



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

### 2023 Request for Applications (RFA) New Investigator Award

	DEADLINES
RFA Release Date	September 15, 2023
<b><u>Key Pre-Submission Items:</u></b>	
<b>REQUIRED Non-Binding Letter of Intent Form</b> (includes eligibility check details for international applicants)	October 18, 2023
<b>Email Requests for <u>Synchronous</u> Consultation Appointments:</b> <ul style="list-style-type: none"><li>o REQUIRED: Biostatistics, Office of Community Engagement</li><li>o OPTIONAL: Budget, Other Core/Scientific Working Group</li></ul>	October 25, 2023
<b>Submissions for <u>Asynchronous</u> Consultations:</b> <ul style="list-style-type: none"><li>o REQUIRED: Budget Consultation Items Sent for Written Feedback</li></ul>	November 1, 2023
<b>Biostatistics, Budget, Office of Community Engagement Feedback Window Ends</b>	November 22, 2023
<b>Application Deadline</b>	December 13, 2023
<b>Review Date</b>	February 2024
<b>Estimated Earliest Award Date</b>	February 2024
<b>Estimated Award Period</b> Projects with US-based sites only Projects with International sites	February 2024 – January 2026 April 2024 – March 2026

Please read the entire RFA for detailed instructions.

## **New Investigator Awards (NIAs)**

### **1) Overview**

#### **Purpose**

The purpose of the UW/Fred Hutch Center for AIDS Research (CFAR) [New Investigator Awards \(NIA\)](#) is to encourage junior investigators (at a senior stage of training or recently independent) to conduct independent research, acquire preliminary data to use for subsequent grant submissions, publish, receive mentorship, and write one or more grants to obtain funding to continue their HIV research careers. The application process is designed to help you formulate a research proposal consistent with National Institute of Health (NIH) requirements for your future grant applications and includes opportunities to consult with experts to strengthen the study design and public health reach of your work.

**We seek submissions reflecting the breadth of scientific disciplines**, and are partnering with the [UW Behavioral Research Center for HIV \(BIRCH\)](#) to strongly encourage those related to mental health and/or behavioral science topics.

**Examples of successful NIA proposals are accessible via the online CFAR [Developmental Core Resources Repository](#).** Please contact us with any questions throughout the process at [cfardev@uw.edu](mailto:cfardev@uw.edu).

#### **Applicant Eligibility**

Applicants must:

1. Have an MD or PhD or equivalent terminal degree (includes an MBChB).
2. Have not had a NIH R01 [or equivalent](#) grant in HIV.
3. Have an appropriate appointment, as follows:
  - a. Junior faculty (including acting positions) at a US-based CFAR affiliate\*, **OR**
  - b. A scientist completing a fellowship at a US-based CFAR affiliate\*, **OR**
  - c. A senior post-doctoral fellow at a US-based CFAR affiliate\* initiating a new area of HIV-related research that will form a basis for their independent program, **OR**
  - d. Faculty-equivalent investigator at an international community-based organization whose primary mission is research.
4. If from non-U.S. institutions, then also have a primary mentor who is appointed at a US-based CFAR affiliate\*. NOTE: In-country co-mentors are strongly encouraged but not required in order to apply.
5. Be a UW/Fred Hutch CFAR [member](#), or have [applied for membership](#) at the time of proposal submission.

\*US-based CFAR affiliates include the University of Washington, Fred Hutch, Seattle Children's, Access to Advanced Health Institute (formerly Infectious Disease Research Institute), and University of Hawai'i at Mānoa.

*UW/Fred Hutch CFAR values diversity and encourages individuals from [underrepresented groups](#) to apply.*

Applicants may submit only one application to this program per cycle. Only individual Principal Investigators (PIs) are eligible to apply; we do not allow Co-PIs to apply.

NIH K awards do not impact program eligibility as long as the requested funds support different items; the research can be on the same topic.

Successful applicants usually have some preliminary data to support their application but preliminary data is not a requirement.

We accept applicant resubmissions of prior-year NIA proposals that have been revised to address previous NIA reviewer critiques.

