

REQUEST FOR PROPOSALS FOR EARLY CAREER INVESTIGATORS AUGUST 2024

http://cfar.globalhealth.harvard.edu

The Harvard University Center for AIDS Research (HU CFAR) is pleased to announce a Request for Proposals in HIV/AIDS research for Scholar Awards beginning August 1, 2024. The application deadline is April 15, 2024 at 5 p.m. EDT.

PURPOSE

Research proposals must address an NIH high or medium priority research area. For more information, visit https://www.oar.nih.gov/hiv-policy-and-research/research-priorities and https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-137.html.

Applications proposing basic science research are greatly encouraged.

Applicants may apply for a one-year or two-year award. The proposed duration should align with the scope of work. Each applicant is limited to one application.

The HU CFAR acknowledges that the diversity of HIV investigators is at an undesirably low level. Investigators from underrepresented racial and ethnic groups, individuals with disabilities, individuals from disadvantaged backgrounds, and women from the above backgrounds are strongly encouraged to apply. *See Notice of NIH's Interest in Diversity for more information*: NOT-OD-20-031.

RFP SCHEDULE

Due Date for Pre-submission Consultation Inquiries to one of the following CFAR Groups: - Biostatistics & Bioinformatics Core - Bio-behavioral & Community Science Core - Clinical Core - Program in Health Economics & Modeling	March 8, 2024
Due Date for Draft Proposal to Biostatistics & Bioinformatics Core	March 15, 2024
Last Date to Submit Applications	April 15, 2024, at 5 p.m. EDT (no exceptions)
Application Review	June – July 2024
Notifications Mailed to Applicants	July – early August 2024
Earliest Possible Award Start Date	August 1, 2024

ELIGIBILITY FOR SCHOLAR AWARDS

Scholar Awards provide salary and research support for promising early career investigators who plan a transition to independence. We recognize this as an extended transition and will consider applications from candidates transitioning from a training grant or similar support up through mentored independent research (NIH K-award mechanism) funding. Early career investigators with a Harvard affiliation and international investigators with a Harvard mentor are eligible to apply. We will accept proposals from junior faculty who have not previously received R01 or similar level NIH funding and who may be 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.

Harvard-affiliated early career investigators:

- **ELIGIBLE:** Harvard-affiliated applicants 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, The Faculty of Arts and Sciences, Harvard Business School, 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
- **NOT ELIGIBLE:** Investigators at the rank of associate professor or above (including senior research scientists and principal research scientists at Harvard Chan School), and investigators of any academic rank with R01-level funding. R01-level funding does not include R21, R34, or R03 funding, or subcontract funding through the R01 mechanism

International investigators:

• **ELIGIBLE:** International applicants who are early career investigators, have not previously received R01 or similar level NIH funding, and who have a Harvard-affiliated mentor

Recipients of CFAR Scholar Awards in the preceding 5 years are not eligible to apply.

All applicants must be eligible to accept an award in response to this RFP with a start date of August 1, 2024.

ELIGIBILITY FOR T32 AND K AWARDEES

T32 Awardees:

Current T32 award recipients may apply for a HU CFAR Scholar Award to support research project costs.
 However, a Scholar Award cannot support training expenses and stipends covered by the T32 award. For additional guidance, refer to NIH Guidance on <u>Institutional Research Training Grants.</u>

K Awardees:

- Current NIH K awardees may apply for the one-year award but are not eligible for the two-year award mechanism. Applicants with an active K99 award are not eligible to apply.
- If you are currently funded by an NIH K award, you are required to submit with your CFAR application a letter (or copy of email) from a relevant NIH program officer stating that you are eligible to receive CFAR funding.
- K awardees can receive compensation on one-year CFAR Scholar Awards 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 <u>NIH guide notice</u> for more details.
- K award policies vary by specific mechanism and may have specific levels of effort and salary restrictions.

MENTORSHIP

Each applicant must identify at least one mentor who will provide clear support to the applicant in the form of scientific mentorship and teaching, career guidance, and a research environment that is able to foster the applicant's work.

