, 2017**. Regardless of whether the preliminary review option is taken, all Developmental Award applications are due by the deadline of **4 p.m. on Monday, May 1, 2017**.

## Request for Assistance Identifying a Primary Mentor

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Applicants may request help identifying a mentor by sending a current CV (or Biosketch) and draft specific aims to Rebecca Zash (rzash@bidmc.harvard.edu) by **March 27, 2017**. A further interview/discussion may be held with the applicant to determine the best potential fit for a mentor.

## Application Appropriateness

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Questions as to the appropriateness of a proposal can be directed to either of the following individuals:

Ingrid Bassett, MD, MPH  
Director, Developmental Core  
IBASSETT@mgh.harvard.edu

Douglas Kwon, MD, PhD  
Associate Director, Developmental Core  
dkwon@mgh.harvard.edu

## Biostatistics and Bioinformatics Consultation

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Applicants may request consultation from Biostatistics and Bioinformatics Core personnel. In order to allow sufficient time for biostatistical and bioinformatics input prior to the application deadline, initial email inquiries to Biostatistics and Bioinformatics Core personnel should be made by **March 27, 2017**. In this initial email inquiry, please include: your institutional or school affiliation, a few sentences about the subject of your project, and a phone number or pager number at which you can be reached. After email inquiries are received, applicants may be asked to submit a 2-3 page draft of the complete application by **April 3, 2017** or to meet with Biostatistics and Bioinformatics personnel.

### Biostatistical questions can be directed to:

Rebecca Gelman  
Director, Biostatistics and Bioinformatics Core  
Dana Farber Cancer Institute  
gelman@jimmy.harvard.edu

Robert Parker  
MGH Biostatistics Center  
Massachusetts General Hospital  
rparker4@partners.org

Laura Smeaton  
Associate Director, Biostatistics and  
Bioinformatics Core  
Harvard School of Public Health  
smeaton@sdac.harvard.edu

John Hutchinson  
Bioinformatics Associate Director,  
Biostatistics and Bioinformatics Core  
Harvard School of Public Health  
jhutchin@hsph.harvard.edu

## Behavioral and Social Sciences Core Consultation

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Applicants may request Behavioral and Social Sciences (BSS) Core consultation by BSS Core personnel. The Core is particularly interested in helping to foster research projects that 1) leverage existing clinical or biomedical cohorts within the HU CFAR to develop new or add-on social-behavioral projects, and 2) utilize community-based participatory research and community engagement as guiding principles for their work. Accordingly, **especially if you have interest in either of these two areas**, the BSS core can help you with your proposal through the core services, which include helping to shape the application, pre-

reviewing the application and/or helping to link you to relevant existing cohorts (for a list please see <http://cfar.globalhealth.harvard.edu/pages/research-cohorts>). In order to allow sufficient time for BSS consultation prior to the application deadline, initial email inquiries to BSS Core personnel should be made by **March 27, 2017**. In this initial email inquiry, please include: your institutional or school affiliation, a few sentences about the subject of your project, and a phone number or pager number at which you can be reached.

**Behavioral and Social Sciences consultation can be directed to either of the following individuals:**

Kenneth Mayer, MD  
Director, BSS Core  
The Fenway Institute  
kmayer@fenwayhealth.org

Conall O’Cleirigh, MD, PhD  
Associate Director, BSS Core  
Massachusetts General Hospital  
COCLEIRIGH@mgh.harvard.edu

**Clinical Core Consultation**

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**HU CFAR Clinical Core:**

**Harvard Catalyst Connection:** Applicants applying for funding for clinical research projects involving patient recruitment are encouraged to contact the HU CFAR Clinical Core liaison for information on how to access helpful resources, including assistance with recruiting patients, either through the Clinical Core or through other available Harvard University programs, including the Harvard Catalyst (the Harvard CTSA), to further support their projects.

The HU CFAR Clinical Core Liaison is Marilyn Shi: MSHI2@mgh.harvard.edu

For more information about the Harvard Catalyst Clinical Research Center, visit:  
<http://catalyst.harvard.edu/programs/hccrc/>

**HIV Cohorts:** The HU CFAR Clinical Core makes available information about studies that have data and specimens available for further investigation. We encourage applicants to review this online information when designing patient-oriented research studies. For more information, visit:  
<http://cfar.globalhealth.harvard.edu/pages/research-cohorts>

**Funding Pre-Requisites**

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**Projects with an International Component:** Start dates for funded awards involving international research will be dependent upon NIH international clearance for the project. Note that no study that involves an international component can be initiated until such clearance is received and a revised Notice of Grant Award is received from the NIH. As a result, the start date of the study can be several months after the anticipated start date of funding. The HU CFAR Financial and Developmental Core Program Manager (bethany\_booth@harvard.edu) will provide guidance to awardees on this process.