Contact [cfardev@uw.edu](mailto:cfardev@uw.edu) if you have questions about eligibility.

### **Types of Projects**

HIV-related research is defined broadly and includes basic science, clinical, epidemiological, behavioral, and implementation science research.

**We can only accept applications in the [NIH's HIV research high or medium priority areas](#).**

Please refer to the following [CFAR Clinical Clearance guidelines](#), which are also available for download from the [Developmental Core Resources Repository](#).

1. **Studies that cannot be funded through the CFAR**
  - a. Any clinical trial ([NIH definition of a clinical trial](#))
  - b. Studies involving new drugs, treatments, or devices
2. **Studies that can be funded via CFAR but require additional NIH review if selected for an Award**
  - a. Studies involving **new ways of using known drugs, treatments, or devices** (allowed on a case-by-case basis)
  - b. Studies that are deemed **above minimal risk** by the Institutional IRB
  - c. Studies involving [vulnerable populations](#)
  - d. Studies with populations with additional considerations for **confidentiality and safety** (transgender, sex workers, refugees, etc.)
  - e. Studies involving **behavioral interventions** (above minimal risk)

**No human participant work may be initiated until clinical approval is received.**

3. **Studies that do not require additional NIH review**

Research activities that do not include vulnerable populations (see Category 2.c. above) and present **no more than minimal risk** to human participants as described in the [OHRP Expedited Review Categories](#). Examples include but are not limited to the following:

- a. Routine blood draws
- b. Non-invasive procedures routinely employed in clinical practice (e.g. ultrasound, MRI)
- c. Surveys, focus groups

### **Mentoring**

Each NIA submission must include a letter of support from the applicant's primary project mentor. International applicants must have primary mentors who are appointed at a US-based affiliate of the UW/Fred Hutch CFAR [University of Washington, Fred Hutch, Seattle Children's, Access to Advanced Health Institute (formerly Infectious Disease Research Institute), University of Hawai'i at Mānoa] and are strongly encouraged to also identify at least one in-country mentor (as primary or co-mentor) while preparing their proposal. However, *only the primary project mentor is required to provide a letter of support stating that they have read and discussed the proposal with the applicant as part of the full application*. If needed, please contact Grace John-Stewart, Developmental Core Director, ([gjohn@uw.edu](mailto:gjohn@uw.edu), cc: [cfardev@uw.edu](mailto:cfardev@uw.edu)) to provide suggestions for possible mentors. Successful NIA applicants will form a Mentoring Committee to provide guidance for their career development and to assess NIA project progress at least annually.

### **Funding Available**

Awards will be up to \$70,000 total (direct costs) for 2-year non-interdisciplinary projects, or \$80,000 total (direct costs) for 2-year interdisciplinary projects. **To qualify for interdisciplinary level funding, successful applicants must demonstrate that the research work itself incorporates methods from multiple disciplines (e.g., behavioral science, implementation science, laboratory sciences).**

### **Budget Development Guidelines and Restrictions**

1. Please note the following regarding institutional indirect (Facilities & Administrative, or "F&A") costs. Applicants who are appointed at the University of Washington should not include indirect costs in their project budget, *unless* there is a foreign or domestic subcontract with an institution that does not have a UW indirect cost waiver. Applicants who are not appointed at the University of Washington should include indirect costs in their project budget, *unless* there is a subcontract with an institution that has a UW indirect cost waiver. **Indirect cost waivers apply to subcontracts with Fred Hutch, Seattle Children's, and**

**Advanced Access to Health Institute. Therefore, proposals with subcontracts to these institutions should not include indirect costs.**

If the proposal requires a subcontract to an international institution, the *maximum allowable indirect cost (F&A) rate is 8%*. **Indirect costs to international institutions must be part of the direct cost budget total of \$70,000 total for 2-year non-interdisciplinary projects, or \$80,000 total for 2-year interdisciplinary projects.** A detailed and complete budget and budget justification must be provided for foreign subcontracts.

