The Harvard University Center for AIDS Research (HU CFAR) is pleased to announce a Request for Proposals in HIV/AIDS research for awards beginning February 1, 2022. The HU CFAR welcomes proposals for research in all HIV-related disciplines.

**RFP Schedule**

| Due Date for Email Inquiries for Consultation with the Biostatistics and Bioinformatics Core: | October 12, 2021 |
| Due Date for Email Inquiries Regarding Clinical, Behavioral, or Medical Care Delivery Research Projects: | October 12, 2021 |
| Due Date for Email Inquiries for Bio-Behavioral and Community Science Core Consultation: | October 12, 2021 |
| Due Date for Draft Proposal to Biostatistics and Bioinformatics Core: | October 19, 2021 |
| Due Date for Developmental Award Pre-Review Materials: | October 19, 2021 |
| Return Date for Developmental Award Pre-Review: | October 26, 2021 |
| Last Date to Submit Applications: | November 17, 2021 at 4 PM EST |
| Application Review: | December 2021 – January 2022 |
| Notifications Mailed to Applicants: | January through early February 2022 |
| Earliest Possible Award Start Date: | February 1, 2022 |

**DEVELOPMENTAL AWARDS**

Developmental Awards provide salary and research support for promising early-career investigators who are transitioning to independent funding. 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 early career researchers who are on a path leading to an independent research project. 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.

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. Applicants may be at the post-doctoral fellow, research fellow, instructor, research associate, research scientist, or assistant professor level at any Harvard University School (e.g., Harvard Medical School, T.H. Chan School of Public Health, Faculty of Arts & Sciences, Business, etc.) or one of its affiliated institutions, including (but not limited to) BIDMC, BWH, BCH, DFCI, Fenway Health, MGH, and Ragon Institute of MGH, MIT and Harvard. Investigators at the rank of associate professor or above (including senior research scientists and principal research scientists at Harvard Chan School) will be judged too senior for consideration.

Applicants must be eligible to accept an award in response to this RFP on the earliest possible start date of **February 1, 2022**. Please see below for additional information for T32 and K awardees.

Applicants can request support up to $60,000 (direct costs) that can be used to support salary and/or research expenses applicable to the study and allocable to federal funding.

- 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:
  
  [https://grants.nih.gov/grants/policy/nihgps/HTML5/section_11/11.3.10_stipend_supplementation__compensation__and__other__income.htm](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_11/11.3.10_stipend_supplementation__compensation__and__other__income.htm)

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

  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 below for more details:


  K award policies vary by specific mechanism and may have specific level of effort and salary restrictions:

  [https://grants.nih.gov/grants/policy/nihgps/HTML5/section_12/12_research_career_development__k__awards.htm](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_12/12_research_career_development__k__awards.htm)

**Applications from senior investigators will not be considered for funding**  Senior investigators, defined as already having received NIH R01 funding as the principal investigator or funding at a similar level, are ineligible for this award. This does not include R21, R34, or R03 funding or subcontract funding through the R01 mechanism.

**Mentorship** Each applicant for a HU CFAR Developmental award must identify **at least one mentor** who will 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 in this proposal 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 proposed research differs
from that covered by the “other support source” or 2. what parts of the research aim(s) in the proposed research will be partially funded by the “other support source” (whether current or pending).

The mentor must also provide their 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. 03/2020 Approved Through 02/28/2023) and should not request salary support: http://grants.nih.gov/grants/funding/phs398/phs398.html.

**International Proposals - Additional Requirements** Applicants 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 U.S.-based mentor at a Harvard University site and a co-mentor centered 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.

Each international site must provide a letter of support describing how the work contributes to local institutional priorities.

Applications which propose one or more international site(s) must include with the application a completed International Checklist, which can be found here: https://www.niaid.nih.gov/research/cfar-research-project-guidelines.

Refer to Cover Letter instructions for additional requirements.

**Developmental Award Funding – Direct Costs:**

- You may request up to $60,000 in salary and/or non-salary costs for one year plus the cost of your institutional fringe. Institutional fringe is calculated on top of the salary amount and is not included when calculating the direct cost maximum budget of $60,000. Please see FAQ #13 for an example.