Mentor Requirements and Expectations:

- 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 and should not request salary support.
- Mentors should provide a letter of support describing the following: a career development plan for the
 applicant; the applicant's potential for an independent research career; research and training support
 available to the mentor and the applicant; and how the applicant's proposal differs from the mentor's (or
 mentors,' if more than one) work.
- The mentor's NIH Biosketch is required with the applicant's grant submission.
- The mentor is expected to critically review the applicant's proposal and all associated documents prior to submission.

International Proposals - Additional Mentorship Requirements:

- Applicants submitting international proposals must identify a primary mentor and a co-mentor.
- One of the two mentors must be a member of a Harvard University institution/department, and one mentor must be based at the foreign institution.
- The mentor and co-mentor must both provide a letter of support and their NIH Biosketch.
- The international site mentor letter should describe the available resources and environment that will enable the successful completion of the applicant's proposed research.

SCHOLAR AWARD FUNDING - DIRECT COSTS

One-Year Award:

- You may request up to \$75,000 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 <u>not</u> included when calculating the direct cost maximum budget of \$75,000. See FAQ #11 for an example.
- Applications proposing one or more international sites may submit a direct cost budget above \$75,000 plus fringe. See below Administrative Costs for International Sites.

Two-Year Award:

- You may request up to \$75,000 in salary and/or non-salary costs <u>per year</u> for two years <u>plus the cost of your institutional fringe</u>. Institutional fringe is calculated on top of the salary amount and is <u>not</u> included when calculating the direct cost maximum budget of \$150,000.
- Applications proposing one or more international sites may submit a direct cost budget above \$150,000 plus fringe. *See below Administrative Costs for International Sites*.

Additional Funding:

• <u>Administrative Costs for International Sites</u>: Applicants can request up to an additional 16% of the direct costs for each international site to cover costs allocable to the proposed research but not included in the NIH IDC rate of 8%. See FAQ #14 for an example.

• <u>Support for the Cost of Humanized Mice</u>: Applicants proposing the use of humanized mice may request up to \$20,000 additional direct costs to access mice through the Human Immune System Mouse Core at the Ragon Institute of MGH, MIT and Harvard. See "Human Immune System Mouse Core" below for more information.

SCHOLAR AWARD FUNDING - INDIRECT (OVERHEAD) COSTS

- If your proposal is funded with NIH 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, consistent with long-standing NIH policy.
- If your proposal is selected to be supported with Harvard University or affiliate institutional funding, *indirect* costs will not be awarded to any domestic performance site(s).
- Each application should include indirect costs in the budget.

APPLICATION SUBMISSION PROCESS

Applications Due Date:

Applications are due no later than **5 p.m. Eastern Daylight Time on April 15, 2024.** After 5 p.m., no applications will be accepted. There will be no exception to this rule.

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.

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. Applications that are missing required materials will not be reviewed. Applications with research plans (specific aims and research strategy) that extend beyond three pages will not be reviewed. There will be no exceptions to these rules.

Application Form:

Applications must be submitted using NIH PHS 398 forms (Revised 03/2020). The text must be Arial, 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 here.

APPLICATION DELIVERY

Pop-Up Blocker Must Be Turned OFF

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

Enter the following:

- 1) Sign into your existing HIGHTAIL by opentext account or sign up to create a free account.
- 2) To: Enter cfar@harvard.edu.
- 3) Confirm you have entered the CFAR email address correctly.

- 4) Subject: Enter HU CFAR RFP application.
- 5) Add your application file to screen by dragging it from your computer or uploading it.
- 6) Do not check any boxes except "Get a download receipt." Otherwise, the HU CFAR will not be able to download your application.
- 7) Click "SEND." Do not exit from the screen until you are notified that your file was sent.

Submission Confirmation:

- If your application is submitted correctly, you will receive an automated email within minutes of submission confirming receipt of your application from Hightail. Be sure to confirm that the receipt is from "Cfar@harvard.edu." Please retain this receipt as proof of submission #1.
- 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. This is proof of submission #2. If you do not receive an email from Bethany Booth or an HU CFAR representative confirming receipt of your application, contact Bethany Booth at bethany booth@harvard.edu within 48 hours of the submission deadline.
- You must receive proof of submission #1 and #2. Without both, there is no guarantee that the HU CFAR has received your application.