2. Requested support for project collaborators who are NOT at the same institution as the awardee should be listed as consultant costs. If the collaborator cannot accept consultancy fees, a subcontract must be issued to their institution. These costs must be listed in the detailed budget as consortium costs with applicable indirect costs included, which will count towards the direct costs limit. Please note that the CFAR has negotiated indirect cost waivers with several local partner institutions (See guideline 1 above).
3. Requested support for equipment and technology, including computers, must be fully justified in the budget justification with a clear connection to the scientific aspects of the project and not for general office use. Be sure to read our [Computer Policy](#) if you would like to budget for a computer. General office supplies are not allowed.
4. Tuition, fees and stipends for graduate students are allowable within the following NIH guidelines for total compensation: [NOT-OD-23-076](#)
5. Costs associated with Institutional Review Board (IRB) review of human research protocols, or Institutional Animal Care and Use Committee (IACUC) review of animal research protocols, are not allowable as direct charges.
6. 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 below to section 7.2 cost principles section of the [NIH Grants Policy Statement](#) for more information.

**UW-based applicants do not need to submit an eGC-1 and institutional signature on their NIA application.**

**Non-UW applicants are required to submit a PHS 398 Form - page 1 with institutional signature as part of their NIA application.**

### **Other Information**

**Interdisciplinary Proposals:** Multidisciplinary projects are encouraged and *are defined as projects where the research work itself incorporates methods from multiple disciplines (e.g., behavioral science, implementation science, laboratory sciences)*. The applicant must provide a rationale during the online submission process as to why the applicant considers the project to be interdisciplinary.

**Human Participants and Animal Subjects IRB Approvals:** A copy of all Institutional Biohazard, Human Participants, Animal Subjects and Institutional Review Board (IRB) approvals (if applicable) are not required before submitting an NIA application, but they must be forwarded to Linh Newcomb, CFAR Grant and Finance Manager ([ltn128@uw.edu](mailto:ltn128@uw.edu)), **prior to receipt** of award funding.

## **2) Pre-Submission Process**

### **\*\*\*Required Items\*\*\***

- Online NIA Letter of Intent Form:** Complete the non-binding [2023 CFAR New Investigator Award Letter of Intent Submission Form](#) by **October 18, 2023**. We use this to line up reviewers with appropriate expertise. You will need to provide the following details.
  - Principal Investigator Name, Title and Contact Details
  - Draft Project Title

- Topic Key Words (5-10 words)
- Draft Project Summary in Plain Language (1-2 sentences)
- Scientific Category (e.g., Basic Science, Clinical Epidemiology, Implementation Science, Mixed Methods)
- Name(s)/Institution(s) of Project Mentor(s)
- Name(s)/Institution(s) of Project Collaborator(s)/Consultants
- International Applicants Only:* Attach your up-to-date NIH biosketch ([NIH Instructions](#))

*Note: All applicants are strongly encouraged to review our Applicant Eligibility requirements closely. Ineligible applicants are disqualified automatically. Please await confirmation of your NIA eligibility from the CFAR Developmental Core prior to requesting pre-submission consultation slots reserved for NIA applicants. (NOTE: CFAR Members may request Core/SWG consultation services at any time by contacting the Cores directly. See Appendix A for details.)*

- Biostatistical Consultation:** All applicants are required to discuss their proposal with a CFAR Data Science and Methods Core biostatistician during the preparation of their proposal. Exceptions apply to applicants with biostatistical expertise, or with prior biostatistical project involvement or review. Biostatistical consultations are best done early in the pre-submission process. Feedback may include recommendations to confer with additional CFAR Core and Scientific Working Group (SWG) experts, and timely CFAR consultation appointment slots are limited.