**Projects Involving Clinical Research or Clinical Trials:** Due to recent NIH changes, CFAR funds can no longer be used for 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. Clinical studies that do not fall under the definition of a clinical trial will still be allowed. A clinical trial is defined as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. For further guidance, visit the following link:

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html>

Applicants considering submission of proposals that might be considered clinical trials are strongly encouraged to seek advice from CFAR personnel (bethany\_booth@harvard.edu) by **March 27, 2017**.

Start dates for funded awards involving clinical research entailing above minimal risk to the subjects will be based on the date that the NIH issues clearance for the project. The HU CFAR Financial and Developmental Core Program Manager (bethany\_booth@harvard.edu) will provide guidance to awardees on this process.

## Conditions of Award

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- You will be required to become an active member of the CFAR Reproductive Health for HIV-Affected Populations SWG and to present your research at one of the SWG meetings.
- You will be required to submit a yearly progress report to the CFAR and present a poster at the annual CFAR Symposium.
- Per NIH CFAR requirements, you must respond to CFAR requests for information for five years after your award is funded.
- You must acknowledge CFAR support in all publications and manuscripts derived from CFAR funding. This language is available on the CFAR web site:

[Click here to find out how to acknowledge CFAR support](#)

- 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 T32 or K award, you must notify the CFAR Administrative Director. 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.
- Prior to funding, if applicable, you must forward a copy of all Institutional Biohazard, Animal Care and IRB approvals to the CFAR Financial and Developmental Core Program Manager. For more information on what is required, please see the following section on the CFAR web site:

[Click here for information on research compliance](#)

- If the pilot project involves human subjects and the institutional IRB Committee has deemed the study “more than minimal risk”, you must submit an Implementation Plan before funding is released. This plan must include the following assurances:
  - 1) You will send any Serious Adverse Event (SAE) reports to your IRB;
  - 2) You will fulfill any FDA requirements; and
  - 3) You will submit a copy of the SAE and a description of the adverse event and action taken to the CFAR Administrative Director within 48 hours.

## Application FAQ

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1. My assistant forgot to include one of the items on the application checklist. May I send it to you to add to the application?

[You may re-send a single, completed PDF before the deadline if you need to make changes. We cannot modify your application for you or accept amended proposals after the deadline.](#)

2. Am I eligible to apply?

Please see the section labeled **Eligibility for Developmental Awards**. If there is still a question, please contact [bethany\\_booth@harvard.edu](mailto:bethany_booth@harvard.edu) for guidance.

3. Do I need to be a U.S. citizen to apply?

You do not need to be a U.S. citizen to apply.

4. How do I request a renewal of my existing CFAR award?

There are no renewals of CFAR awards.

5. What contact information do you need?

All the items on the Face Page (first page of the application) must be completed.

6. How do I fill out the budget if there is more than one site?

Each performance site/location and/or institution, HU CFAR affiliated and/or non-affiliated, domestic and/or international, requires a separate detailed budget page. A separate institutionally signed face page should be submitted for each performance site wherein the total direct costs and total costs (direct costs plus indirect costs) are indicated.

7. Where do I enter indirect costs?

Indirect costs are shown as the difference between direct costs and total costs on the Face Page (first page) of the application. Indirect costs may be shown on the detailed budget page(s) within the application for each performance site for which you are requesting funding.

8. My institution charges a higher overhead rate. May I use this overhead rate?

No. The HU CFAR Developmental Core Awards have a special indirect cost rate of 25 percent, negotiated with the NIH.

9. My application includes work at a foreign site. How does this affect my budget?

Any part of the award which would be paid to a foreign site is granted an indirect cost rate of 8 percent. Each site requires separate budget pages and a signed Face Page.

10. When developing my budget, are indirect costs included when calculating the total amount of funds that I can request?

No, indirect costs are calculated based on direct costs. For example, a research project with a budget of \$30,000 total direct costs could calculate up to \$7,500 in indirect costs for a total budget of \$37,500.

11. I have multiple sites for my study. Will my institution be setting up subcontracts with each site if my application is funded?

No. Your institution will not be setting up subcontracts with each of your funded sites. HU CFAR will be establishing the subcontracts with each site affiliated with your study, including your applicant institution.

12. Do I list my mentor under Senior/Key Personnel or Other Significant Contributors?

Mentors should at least meet the definition of Other Significant Contributors, which are "individuals who have committed to contribute to the scientific development or execution of the project, but are not committing any specified measurable effort (*i.e.*, person months) to the project". Mentors should not request salary support, but should submit a Biosketch (see checklist).