The following will not be accepted:

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

INSTITUTIONAL APPROVAL

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.

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
617-495-8236

Mark Ingaciola
Administrative Director
mark ingaciola@harvard.edu
617-384-9039

PLAN FOR ENHANCING DIVERSE PERSPECTIVES

To enhance diverse perspectives in HIV research, this RFP pilots a new requirement as a *non-scorable* element of a complete application. The submission of a "Plan for Enhancing Diverse Perspectives" (PEDP) is one paragraph and no more than a half page in length and summarizes the strategies to include diverse perspectives that advance the scientific and technical merit of the proposal. Diverse perspectives may refer to the people who do the research, the places where research is done, and/or the research participants. The specifics of any given PEDP will depend on the scientific aims, required expertise, environment, performance site(s), and career stages of the investigators.

Key elements to be included in a PEDP:

- Summary of strategies (and their rationales) for inclusion of diverse perspectives
- Timeline and milestones for assessing progress

Examples of potential strategies for the PEDP include but are not limited to:

- Inclusion of study personnel or recruitment of research participants from diverse backgrounds, including groups historically underrepresented in the biomedical, behavioral, and clinical research workforce, such as underrepresented racial and ethnic groups, people with disabilities, people from disadvantaged backgrounds, and women.
- Teams with researchers from different scientific fields, different types of institutions and organizations (e.g., minority-serving, community-based, research-intensive, undergraduate-focused), different career stages, or different geographic areas.
- Training, mentoring, and/or research opportunities to encourage participation or career enhancement of students, fellows, or co-investigators from diverse backgrounds.
- Publication or presentation plans that describe equitable processes to determine authorship or promote visibility of trainees or junior faculty.
- Partnerships with stakeholders (e.g., community advisory boards, advocacy groups, policymakers) to inform research project design or dissemination of results.

APPLICATION APPROPRIATENESS

Questions regarding the appropriateness of a proposal for this RFP can be directed to:

Athe Tsibris, MD, MS
Co-Director, Developmental and Mentoring Core
atsibris@bwh.harvard.edu

Molly Franke, SD Co-Director, Developmental and Mentoring Core molly franke@hms.harvard.edu

OPTIONAL PRE-SUBMISSION CONSULTATIVE SERVICES ARE AVAILABLE THROUGH THE CFAR

BIOSTATISTICS AND BIOINFORMATICS CONSULTATION

Applicants may request consultation from Biostatistics and Bioinformatics Core personnel. This request *must be made by* March 8, 2024 by completing the <u>Biostatistics and Bioinformatics Core form</u>. Information about Biostatistics and Bioinformatics Core expertise can be found <u>here</u>.

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 **March 15**, **2024** or meet with Biostatistics and Bioinformatics personnel.

BIO-BEHAVIORAL AND COMMUNITY SCIENCE CORE CONSULTATION

Applicants may request consultation from Bio-behavioral and Community Science (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, 2) utilize community-based participatory research and community engagement as guiding principles for their work, or 3) use implementation science approaches. Accordingly, **especially if you have interest in one of these areas**, the BB&CS Core can help you with your proposal, which includes helping to shape the application, pre-reviewing the application and/or helping to link you to <u>relevant existing cohorts</u>. Information about Bio-behavioral and Community Science Core expertise can be found <u>here</u>.

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 **March 8, 2024**. In this initial email inquiry, 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.

Implementation science consultation requests can be directed to:

Christina Psaros, PhD Courtney Yuen, PhD Associate Director, MGH Associate Director, BWH

cpsaros@mgh.harvard.edu courtney yuen@hms.harvard.edu

All other Bio-behavioral and Community Science Core consultation requests can be directed to:

Kenneth Mayer, MD Conall O'Cleirigh, PhD

Director, BBCSC Associate Director, BBCSCMGH
The Fenway Institute COCLEIRIGH@MGH.harvard.edu

kmayer@fenwayhealth.org

CLINICAL CORE CONSULTATION

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. Information about Clinical Core expertise can be found here.