Fill out the [consultation request form](#) by **October 25, 2023** to schedule your virtual biostatistics consultation appointment, or to request a waiver. *You must also forward your draft Aims and Methods to your assigned biostatistician at least 48 hours prior to your scheduled consultation.*

Exceptions may apply to applicants with biostatistical expertise, or with prior biostatistical project involvement or review. **Waiver requests should include justifications based on project details and/or applicant expertise, including biosketch content when relevant.**

- The [Office of Community Engagement](#) (OCE) helps to link our researchers with our communities 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 dissemination in order to effectively impact and engage communities affected by HIV. The value added by OCE consultations may include:
  - Access to perspectives from underrepresented populations affected by HIV
  - Improved feasibility and acceptability of research design, methods, and results
  - Improved application review scoring

#### REQUIRED OCE Consultation Items for Written Feedback

- Complete an [OCE Consultation Form](#).** In part #5 “Brief Summary of Proposed Study” of the OCE Consultation Form, include the following:
  - a summarization of your project
  - your project’s significance
  - community engagement opportunities, including how you will engage the communities in research.
- Forward your completed OCE Consultation Form** to [cfaroce@uw.edu](mailto:cfaroce@uw.edu) (cc: [cfardev@uw.edu](mailto:cfardev@uw.edu)) at your *soonest opportunity* and no later than **November 1, 2023**.
  - In the same email, you must request a required synchronous 30-minute consultation meeting.** Feedback for all applicants will be provided during your synchronous consultation meeting. Written feedback will be provided on a rolling basis in the order of which your application has been received.

#### Tips for Optimizing Your OCE Consultation Feedback

- Review our [OCE Community Engagement Considerations for Research Proposals](#).
- Consider the [NIEHS Framework for Community-Engaged Research and Citizen Science](#) and these [Models of Community-Engaged Research Proposals](#).
- Draft a project summary for the OCE Consultation Form and Zoom Presentation: Your project summary should include the following information in plain language:
  - Key research questions and why they are important
  - Anticipated key findings
  - How is this related to HIV prevention/treatment/cure?
  - Why should community be excited about this project?
- Prepare questions for your OCE consultation: Refer to the table below for examples of topics on which you may request specific feedback.

Phase of Research	Suggested OCE Consultation Topics
Research Question Development	Research question consultation: discuss appropriateness and relatedness to the community
Proposal Development	Methods consultation: discuss feasibility, acceptability, consent process, recruitment and retention, dissemination
Project Implementation	Implementation consultation: discuss the development of protocols, educational materials, recruitment and retention, dissemination; Optional: Implementation solutions consultation

- Develop a slide presentation. It is recommended, but not required, to use presentation slides for your OCE consultation. To help you get started, the [OCE Resources](#) page offers a wide variety of additional tools for scientists, including:
  - [Plain Language Slide Template](#) (optional)
  - [Plain Language Summary - Introduction](#)
  - [Sample community-oriented presentation slides](#)
  - [NIAID HIV Language Guide](#)
- **Budget Consultation:** All applicants are required to e-mail their draft budget and budget justification to Linh Newcomb, CFAR Grant and Finance Manager, at [LTN128@uw.edu](mailto:LTN128@uw.edu) (cc: [cfardev@uw.edu](mailto:cfardev@uw.edu)), by **November 1, 2023** in order to clarify related issues.

OPTIONAL: Budget Consultation Appointment: In addition to sending your draft budget items for written feedback, you may request a synchronous consultation meeting. To request an appointment, contact Linh Newcomb at [LTN128@uw.edu](mailto:LTN128@uw.edu) (cc: [cfardev@uw.edu](mailto:cfardev@uw.edu)) at your *soonest opportunity* and no later than **October 25, 2023**. Availability is limited. (NOTE: In some instances, the CFAR Developmental Core may initiate a request to meet with an applicant to clarify budget issues as needed.)

**Strongly Encouraged Items**

- **"Qualitative Methods Consultation:** Applicants proposing a study involving qualitative research are **strongly encouraged** to obtain a consultation from the Data Sciences and Methods Core with regard to methods and study design. To request a consultation for qualitative methods review, please complete the [DSMC Consultation Request Form](#) on the DSMC webpage and indicate that you are requesting a review of your qualitative methods plan. Please also email Dr. Kristin Beima-Sofie ([beimak@uw.edu](mailto:beimak@uw.edu)) to flag your NIA-related request within the DSMC Core’s queue. *Be prepared to send your draft Aims and Methods upon request to your assigned Core advisor.* Requests for NIA consultations should be made no later than **October 25, 2023** to allow time for completion and integration of feedback into your proposal prior to the December 13, 2023 application deadline.