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

- If your proposal is funded with grant funding, the HU CFAR will award indirect costs at the rate of 25 percent for the domestic portion of the budget and 8 percent for the international portion of the budget, if any.
- If your proposal is selected to be supported with Harvard University or affiliate institutional funding, indirect costs will not be awarded.

**APPLICATION SUBMISSION PROCESS**

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. Eastern Standard Time on November 17, 2021. 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: https://vpr.harvard.edu/2021/02/17/provost-criteria-for-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. There will be no exceptions to this rule.

Cover Letter Requirement: Applicants must submit a cover letter (front page of the application) that is no longer than one page in length describing 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.

Applicants who are Harvard-based and proposing global health research/research in a low- or middle-income country (LMIC) must include an additional statement, maximum ½ page, in the cover letter explaining i) how the work contributes to equity in the practice of global health research and ii) how collaborator(s) in the LMIC will be acknowledged and included in the research deliverables, e.g., as co-authors, presenters at conference, etc.

Application Form: Applications must be submitted using NIH PHS 398 forms dated Rev. 03/2020 Approved Through 02/28/2023. 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:

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

Enter the following:

1) Sign into your existing OpenText Hightail account or sign up to create a free account.
2) To: Enter cfar@harvard.edu.
3) Subject: Enter HU CFAR RFP application.
4) On right side of screen, add your application file to OpenText Hightail.
5) Click “NEXT” button.
6) Please do not check the box “Verify recipient identity”.
7) Click “SEND”. Do not exit from the screen until you are notified that your file was sent.

If you have any questions regarding the file transfer process, please contact Bethany Booth at bethany_booth@harvard.edu or 617-495-8236. If your application is submitted correctly, you will receive an automated email within minutes of submission confirming receipt of your application from OpenText Hightail. Please retain this receipt as proof of submission. If you do not receive this email within a few minutes of submission, you should resubmit the application or contact Bethany Booth for assistance. You will also receive email confirmation within 24 hours of the application deadline from Bethany Booth. If you do not receive an email from the HU CFAR confirming receipt of your application, please contact Bethany Booth at bethany_booth@harvard.edu as soon as possible.

The following will not 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, you are required to 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. If your application includes more than one performance site and budget, you are required to include a separate signed face page for each site in order for your application to be eligible for review.

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

Bethany Booth       Mark Ingaciola
Financial and Developmental Core Program Manager  Administrative Director
bethany_booth@harvard.edu      mark_ingaciola@harvard.edu
617-495-8236        617-384-9039

Developmental Application Pre-Review

Developmental applicants may request a preliminary review and unofficial critique by submitting a draft of the Research Plan (specific aims and research strategy) by October 19, 2021 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 October 26, 2021. Regardless of whether the preliminary review option is taken, all Developmental Award applications are due by the deadline of 4 p.m. EST on November 17, 2021.

Application Appropriateness

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

Athe Tsibris, MD, MS       Louise Ivers, MD, MPH
Co-Director, Developmental and Mentoring Core  Co-Director, Developmental and Mentoring Core
atsibris@bwh.harvard.edu      livers@mgh.harvard.edu

Biostatistics and Bioinformatics Consultation

Applicants may request consultation from Biostatistics and Bioinformatics Core personnel. This request must be made by October 12, 2021 by completing the information requested at the following link:


After Biostatistics and Bioinformatics Core personnel receive this request, applicants may be asked to submit a 2-3 page draft of the complete application by October 19, 2021 or to meet with Biostatistics and Bioinformatics personnel.

Bio-Behavioral and Community Science Core Consultation

Applicants may request Bio-Behavioral and Community Science (BB&CS) Core consultation by BB&CS 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 BB&CS Core can help you with your proposal, 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). To allow sufficient time for BB&CS Core consultation prior to the application deadline, initial email inquiries to BB&CS Core personnel must be made by October 12, 2021. In this initial email inquiry, please include: your institutional or school affiliation, a few
Bio-Behavioral and Community Science Core consultation can be directed to any of the following individuals:

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<tr>
<th>Name</th>
<th>Role</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kenneth Mayer, MD</td>
<td>Director, BBCSC</td>
<td><a href="mailto:kmayer@fenwayhealth.org">kmayer@fenwayhealth.org</a></td>
</tr>
<tr>
<td>Conall O’Cleirigh,</td>
<td>PhD Associate Director, BBCSC</td>
<td><a href="mailto:COCLEIRIGH@MGH.harvard.edu">COCLEIRIGH@MGH.harvard.edu</a></td>
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Clinical Core Consultation

HU CFAR Clinical Core:
Applicants applying for funding for clinical research projects involving patient recruitment are encouraged to contact the Clinical Core 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.