Clinical Core consultation requests can be directed to:

Jonathan Li Boris Juelg Doug Krakower

Clinical Core Director Clinical Core Associate Director Clinical Core Associate Director

BWH MGH BIDMC

jli@bwh.harvard.edu bjulg@mgh.harvard.edu dkrakowe@bidmc.harvard.edu

Harvard Catalyst Connector: For more information, visit the Harvard Catalyst Clinical Research Center website.

HIV Cohorts: The Clinical Core makes available information about studies that have data and specimens available for further investigation. We encourage applicants to review <u>this online information</u> when designing patient-oriented research studies.

PROGRAM IN HEALTH ECONOMICS AND MODELING CONSULTATION

Applicants considering proposals that involve simulation modeling or cost-effectiveness analysis are encouraged to request consultation from Program in Health Economics and Modeling (PHEM) personnel. PHEM investigators can provide advice about whether projects are suitable for these methodologies and how to ensure adequate cost and clinical outcome data are collected, can advise on proposed costing and modeling methods, and, where appropriate, can suggest potential collaborators or methods experts to participate in proposed projects. Requests should be made by **March 8, 2024** by emailing Andrea Ciaranello, PHEM Director, at aciaranello@mgh.harvard.edu.

HUMAN IMMUNE SYSTEM MOUSE CORE

For more information about the Human Immune System Mouse Core at the Ragon Institute of MGH, MIT and Harvard, visit the humanized immune system mouse core website.

For HISMC operational questions, contact Vlad Vrbanac at: VVRBANAC@mgh.harvard.edu. For HISMC scientific questions, contact Alex Balazs at: abalazs@mgh.harvard.edu.

PROCEDURE FOR RESUBMISSION

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

- 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. Contact Bethany Booth (bethany booth@harvard.edu) with any questions about this process.

Projects Involving Clinical Trials:

- CFAR funds cannot be used for studies that meet the NIH definition of a clinical trial. 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. The following link provides further information and case studies to better explain the difference between a clinical trial and a clinical study. 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 8, 2024.
- Clinical studies that do not fall under the definition of a clinical trial will still be allowed.
- The start date for a study involving clinical research entailing above minimal risk to the subjects or vulnerable populations 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 Al060354) 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 https://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. More information on research compliance can be found here.
- 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 <u>before the deadline</u> 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?

See the section labeled **Eligibility for Scholar Awards.** If there is still a question, contact <u>bethany booth@harvard.edu</u> 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. HU CFAR Scholar 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. 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.

10. 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.

11. I am applying for a One-Year Scholar Award for salary support. Can I only request \$75,000 in total direct costs, including both salary and fringe?

No, the \$75,000 limit does not include fringe, just salary and non-salary costs, or salary alone costs. After requesting \$75,000, 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 \$75,000 in salary and \$27,000 in fringe, for total direct costs of \$102,000. Indirect costs are then calculated on the total direct costs. If you are requesting funds to access humanized mice, you can request up to \$95,000 plus fringe.

12. I have a T32. Can I apply for a Scholar 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.

13. I have a K award. Can I apply for a Two-Year Scholar Award?

No. You can, however, apply for the One-Year Scholar Award if it is allowed by your current awarding agency. K awardees can receive compensation on one-year 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.

14. I have an international site with a budget. How do I determine the *additional direct costs* allowed for this international site?

You can request up to an additional 16% of the direct costs for each international site's budget to cover costs allocable to the proposed research but not included in the IDC rate of 8%. For example, the direct costs for your international site are \$50,000 plus \$12,000 for fringe for a total direct costs budget of \$62,000. You can add to the budget another 16% of the calculated total direct costs, which is \$9,920 ($16\% \times $62,000$) for a final total direct costs budget of \$71,920. Indirect costs of 8% are then calculated on total direct costs of \$71,920, for a total indirect costs request of \$5,754 ($8\% \times $71,920$). The entire budget then totals \$77,674 (direct costs plus indirect costs).