- **Behavioral Innovation Consultation:** 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 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](mailto:dkatz7@uw.edu)), BIC Faculty, and Morgan Aurelio ([mca1@uw.edu](mailto:mca1@uw.edu)) BIC Research Coordinator, to flag your NIA-related request within the Core's queue. *Be prepared to send your draft Aims and Methods upon request to your assigned Core advisor.* Requests for NIA consultations should be made no later than **October 25, 2023** to allow time for completion and integration of feedback into your proposal prior to the December 13, 2023 application deadline.
- **Additional CFAR Core/SWG Consultations:** We strongly encourage you to utilize services from additional CFAR Cores and Scientific Working Groups (SWGs) early in the pre-submission process. See the consultation services descriptions in Appendix A: UW/Fred Hutch CFAR Core/SWG Consultation Services below for more details and/or visit the CFAR website to [search available services](#). Requests for NIA consultations should be made no later than **October 25, 2023** to allow time for completion and integration of feedback into your proposal prior to the December 13, 2023 application deadline.

### 3) Post-Award Requirements (if funded)

The following approvals (human participants or animal subjects, international sites, vulnerable populations) are required prior to funding, submitted to Linh Newcomb, CFAR Grant and Finance Manager, [LTN128@uw.edu](mailto:LTN128@uw.edu):

- (If applicable) a copy of all Institutional Biohazard, Animal Subject and Institutional Review Board (IRB) approvals
- If the project involves international sites, the awardee must submit an International Study Checklist for NIH international clearance approval and provide human participants training certification for all key personnel
- If the project involves human participants and falls under a vulnerable population category that requires additional NIH review, the awardee must submit their protocol and consent forms for NIH clinical clearance approval

Please note that NIH international clearance and/or clinical clearance take several months to obtain all required approvals and therefore applicants should incorporate this into their study timeline.

Mentoring Committee and Agreement: The Awardee will work with their NIA project mentor(s) to develop a brief written agreement identifying members of a Mentoring Committee and setting terms and expectations for the mentoring process. The Mentoring Committee serves to provide career development guidance and progress assessments at least annually. *CFAR strongly encourages the Awardee to engage in-country co-mentors as part of this process, and as Mentoring Committee members when feasible and aligned with their mentoring plan.*

Reporting and Presentation Requirements: Awardees will be required to submit yearly progress reports to the CFAR and, after their project is finished, make an oral presentation at the annual UW STI & HIV Research Symposium or another appropriate CFAR-sponsored event. The chair of the mentoring committee will also be required to submit a brief progress report annually before Year 2 funding can be received. Additionally, *awardees are expected to disseminate the results from NIA projects to the communities relevant to the research, ideally both through scientific and community forums, and where appropriate, shared with public health decision makers.*

CFAR Professional Development Activities: Awardees are strongly encouraged to participate in periodic professional development and networking events with other CFAR honorees, to consider collaboration and peer mentoring inquiries from CFAR members, and to pursue CFAR leadership roles.

CFAR Support: CFAR support (P30 AI027757) must be acknowledged in all publications and presentations derived from CFAR funding (see: <http://depts.washington.edu/cfar/discover-cfar/acknowledge-cfar>). Publications supported by this award must have PMCID numbers in order to comply with the NIH Public Access Policy.

Other Support: In the event that pending other support is funded which overlaps with or reduces your effort on this CFAR project, you must notify the Linh Newcomb, CFAR Grant and Finance Manager ([LTN128@uw.edu](mailto:LTN128@uw.edu)). Your application aims and budget will be reviewed and if it is determined that you are unable to meet the specific aims of your CFAR proposal, the CFAR award will be revoked.