13. I am applying for a Developmental Award for salary support. Can I only request \$30,000 in total direct costs, including both salary and fringe?

No, the \$30,000 limit does not include fringe, just salary and non-salary costs, or salary alone costs. After requesting \$30,000, your institutional fringe rate can be calculated on top of the total salary amount. For example, if your fringe rate is 36%, you can request \$30,000 in salary and \$10,800 in fringe, for total direct costs of \$40,800.

14. I have a T32. Can I apply for a Developmental Award?

You may submit an application in response to this RFP. However, HU CFAR funding cannot pay for training and stipends that are already paid for by the T32.

## **Review Process**

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Applications will be reviewed by the CFAR Review Committee, which will be appointed by the CFAR leadership. If necessary, the Review Committee may request outside expertise to evaluate the scientific merit of a proposal.

The Committee will review the applications based on the following criteria:

- Overall scientific merit, level of innovation, and relevance of the proposal to AIDS research.
- Specific and narrowly focused application with realistic goals.
- Potential for generating independent funding.
- Potential for drawing investigators from other fields into AIDS research.
- Collaborative proposals that extend the scope of current CFAR activities across multiple participating Harvard laboratories/institutions are highly encouraged. Collaborative proposals will be evaluated on the scientific merits of each individual component of the project, as well as the overall integration of the projects.

Awardees will be notified in writing, and all applicants will receive a written review of their proposals, regardless of funding.

## **Harvard University Center for AIDS Research Overview and Mission**

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The mission of the HU CFAR is to expand, promote and facilitate collaborative innovative multidisciplinary activities in HIV/AIDS research in order to bring an end to the epidemic.

### *National Institute of Allergy and Infectious Diseases*

The mission of the Centers for AIDS Research (CFAR) program of the Division of AIDS is to support a multidisciplinary environment that promotes basic, clinical, epidemiologic, behavioral, and translational research in the prevention, detection, and treatment of HIV infection and AIDS.

NIH Co-Funding and Participating Institutes and

Centers: [NIAID](#), [NCI](#), [NICHD](#), [NHLBI](#), [NIDA](#), [NIMH](#), [NIA](#), [NIDDK](#), [NIGMS](#), [NIMHD](#), [FIC](#), and [OAR](#).

## APPLICATION REQUIREMENTS: DEVELOPMENTAL PILOT STUDY

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- NIH 398 Form Page 1: Face Page. **Note that signature of an authorized Institutional Official of your Research Administration Department is required prior to submission and review of your application.**
- In Box 2 of the Face Page, indicate the applicable CFAR discipline area of your proposal as being “Reproductive Health for HIV–Affected Populations Research”.
- NIH 398 Form Page 2. Note: This “form page” is actually two pages – both must be included. The following items must be completed:
  - 1) Description.
  - 2) Performance Sites.
  - 3) Key Personnel.
  - 4) Other Significant Contributors (if applicable).
  - 5) Human Embryonic Stem Cells (if applicable).
- NIH 398 Form Page 3: Table of Contents.
- NIH 398 Form Page 4: Detailed Budget Page for the Initial Budget Period. Each site requires a separate page. Please note: Requests for travel to attend scientific meetings will not be funded.
- Budget Justification.
- Five-page NIH Biographical Sketch Page for all Key Personnel. Please use the NIH PHS 398 General Biographical Sketch Format Page (Rev. 03/16).
- NIH Other Support Page for all Key Personnel. Please list **all** active and pending funding. Explicitly address potential **overlap** of active or pending funding with the current proposed CFAR research.
- NIH 398 Resource Format Page.
- Research Plan. Items 2-3 must not exceed three pages in total (see Form Page 3 for reference).
  - 1) Introduction to Application - Not Applicable
  - 2) Specific Aims
  - 3) Research Strategy (Significance, Innovation and Approach)
  - 4) Bibliography and References Cited
  - 5) Protection of Human Subjects
  - 6) Data Safety Monitoring Plan
  - 7) Inclusion of Women and Minorities
  - 8) PHS Inclusion Enrollment Report
  - 9) Inclusion of Children
  - 10) Vertebrate Animals
  - 11) Select Agent Research
  - 12) Not Applicable
  - 13) Not Applicable
  - 14) Letters of Support
  - 15) Not Applicable
  - 16) Not Applicable
- A cover letter (front page of the application) from the Applicant (no longer than one page) describing how, if applicable, the proposed research differs from the Mentor’s or Mentors’ research topics and/or methods and/or study designs and how the award will help on the path to independence and future funding opportunities.
- Letter of Support from Division Chief of applicant’s base institution.
- For Early Career Investigators, Letter of Support from Mentor, including:
  - Research training plan for the applicant.
  - Research and training support available to the Mentor and the applicant.
  - Future scientific and funding opportunities that would be facilitated by receipt of the CFAR award.
  - Applicant’s potential for an independent research career. If appropriate, **please explain how the research topics and/or methods and/or study designs research to be used or developed by the applicant on this grant differ from the research topics and/or methods and/or study designs of the mentor (or mentors, if more than one).**
  - If any of the *mentor’s* “other support sources” (current or pending) have titles or research areas that appear similar to the research proposed, please explain either: 1. how the research in the HU CFAR pilot proposal differs from that covered by the “other support source” or 2. what parts of the research aim(s) in the HU CFAR pilot proposal will be partially funded by the “other support source” (whether current or pending).

