



ACCESS TO ADVANCED HEALTH INSTITUTE
SEATTLE CHILDREN'S
UNIVERSITY OF HAWAII AT MANOA

UNIVERSITY OF WASHINGTON/FRED HUTCH
CENTER FOR AIDS RESEARCH

**University of Washington / Fred Hutch
Center for AIDS Research (CFAR)**

**2024 Request for Applications (RFA)
International Pilot Awards**

| Key Deadlines | Date Due |
|---|-----------------|
| RFA Release Date | March 25, 2024 |
| Behavioral or Biomedical Intervention Eligibility Check | April 29, 2024 |
| Applications Due | June 18, 2024 |
| Estimated Award Date | August 2024 |

See the following pages for a description of the award program and application process.

International Pilot Awards

Purpose

The International Pilot Awards are for development and implementation of innovative and collaborative HIV-related research projects in developing countries by early-stage investigators. Pilot awards provide an opportunity to initiate new research or to leverage new directions for research within ongoing projects that will provide important preliminary data to seed future larger proposals by early-stage investigators in international settings. Studies with potential to obtain pilot data for development of future grant proposals are given priority.

Eligibility

Applicants must:

- 1) Be a UW/Fred Hutch CFAR [member](#)
- 2) Have an MD or PhD or equivalent terminal degree (includes an MBChB).
- 3) Have not had an NIH R01 [or equivalent](#) grant in HIV/AIDS.
- 4) Have an appropriate appointment, as follows:
 - (a) Early-stage faculty (including acting positions), **OR**
 - (b) a scientist completing a fellowship, **OR**
 - (c) a senior post-doctoral* fellow initiating a new area of HIV-related research that will form a basis for their independent program, **OR**
**Senior post-doctoral fellows must be >1 year into fellowship*
 - (d) faculty-equivalent investigator at an international community-based organization whose primary mission is research.
- 5) Have an appropriate affiliation, as follows:
 - (a) Be appointed at, or being recruited to, a UW/Fred Hutch CFAR affiliate institution (University of Washington, Fred Hutch, Access to Advanced Health Institute, Seattle Children's, University of Hawai'i at Manoa), **OR**
 - (b) Be a citizen or permanent resident of an [Eligible Low or Middle Income Country](#), **and** have a primary mentor appointed at a US-based UW/Fred Hutch CFAR affiliate (University of Washington, Fred Hutch, Access to Advanced Health Institute, Seattle Children's, University of Hawai'i at Manoa).

Applicants are only allowed to submit one application to this program per cycle.

CFAR values diversity and encourages individuals from [underrepresented groups](#) to apply.

Project Eligibility

- The project must be conducted primarily in an international location.
- If the PI is a US-based applicant, an international co-investigator must be included as key personnel.
- Each international PI must partner with a faculty co-investigator from a UW/Fred Hutch CFAR affiliate institution (University of Washington, Fred Hutch, Access to Advanced Health Institute, Seattle Children's, University of Hawai'i at Manoa).
- Research topics could include any aspect of HIV and HIV-related research, but may not include [clinical trials](#), as defined by the NIH.
- Studies of animal models, stored samples from existing cohorts, small pathogenesis studies or *in vitro* trials are acceptable. Project must be primarily conducted in an international location.
- **If your proposed study design involves testing a biomedical or behavioral intervention (including approved drugs and/or standard of care), complete the [CFAR IPA Intervention Eligibility Check Form](#) by **April 29, 2024** for an eligibility review.** Include a brief description of 1) the study group(s), 2) the planned intervention and how it will be assigned, and 3) your proposed outcomes.

Funding Available

- Direct costs: **\$15,000 US over one year.**
- Previously funded projects will not be considered.
- Funding cannot be applied to alterations or renovations of any facilities or IRB/ERC fees.
- If the proposal requires a subcontract, subcontractor F&A costs must be budgeted as a direct cost.
- Please note that the CFAR has negotiated indirect cost waivers with several institutions, including Fred Hutch, Seattle Children's, and University of Hawai'i at Manoa.
- For international institutions, the allowable F&A rate to be budgeted as a direct cost is 8%.
- For domestic organizations without an established F&A rate, the default F&A rate is 10%. If the proposal funds work through UW Kenya, the UW Kenya recharge fee must be budgeted as a direct cost. Please contact uwkenya1@uw.edu for current rate details.

Pre-Submission Requirements

Intervention Eligibility Check: If your proposed study design involves testing a biomedical or behavioral intervention (including approved drugs and/or standard of care), complete the [CFAR IPA Intervention Eligibility Check Form](#) by **April 29, 2024** for an eligibility review. Include a brief description of 1) the study group(s), 2) the planned intervention and how it will be assigned, and 3) your proposed outcomes.