#### 4) Review Criteria

- Impact and Scientific Merit of the proposal and the likelihood of the project to exert a sustained powerful influence on the field. Will this proposal be likely to provide information that can significantly advance our understanding of HIV and/or provide preliminary data that is likely to lead towards independent research grant funding? Does the proposal reflect a community-sourced research priority?
- Significance – Does the study address an important problem consistent with the objective to advance our understanding of HIV? If the aims are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive the field of HIV research? How will impacted communities benefit directly via advancement of HIV prevention, treatment and/or cure?
- Investigator – Are the PI, mentor(s), collaborators, and other researchers well suited to the project? Does this person have appropriate experience and training? If the project is collaborative, do the investigators/mentors have complementary expertise? Will the project team include community-based advisors?
- Approach – Are the conceptual framework, design methods, and analyses adequately developed, well integrated and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternatives? How is community engaged and empowered?
- Innovation – Does the project employ novel concepts, approaches, or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies? How does the innovation reflect the needs and preferences of impacted communities?
- Impact of Project on Pathway to Independence and Mentorship Plan – Will the project help prepare the applicant for a career as an independent HIV researcher (**we recommend that this be described in section A of the applicant's biosketch**)? Does the project take the NIH guidelines on rigor and reproducibility into consideration? (Please also refer to the [NIH's Rigor and Reproducibility Guidelines](#)). Will the proposed mentorship aid in the investigator's career development? Does the mentoring plan consider community-based participatory research methods as a core PI competency?

#### Appendix A: UW/Fred Hutch CFAR Core/SWG Consultation Services

- 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 refer to the detailed instructions above (page 5).
- 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 should refer to



the detailed instructions above to have an expert consult with them regarding their study. To request a consultation, please refer to the detailed instructions above (page 7).

- [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](mailto: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 methods consultation for a NIA application, please refer to the instructions under "Biostatistical Consultation" on page 5.** For *non*-NIA application requests, please visit our core webpage and complete the [Data Science and Methods Core - 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 refer to the detailed instructions above (page 6).
- [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](mailto: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](mailto: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 [uwwhivishub@uw.edu](mailto:uwwhivishub@uw.edu) (cc: [cfar@uw.edu](mailto:cfar@uw.edu)) for assistance completing the form as needed. NIA applicants should also email [uwwhivishub@uw.edu](mailto:uwwhivishub@uw.edu) (cc: [cfar@uw.edu](mailto:cfar@uw.edu)) in order to flag their NIA-related requests 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](mailto:tsuij@uw.edu)) and Sara Glick ([snglick@uw.edu](mailto: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](mailto:jggraff@uw.edu)) to have a professional consult with them regarding their study.

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## APPLICATION INSTRUCTIONS

After fulfilling all pre-submission requirements, please complete the [CFAR NIA Application Submission Form](#) by **December 13, 2023 at 11:59pm PT**. The form will request the following information:

1. *Required:* Attach your proposal as a single **PDF (preferred)** or **MS Word file**.
2. *Required:* Complete the **NIA Application Addendum** section. The addendum fields are listed below so you can prepare your answers in advance.
3. *Optional:* Complete **Investigator Demographic Information** section. We ask that you provide demographic data so we can track our ability to reach applicants who are underrepresented in biomedical research.

- The proposal should be written in English on [PHS 398 forms](#) and should follow a modified NIH investigator-initiated grant application (R01) format.
- Bibliography and References Cited do not count toward the 5-page limit for the Research Plan (Specific Aims through Approach). Please see details below.
- No appendices are allowed.
- Do not submit Targeted/Planned Enrollment Tables.
- Submit a detailed budget, and not a modular budget.