- ❑ Five-page NIH Biosketch of Mentor, if applicable. Please use the NIH PHS 398 General Biographical Sketch Format Page (Rev. 03/16).
- ❑ Applicants who receive salary or stipend from other sources of funding, including but not limited to NIH F and K award mechanisms, will need to provide verification from their current awarding agency that they are eligible to receive developmental funds from the HU CFAR, a NIH P30 award.
- ❑ Please include a submission letter (limited to one page in length) to include statements on any of the issues below that apply to this pilot award proposal:
  - If this proposal intends to obtain preliminary data necessary to justify a NIH R01, R21, or R34 grant, use a few sentences to specify exactly what data is needed. Examples include but are not limited to: development and validation of a new assay or new cell lines, development and validation of new survey instruments or data collection instruments, assessments of whether new interventions or changes in the provision of medical care will be acceptable, estimates of variability within groups or experimental conditions, estimates of differences between groups or experimental conditions, evaluation of whether a particular model (biologic, animal, mathematical, statistical) is appropriate. Also, if there is a possibility that the preliminary data obtained by this proposal could indicate that an NIH grant would not be appropriate, please use a sentence or two to explain what decision rule you will use to decide this.
  - Please state if this proposal represents a new multidisciplinary collaboration between several investigators who have never collaborated before, particularly investigators in different HU CFAR institutions or between different CFARs.
  - If the proposal involves high risk/possibly high impact HIV-related studies that broadens the current scope of the research being done by investigators at Harvard-affiliated research sites, please provide one or two statements explaining in what way it will broaden the scope of research.
  - If the proposal will use any HU CFAR resources (*e.g.*, clinical cohorts, animal model systems, stored specimens from clinical trials or animal studies, large computerized datasets) in new or unique ways, please describe (no more than a sentence for each resource).
  - If any of the investigators' "other support sources" (current or pending) have titles or research areas that appear similar to the research proposed by the pilot proposal, please explain either: 1) how the research in the HU CFAR pilot proposal differs from that covered by the "other support source" or else 2) what parts of the research aim(s) in the HU CFAR pilot proposal will be partially funded by the "other support source".
- ❑ Please complete Page 13 of the RFP application and attach as back page of your submission.
- ❑ Proposal is a single document in PDF format.
- ❑ Proposal in final form has been reviewed by the PI.



**Principal Investigator Name:**

**Title of Project:**

**Please provide the additional information below and attach this page as the final page of your application. Please submit this page for each PI of the project.**

**Please check the boxes below which best describe your investigator status:**

- Category 1: Individuals who have ever been the PI on an R01 equivalent grant in HIV/AIDS (R01 equivalents include R01, R23, R29, R37 and, after 2008, DP2).
- Category 2: Individuals who are or have ever been the PI on an R01 equivalent grant, *but never in HIV/AIDS*
- Category 3: NIH "New Investigators," An NIH definition that encompasses individuals who have received funding as a PI directly from NIH\*, but not yet at the R01 equivalent level.
- Category 4: CFAR Users who have not yet received direct funding from NIH\* as PI or Co-PI funding on any NIH grant mechanism

\*Individuals whose only NIH funding at the PI or PD level has come indirectly from NIH, for example via an NIH CFAR Administrative Supplement, fall into Category 4

- Category 5: Recipients of Core B research funding, mentoring, and/or other services
- Category 6: Recipients of NIH CFAR administrative supplements
- Category 7: Members of underrepresented groups in AIDS research. These include African-Americans, Hispanics, American Indians, Alaska natives, native Hawaiians, and Pacific Islanders.
- Category 8: Women.

**Please indicate the NIH ICs (Institutes or Centers) that may have interest and support research on the areas covered by your project.** For example, FIC, NCCAM, NCI, NHLBI, NIAID, NICHD, NIDA, NIMH, etc.:

*\*see the following link for more information about Institutes and Centers*  
<http://www.nih.gov/icd/>