Letters of Support: Applications must include letters of support from all key personnel including faculty co-investigator(s). **International applicants must also provide a letter of support from a primary mentor appointed at a US-based UW/Fred Hutch CFAR affiliate** (University of Washington, Fred Hutch, Access to Advanced Health Institute, Seattle Children's, University of Hawai'i at Manoa).

CFAR Membership: All applicants are required to be UW/Fred Hutch CFAR Members. Information about membership can be found on the [CFAR website](#) or by contacting cfar@uw.edu.

Review Criteria

- **Significance:** Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced?
- **Approach:** Are the conceptual framework, design, methods, and analyses adequate and appropriate to the aims of the project?
- **Innovation:** Does the project employ novel concepts, approaches or method? Are the aims original and innovative?
- **Investigators** (including relationship to UW/Fred Hutch CFAR): Is the investigator appropriately trained and well suited to carry out this work? CFAR prioritizes early-stage investigators and the investigators must meet the eligibility criteria described above.
- **Environment:** Does the scientific environment in which the work will be done contribute to the probability of success? Is there evidence of institutional support?
- **Feasibility:** Is the study feasible given the duration of one year and a budget of \$15,000?
- **Potential for new collaborations:** Although we prioritize CFAR links and target particular countries, we are also encouraging relationships with new investigators who are not currently linked to CFAR. We welcome new investigators who bring expertise in new, relevant disciplines to forge interdisciplinary collaborations.
- **Potential for new research projects and career development:** The projects should aid in the development of the investigator by providing important data for a larger NIH (or other) funded study such as an R01.

Pre-Award Requirements

Per NIH policy, UW/Fred Hutch CFAR may not release pilot research funds until awardees complete the NIH administrative clearance process. Clearance will require final IRB approval from all participating institutions

and documentation of human subjects training from all investigators. This process often takes several months, so please consider it in your timeline. More information on NIH requirements for international studies can be found [here](#).

****Projects that are unable to complete the NIH clearance process within one year of award date are at risk of losing funding****

Post-Award Requirements

CFAR support must be acknowledged in all publications derived from CFAR funding. Suggested wording is available [here](#).

A progress report is required annually and upon completion of the project. This should include information about publications, collaborations, and future grants related to your CFAR project.

Application Instructions

After fulfilling all pre-submission requirements, please complete the [CFAR IPA Application Submission Form](#) by **June 18, 2024**, using the application, budget, and budget justification templates below. The application, any letters of support, biosketches and any other supporting documentation must be combined into a single PDF. **Application sections can be expanded or shortened, however proposal narratives (the application form sections 1 – 12, excluding the budget and biosketches) should be no longer than five pages.**

Use of CFAR Resources:

We encourage you to utilize services from the CFAR Cores and/or Scientific Working Groups early in the preparation of your application. The Cores and Scientific Working Groups have explicitly offered their consultations services (see list below). More information about CFAR Cores and services can be found at [Find a Service – UW/Fred Hutch Center for AIDS Research \(washington.edu\)](#).

- [Administrative Core – Office of Community Engagement \(OCE\)](#): Facilitates community-engaged research with the goal of ensuring that all people can benefit from scientific advances in prevention, treatment, and cure of HIV. The OCE utilizes a Community Consultative Group (CCG) of experts to provide constructive feedback and technical assistance to investigators on research proposals, grant applications, grant implementation, and research to effectively impact and engage communities affected by HIV. To arrange for an OCE consultation, please email your completed [OCE Consultation Form](#) to cfaroce@uw.edu.
- [Behavioral Innovations Core](#): Provides support, knowledge, and skills in diverse contexts at the intersection of behavioral science and digital health to further HIV prevention and care research while addressing health equity, access, ethics, and policy. Applicants proposing a study involving behavioral innovation research (i.e. use of structural and multilevel models; digital data capture and intervention; behavioral outcomes measurement (including geospatial and social networking data); telePrEP and other telehealth services; health access, equity, and policy) are **strongly encouraged** to obtain a consultation from the Behavioral Innovations Core (BIC) with regard to methods and study design. To arrange for a behavioral methods consultation, please complete the [Behavioral Innovations Research Consultation Form](#) and email Dr. David Katz (dkatz7@uw.edu), BIC Faculty, and Morgan Aurelio (mca1@uw.edu) BIC Research Coordinator, to flag your request within the Core's queue. *Be prepared to send your draft Aims and Methods upon request to your assigned Core advisor.*
- [Biomarkers, Prevention and Interventions for HIV-associated Malignancies & NCDs Core](#): Provides assays and data instruments to enable studies of HIV-associated malignancies and other non-communicable disease. Applicants proposing a clinical or translational study involving HIV-associated malignancies or other non-communicable disease may contact Manoj Menon (mmenon@fredhutch.org) to have a consultation regarding their study.
- [Clinical and Comorbidity Research Core](#): Provides a central resource for high-quality HIV clinical data, ready access to eligible study participants and biologic specimens, and consultation for investigators conducting