### **REQUIRED: The Proposal must include:**

- 1. First Page (PHS 398 Form page 1). Download: [MS Word](#) or [PDF](#).
  - Institutional sign-off for non-UW applicants is required.**
- 2. Project Summary Page: (PHS 398 Form page 2 - Download: [MS Word](#) or [PDF](#))
- 3. Detailed budget for first 12 month period: (PHS 398 Form page 4 - Download: [MS Word](#) or [PDF](#))
- 4. Complete 2-year budget and justification: (PHS 398 Form page 5 - Download: [MS Word](#) or [PDF](#))
- 5. Resources page (PHS 398 Format - Download: [MS Word](#) or [PDF](#); maximum length 1 page)
- 6. Biographical Sketch for the NIA applicant ([NIH instructions](#); Download: [MS Word](#))
  - In section A, include an answer the question: *How will the CFAR NIA prepare you for a career as an independent HIV investigator?***
- 7. Biographical Sketch for only the primary NIA mentor and any mentors who are located at institutions that are outside of the UW/Fred Hutch CFAR consortium [University of Washington, Fred Hutch, Seattle Children's, Access to Advanced Health Institute (formerly Infectious Disease Research Institute), and University of Hawai'i at Mānoa].
- 8. Resubmission Information (if applicable; maximum **1** page) Use PHS 398 Continuation Format pages (Download: [MS Word](#) or [PDF](#)).
  - Previous application title and date submitted
  - Major changes from the prior application
  - Your response to the reviewers' comments from your prior submission
  - Any other information relevant to the submission
- 9. Research Plan (**Maximum 5 pages for sections a-d below**). Use PHS 398 Continuation Format pages (Download: [MS Word](#) or [PDF](#)).
  - Specific Aims (suggested length ½ page)
  - Significance (suggested length 1½ pages).
  - Innovation (suggested length ½ page)
  - Approach (suggested length 2½ pages)

- 10. Bibliography and References cited (as needed)
- 11. Plan for Protection of Human Participants (if applicable; maximum 1 page)
- 12. Plan for Care and Ethical Treatment of Animal Subjects (if applicable; maximum 1 page)
- 13. Mentor's Letter of Support (should include the statement, "**I have read and discussed this application with [applicant name] and am supportive of its submission.**")
- 14. Letters of support (restricted to **mentor(s)** and any **community-based collaborators** for the proposed project).

**REQUIRED:** The [CFAR NIA Application Submission Form](#) will request the following information under the "NIA Application Addendum" section.

- PI contact details
- Primary project mentor name, institution and email address
- Any additions/deletions to project mentors as listed in the Letter of Intent, including names/institutions
- Any additions/deletions to project collaborators/consultants as listed in the Letter of Intent, including names/institutions
- Final project title
- Are you submitting an interdisciplinary proposal? (YES/NO)
  - If yes, provide an interdisciplinary justification: *Explain how the research work itself incorporates methods from multiple disciplines (e.g., behavioral science, implementation science, laboratory sciences).*
- Does your project investigate health disparities in U.S.-based, underrepresented racial/ethnic minority populations? *Health disparity populations include racial/ethnic minorities, socioeconomically disadvantaged populations, underserved rural populations, and sexual and gender minorities.* (YES/NO)
- Annual Budget Amounts: Year 1 Direct/Total Costs, Year 2 Direct/Total Costs
- Suggested external reviewer names/institutions/email addresses (Required: 2 non-Seattle-based, non-conflicted senior investigators)
- Any additional suggested external reviewers
- Regulatory Information:
  - Will any research or other work be conducted in a foreign country? (YES/NO)
  - Does this study involve animals? (YES, live animals/YES, stored specimens/NO)
  - Does this study involve human participants? (YES, involves human participants/YES, but is human participants exempt/NO, does not involve human participants)
    - If yes, does your study involve procedures or behavioral interventions deemed above minimal risk? (YES/NO)
    - If yes, does your study include vulnerable populations? (Please specify below)
      - Prisoners
      - Refugees
      - Children (up to age 18 years)
      - Pregnant persons, neonates, fetuses
      - Other (please specify): \_\_\_\_\_

**OPTIONAL:** The following information will be requested under the "Investigator Demographic Information" section of the [CFAR NIA Application Submission Form](#). NOTE: The 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, these prompts enable applicants to describe their gender(s) beyond the binary options provided by our funders. Additional details are below.

- PI Name (*used solely to compare aggregate applicant pool and awardee pool data*)
- Gender identity(ies) (Indicate or DECLINE TO STATE)
- Racial category(ies) (Indicate or DECLINE TO STATE)
- Ethnic category(ies) (Indicate or DECLINE TO STATE)
- NIH disabled? (YES/ NO/ DECLINE TO STATE)
- NIH disadvantaged? (YES/ NO/ DECLINE TO STATE)