Clinical Core consultation requests can be directed to Efe Airewele, HU CFAR Clinical Core Liaison: EAIREWELE@mgh.harvard.edu.

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

HIV Cohorts: The 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

Procedure For Resubmission
If you have applied in the past and wish to resubmit your application, please add a letter no longer than one page in length on page two of your application which indicates:

- That the application is a resubmission.
- The date of the previously submitted application.
- Any material changes from the prior application.
- Your response to the reviewers’ comments from your prior submission.
- Any other information germane to the resubmission.

The application is otherwise the same in all respects; the application must be submitted as a single PDF document. Please note that, during the review process, reviewers will have access to the feedback from your prior application.

Funding Pre-Requisites
Projects with an International Component: Start dates for funded awards involving international research will be dependent upon NIH international clearance for the project. No study that involves an international component can be initiated until such clearance 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. To expedite international clearance, a completed International Checklist is required with your application. See https://www.niaid.nih.gov/research/cfar-research-project-guidelines for the international checklist. Please contact Bethany Booth (bethany_booth@harvard.edu) with any questions about this process.
Projects Involving Clinical Research or Clinical Trials: CFAR funds cannot 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:


In addition, the following link provides further information and case studies to better explain the difference between a clinical trial and a clinical study:

https://grants.nih.gov/policy/clinical-trials/definition.htm

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 October 12, 2021.

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.

Project Involving Multiple Funded Sites: All performance sites proposed in a multi-site application must have a SAM.gov registration in place by the time of award. SAM is the System for Award Management. Without a current SAM registration, collaborators cannot subcontract with the CFAR nor work on a CFAR research project. It is highly recommended that applicants ensure this registration is in place or initiated for all performance sites prior to application submission. See Online SAM Registration for further information.

Conditions of Award

- Per NIH CFAR requirements, 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 will agree to respond to CFAR requests for information for five years after your award is funded.

- You will be required to present your work at the HU CFAR Research in Progress meeting at least once during the year of the award or during the subsequent three years.

- You will cite HU 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

- You will ensure that all publications resulting from CFAR support cite the CFAR grant (P30 AI060354) and comply with NIH Public Access policy.

- 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, Mark Ingaciola, at mark_ingaciola@harvard.edu. 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 provide a copy of all Institutional Biohazard, Animal Care, and IRB approvals to the CFAR Financial and Developmental Core Program Manager. Applicants
are highly encouraged to apply for IRB approval at the time of application to avoid delay in the start date of the proposed study should it be chosen for funding. For more information on what is required, please 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**

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 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. The Face Page must be signed before submission.

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 and Mentoring Core Awards have a special indirect cost rate of 25 percent, as awarded by the NIH, for domestic budgets and 8 percent for international budgets.

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 direct costs that I can request?
No, indirect costs are calculated based on direct costs. For example, a research project with a budget of $60,000 total direct costs could calculate up to $15,000 in indirect costs for a total budget of $75,000.

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 $60,000 in total direct costs, including both salary and fringe?
No, the $60,000 limit does not include fringe, just salary and non-salary costs, or salary alone costs. After requesting $60,000, 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 $60,000 in salary and $21,600 in fringe, for total direct costs of $81,600. Indirect costs are then calculated on the total direct costs.

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

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

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.

The Harvard University Center for AIDS Research (CFAR) is an NIH funded program (P30 AI060354), which is supported by the following NIH Co-Funding and Participating Institutes and Centers: NIAID, NCI, NICHD, NIDCR, NHLBI, NIDA, NIMH, NIA, NIDDK, NINR, NIMHD, FIC, and OAR.