clinical, translational, and basic research. Core scientists with expertise in epidemiology, data science, health informatics, biostatistics, clinical medicine, socio-behavioral, basic and translational research provide assistance with study feasibility, design, methods (qualitative, quantitative), statistical analysis, grant preparation, and analytic datasets including adjudicated outcomes (e.g., myocardial infarction, stroke, cancer) and patient-reported outcomes (e.g., current substance use, mental health). We lead and facilitate participation in national ([CNICS](#)) and international ([NA-ACCORD](#)) HIV Cohort Collaborations. To request Core services, please visit our [core webpage](#) and use the link below 'Services'.

- [Data Sciences and Methods Core](#): Provides a central resource for biostatistical and qualitative research expertise to improve the conception, design, and analysis of HIV/AIDS-related studies. Any CFAR investigator can consult with quantitative or qualitative Core scientists for assistance with study planning and design for grant applications (e.g., study design, sample size, and development of analytical plans for NIA, K, or R01 grants), study implementation (e.g., data management, data analysis), and research communication (e.g., drafting of abstracts, posters, or articles). To request a consultation, please visit our core webpage and complete the [quantitative](#) or [qualitative](#) consultation request form.
- [Developmental Core](#): Provides career development services for UW/Fred Hutch CFAR members with a special focus on funding opportunities, skills training and mentoring support services. In tandem with its sponsored award programs, the Developmental Core offers pre-submission budget consultations to help position applicants for efficient proposal reviews and award releases if funded. To request a budgetary consultation, please cfardev@uw.edu.
- [Health Equity SWG](#): Aims to catalyze efforts to investigate and understand the complex social and structural determinants of health disparities and to promote innovative research to attain health equity and remove sources of unfair health differences among historically marginalized populations. Applicants proposing a study relevant to health equity should contact Roberto Orellana (popolvuh@uw.edu) to have a consult with them regarding their study.
- [Immunology, Retrovirology, and Cure Core](#): We encourage applicants to contact the IRC Core manager, Tom Andrus (tandrus@fredhutch.org), for projects in any way related to humoral and cellular responses to HIV infection, virology, sequencing assays/analysis, animal/tissue models of HIV infection, HIV cure. Mr. Andrus will facilitate communication with the relevant IRC Core faculty.
- [Implementation Science Core](#): Provides resources to develop implementation science expertise within the CFAR community. Applicants proposing a study in the field of implementation science should request an expert consult regarding their study by completing the Core's online [Request for Consultation](#) form. Contact uwshivishub@uw.edu (cc: cfar@uw.edu) for assistance completing the form as needed. Applicants should also email uwshivishub@uw.edu (cc: cfar@uw.edu) in order to flag their request within the Core's queue.
- [Substance Use SWG](#): Supports a multi-disciplinary network of researchers to develop substance use research, receive critical feedback on projects and grants, and cultivate new skills and knowledge related to substance use, particularly those from diverse and underrepresented backgrounds. To arrange for a consultation for substance used-related proposals, contact Judith Tsui (tsuij@uw.edu) and Sara Glick (snglick@uw.edu).
- [Translational Research Subcore](#): The Translational Research Subcore helps investigators perform clinical studies by supporting enrollment of people living with HIV, prospective collections of samples, facilitating use of repository specimens, and assisting with overall study logistics and implementation. Applicants proposing clinical, translational, sociobehavioral or basic research projects that require access to research space, local research participants, and/or clinical specimens/procedures should contact Jordan Graff (jggraff@uw.edu) to have a professional consult with them regarding their study.



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UW/Fred Hutch Center for AIDS Research 2024 International Pilot Award Application Form

1. Title of Project

City and Country of Project:

Field Site:

2. Principal Investigator

Name:

Academic Title:

Primary Institution/Organization:

Address:

City:

State:

Zip:

Phone:

Fax:

Email:

3. Collaborating Investigator

Name and Title:

Organization:

Address:

City:

State:

Zip:

Phone:

Fax:

Email:

4. UW/Fred Hutch CFAR Mentor (for applicants stationed outside of the US)

Name and Title:

Organization:

Address:

City:

Country:

Phone:

Fax:

Email:

5. Background Statement

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| 6. Study Description (Include objectives, study population, and methodology) |
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7. Site (City, Country and Treatment Setting)

8. FWA # for all sites

| Institution | Number |
|-------------|--------|
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9. Describe in lay language how human subjects protection will be maintained (confidentiality, risk and benefits of participation, minimizing risk of harm, and informed consent)

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10. Describe your future plans for the data you will collect in this study and how this pilot study will promote career development and/or new collaborative research activities.