REVIEW PROCESS

Applications will be reviewed by the CFAR Review Committee, which will be appointed by the CFAR leadership. The CFAR Review Committee also includes personnel from the Biostatistics and Bioinformatics Core. 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 overall scientific merit, with emphasis on the following criteria:

- **Significance.** The proposal addresses an NIH HIV/AIDS high-priority research area. If successful, the application has the potential to generate highly impactful research that fills an important gap and/or will advance the field.
- **Feasibility.** The application is specific and focused, with realistic goals. The activities of the grant are likely to be completed within the grant period with the requested resources.
- **Methodologic rigor.** The approach (study design, laboratory methods, statistical analyses) is sufficiently detailed for evaluation and free of major methodologic flaws.
- **Mentorship.** The proposed mentor has relevant expertise and demonstrated commitment to the candidate and their career development.
- **Potential for the Award to advance the applicant's career.** It is more likely than not that the award will catalyze meaningful career advancement, to include acquisition of independent funding.

Applications drawing investigators from other fields into AIDS research and 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 research, both locally and internationally, to bring an end to the epidemic and to mitigate its impact on the health of people with HIV (PWH).

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: SCHOLAR AWARD 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 below for your proposal. If your proposed research links to more than one discipline, indicate your primary and secondary discipline. Note that for studies involving International Research, you must specify International Research and one additional programmatic area below 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 Monkeypox Research in the Context of HIV Non-Communicable Diseases Research Pathogenesis Research Reproductive Health Research Substance Use & HIV 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 two pages – both must be included. The following items must be completed: Project Summary and Relevance. Project/Performance Sites. Senior/Key Personnel. Other Significant Contributors (if applicable). Human Embryonic Stem Cells (if applicable). NIH 398 Form Page 4: Detailed Budget Page for the Initial Budget Period. Each site requires a separate page. 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 and Mentors. Refer to the NIH PHS 398 General Biographical Sketch Format Page (Rev. 10/2021 Approved Through 01/31/2026). NIH 398 Checklist Form Page. Research Plan. Items 1-2 must not exceed three pages in total (see Form Page 3 for reference). 1) Specific Aims 2) Research Strategy (Significance, Innovation and Approach) 3) Bibliography and References Cited 4) Vertebrate Animals 5) Select Agent Research 6) Letters of Support

7) Plan for Enhancing Diverse Perspectives (PEDP) – one paragraph and no more than a half page in length			
A completed International Checklist if you are proposing one or more international sites. The checklist can be found here.			
Cover letter from the Applicant (one page for domestic research, one and ½ pages for global health research) to include the following information: • How the award will advance the applicant's independence, including advancement to an NIH mentored scientist award and future funding opportunities. • For Harvard-based applicants proposing global health research/research in a low- or middle-income country (LMIC), a 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. • If this proposal intends to obtain preliminary data necessary to justify a NIH R01, R21, or R34 grant, briefly explain 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. If there is a possibility that the preliminary data obtained by this proposal could indicate that an NIH grant would not be appropriate, briefly explain what decision rule you will use to decide this. • 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 proposed research aligns with the scientific priorities of one or more HU CFAR Scientific Working Groups ("SWGs"), specify the SWG(s) and the priority area(s). • If the research being done by investigators at Harvard-affiliated research sites, briefly sta			
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(s): see guidance in section labeled Mentor Requirements and Expectations .			
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, include a response letter (in addition to the one-page Applicant Cover Letter): see guidance section labeled Resubmission Process .			
Complete Page 15 of the RFP application and attach it as back page of your submission.			
Proposal is a single document in PDF format.			
Proposal in final form has been reviewed by the Principal Investigator.			



Principal Investigator Name:

T:+1 -	_ £	D 1	· • ·
Title	OΤ	Pro	IECT:

vide the additional information below and attach this page as the final page of your application. Submit for <u>each PI</u> of the project. Check the boxes below which best describe your investigator status (select all y):
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 racial/ethnic groups in AIDS research. These include African Americans, Hispanics, American Indians, Alaska natives, native Hawaiians, and Pacific Islanders.
Category 8: Women.
Category 9: Individual with disabilities (defined as those with a physical or mental impairment that substantially limits one or more major life activities, as described in the Americans with Disabilities Act of 1990, as amended. <i>See https://extramural-diversity.nih.gov/diversity-matters/individuals-with-disabilities</i>).
Category 10: Individual from disadvantaged backgrounds (see https://extramural-diversity.nih.gov/diversity-matters/disadvantaged-backgrounds for definition).

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.:

*Refer to the following page for more information about NIH Institutes and Centers http://www.nih.gov/icd/