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 multidisciplinary research aimed at reducing the burden of HIV both in the United States and around the globe. The continuing spread of HIV in the US and globally underscores the need for ongoing, nationally coordinated collaborative conduct of basic, clinical, epidemiologic, behavioral, and translational research to improve the prevention, detection, treatment and cure/remission of HIV infection and the associated complications / comorbidities.
APPLICATION REQUIREMENTS: DEVELOPMENTAL PILOT STUDY

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(s) listed on page one of the RFP for your proposal. If your proposed research links to more than one discipline, please indicate your primary and secondary discipline. Note that for studies involving International Research, you must specify International Research and one additional programmatic area specific to your study:

- Adolescence & HIV Research
- Bio-behavioral and Community Science Research
- Clinical Epidemiology and Outcomes Research
- COVID-19 & HIV Research
- Health Economics and Modeling Research
- Health Equity Research
- HIV Eradication Research
- HIV & Aging Research
- International Research
- Non-Communicable Diseases Research
- Pathogenesis Research
- Reproductive Health Research
- TB/HIV Co-Infection Research
- Therapeutics Research
- Vaccines Research
- Other Discipline Not Listed Above (Please Specify)

NIH 398 Form Page 2. Note: This “form page” is actually two pages – both must be included. The following items must be completed:

1) Project Summary and Relevance.
2) Project/Performance Sites.
3) Senior/Key Personnel.
4) Other Significant Contributors (if applicable).
5) Human Embryonic Stem Cells (if applicable).

NIH 398 Form Page 3: Research Grant 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 for Entire Proposed Project Period and Budget Justification.

Five-page NIH Biographical Sketch Page for all Key Personnel. Please use the NIH PHS 398 General Biographical Sketch Format Page (Rev. 03/2020 Approved Through 02/28/2023).

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 Resources Format Page.

NIH 398 Checklist Form 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) Vertebrate Animals
6) Select Agent Research
7) Multiple PD/PI Leadership Plan - Not Required
8) Consortium/Contractual Arrangements - Not Required
9) Letters of Support
10) Resource Sharing Plan(s) - Not Required
11) Authentication of Key Biological and/or Chemical Resources - Not Required
12) PHS Human Subjects and Clinical Trials Information – The PHS 398 form for consolidated human subjects, inclusion enrollment report, and clinical trial information is not required at the time of application submission. Instead, if applicable, please describe your project’s Protection of Human Subjects. The HU CFAR cannot fund clinical trials (see page 7 for additional information). If your application is selected for funding, you will be required to complete the PHS Human Subjects and Clinical Trials Information PHS 398 form.

☐ A completed International Checklist if you are proposing one or more international sites (see https://www.niaid.nih.gov/research/cfar-research-project-guidelines for the checklist)

☐ A cover letter from the Applicant (one page for domestic research, one and ½ pages for global health research) describing how 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. Harvard-based applicants proposing global health research/research in a low- or middle-income country (LMIC) must include an additional statement explaining i) how the work contributes to equity in the practice of global health research and ii) how collaborator(s) in the LMIC will be acknowledged and included in the research deliverables, e.g., as co-authors, presenters at conference, etc.

☐ Letter of Support from Division Chief of applicant’s base institution.

☐ Letter of Support for studies involving international sites: the collaborating international institution must provide a letter describing how the work contributes to local institutional priorities.

☐ 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(s). Please use the NIH PHS 398 General Biographical Sketch Format Page (Rev. 03/2020 Approved Through 02/28/2023).

☐ 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.

☐ If this application is a resubmission, please include a letter (in addition to the one-page Applicant Cover Letter) no longer than one page in length on page two of the application which states:
  - That this application is a resubmission.
  - The date of the previously submitted application.
Any material changes from the prior application.
Your response to the reviewers’ comments from your prior submission.
Any other information germane to the resubmission.

Please include a submission letter (limited to one page in length) explaining any of the issues below that apply to this pilot award proposal (note that you may combine this with the cover letter):

- 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 area of the proposal is an area that one of the three HU CFAR Scientific Working Groups (“SWGs”) have listed as being high priority, please specify the SWG and the research area within the SWG (http://cfar.globalhealth.harvard.edu/scientific-working-groups-swgs-0).

- 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 14 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/