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**11. IRB # if approved or applying for a modification.
(if no number, state plan for human subjects approval: new, pending modification, etc.)**

| Study | Number | PI |
|-------|--------|----|
| | | |

12. Describe any NIH programs linked to this study

| Title | Grant # | PI |
|-------|---------|----|
| | | |

13. Co-Investigators

| Name | Affiliation | Email |
|------|-------------|-------|
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Attach:

- **Biosketches of key personnel**
- **Letters of support from key personnel and UW mentor**

Please note: If your application is selected, all investigators will need to complete Human Subjects Training. Link to free on-line training is available at:

<https://www.washington.edu/research/hsd/training/required-training/web-based-citi-training/>

Please complete the budget and budget justification below. All costs must conform to the NIH Grants Policy Statement (GPS) and applicable U.S. Office of Management and Budget OMB circulars for necessity and reasonability, allocability, conformance and consistency, as well as allowability. Please follow the [link](#) to section 7.2 cost principles section of the NIH Grants Policy Statement for more information.

Submit application using the [CFAR IPA Application Submission Form](#) by **June 18, 2024 at 11:59pm PDT.** Please be prepared to provide the following information:

1. Upload application ([single PDF \(preferred\)](#) or **MS Word file**), including biosketches of key personnel, letters of support from key personnel and UW mentor, and your budget and budget justification.
2. Principal Investigator Name (Last, First)
3. Email
4. CFAR Membership Status
 - a. I am a CFAR member.
 - b. I have completed the CFAR membership form and am awaiting confirmation.
5. Optional **Investigator Demographic Information** section. To facilitate completing the online form, we list the included questions below for your information.
 - a. PI Name (used solely to compare aggregate applicant pool and awardee pool data)
 - b. Gender identity(ies) (Indicate or DECLINE TO STATE)
 - c. Racial category(ies) (Indicate or DECLINE TO STATE)
 - d. Ethnic category(ies) (Indicate or DECLINE TO STATE)
 - e. NIH disabled? (YES/ NO/ DECLINE TO STATE)
 - f. NIH disadvantaged? (YES/ NO/ DECLINE TO STATE)

NOTE: The demographic information provided is confidential and will not affect consideration of your grant application or access to services. Reporting the requested information is **voluntary**. Additionally, as part of UW/FH CFAR's commitment to diversity and inclusion, this form enables applicants to describe their gender(s) beyond the binary options provided by our funders.

**DETAILED BUDGET FOR INITIAL BUDGET PERIOD
DIRECT COSTS ONLY**

FROM

THROUGH

List PERSONNEL (*Applicant organization only*), Use Cal, Acad, or Summer to Enter Months Devoted to Project
Enter Dollar Amounts Requested (*omit cents*) for Salary Requested and Fringe Benefits

| NAME | ROLE ON PROJECT | Cal. Mnths | Acad. Mnths | Summer Mnths | INST.BASE SALARY | SALARY REQUESTED | FRINGE BENEFITS | TOTAL |
|--|-----------------|------------|-------------|--------------|------------------|-------------------------------------|-----------------|-------|
| | PD/PI | | | | | | | |
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| SUBTOTALS | | | | | | | | |
| CONSULTANT COSTS | | | | | | | | |
| EQUIPMENT (<i>Itemize</i>) | | | | | | | | |
| SUPPLIES (<i>Itemize by category</i>) | | | | | | | | |
| TRAVEL | | | | | | | | |
| INPATIENT CARE COSTS | | | | | | | | |
| OUTPATIENT CARE COSTS | | | | | | | | |
| ALTERATIONS AND RENOVATIONS (<i>Itemize by category</i>) | | | | | | | | |
| OTHER EXPENSES (<i>Itemize by category</i>) | | | | | | | | |
| CONSORTIUM/CONTRACTUAL COSTS | | | | | | DIRECT COSTS | | |
| SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD (<i>Item 7a, Face Page</i>) | | | | | | \$ | | |
| CONSORTIUM/CONTRACTUAL COSTS | | | | | | FACILITIES AND ADMINISTRATIVE COSTS | | |
| TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD | | | | | | \$ | | |

BUDGET JUSTIFICATION PAGE