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

2022 Request for Applications (RFA)
New Investigator Awards (NIAs)
UDPATED 5/4/2022

	DEADLINES
RFA Release Date	**April 1, 2022**
Key Pre-Submission Items: ***REQUIRED* Non-Binding Letter of Intent Form** (includes eligibility check details for international applicants)	~~**April 22, 2022**~~ **May 6, 2022**
Email Requests for <u>Synchronous</u> NIA Consultation Appointments: • ***REQUIRED*:** Biostatistics • ***OPTIONAL*:** Office of Community Engagement, Other Core/Scientific Working Group Consultations	~~**April 22, 2022**~~ **May 6, 2022**
***REQUIRED* Submissions for <u>Asynchronous</u> NIA Consultations:** • Biostatistics (option for international applicants only) • Office of Community Engagement • Budget	~~**April 22, 2022**~~ **May 6, 2022**
Biostatistics, Budget, Office of Community Engagement Feedback Window Ends	**May 13, 2022**
Application Deadline	**May 20, 2022**
Review Date	**June 21, 2022**
Estimated Earliest Award Date	**July 2022**

Estimated Award Period
    Projects with US-based sites only
    Projects with International sites
	July 2022 – June 2023
	September 2022 – August 2023

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 (NIAs) 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.

Applicant Eligibility

Applicants must:
1. Have an MD or PhD or equivalent terminal degree (includes an MBChB plus a Master's Degree).
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 if you have questions about eligibility.
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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 <u>cannot</u> 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 <u>require additional NIH review if selected</u> 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)

   If you are considering a study involving approved drugs and/or standard-of-care, please contact Renee Heffron, Developmental Core Director, (rheffron@uw.edu, cc: cfardev@uw.edu) to determine whether your proposed project would be eligible for funding through CFAR.

   <u>**No human participant work may be initiated until clinical approval is received.**</u>

3. **Studies that <u>do not require</u> 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 <u>primary</u> 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 Renee Heffron, Developmental Core Director, (rheffron@uw.edu, cc: 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 $45,000/year (direct costs) for non-interdisciplinary projects or up to $55,000/year (direct costs) for 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).** Applicants may apply for up to 2 years of funding.

Please note that for those requesting a two-year project, second year funding is contingent upon demonstration of satisfactory progress during year one.

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 <u>does not</u> 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 University of Hawaii. Therefore, proposals with subcontracts to these institutions should <u>not</u> 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 $45,000/year or $55,000/year.** 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 guideline: Total compensation (salary, fringe, and tuition/fees) cannot exceed $53,760. ([NOT-OD-21-049](#))

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.

<u>Other Information</u>

<u>Interdisciplinary Proposals</u>: 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.

<u>Human Participants and Animal Subjects IRB Approvals</u>: 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), <u>prior to **receipt** of award funding</u>.

2) Pre-Submission Process

<u>*Required Items***</u>**

- **Online NIA Letter of Intent Form:** Submit your <u>non-binding</u> <u>2022 CFAR New Investigator Award Letter of Intent</u> via online form by **May 6, 2022.** 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 Lay 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*: Email your up-to-date NIH biosketch or curriculum vitae to cfardev@uw.edu by **May 6, 2022**.

  Note: All applicants are strongly encouraged to review our Applicant Eligibility requirements closely. Ineligible applicants are disqualified automatically. Please refer to the Applicant Eligibility section above for details, and contact cfardev@uw.edu with any questions, prior to requesting pre-submission consultations.

- **Biostatistical Consultation:** All applicants are required to discuss their proposal with a CFAR biostatistician during the preparation of their proposal. 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 on the proposal.

  Contact cfardev@uw.edu (subject: NIA Biostats Consultation) by **May 6, 2022** to schedule your virtual biostatistics consultation appointment, or to request a waiver. You must *also forward your draft Aims <u>and</u> Methods to your assigned biostatistician (cc: cfardev@uw.edu) 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.**

- **Office of Community Engagement Consultation:** The <u>Office of Community Engagement</u> (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.

  REQUIRED OCE Consultation Items for Written Feedback
  - **Complete an <u>OCE Consultation Form</u>**
  - **Record a 3-5 minute Zoom video presentation** summarizing your project, its significance, community engagement opportunities, and questions for our Community Consultative Group (CCG) advisors, who will reply with written feedback. An <u>online tutorial</u> is available for instructions on how to record videos using Zoom. *Please refer to the Tips for Optimizing Your OCE Consultation Feedback below.*
  - **Forward both your completed OCE Consultation Form <u>and</u> video presentation** files to cfaroce@uw.edu (cc: cfardev@uw.edu) at your *soonest opportunity* and no later than **May 6, 2022**. Feedback for all applicants will be provided on a rolling, first-come, first-served basis and no later than **May 13, 2022**.

  OPTIONAL OCE Consultation Appointment: In addition to sending your required OCE Consultation Form and video presentation, you may request a synchronous consultation meeting. To request a 30-minute appointment, contact cfaroce@uw.edu (cc: cfardev@uw.edu) at your *soonest opportunity* and no later than **May 6, 2022**.

  Tips for Optimizing Your OCE Consultation Feedback

  - Review our <u>OCE Community Engagement Considerations for Research Proposals</u>.

☐ Consider the [NIEHS Framework for Community-Engaged Research and Citizen Science](#) and these [Models of Community-Engaged Research Proposals](#).

☐ <u>Draft a project summary for the OCE Consultation Form and Zoom Presentation</u>: 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?

☐ <u>Prepare questions for your OCE consultation</u>**:** 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

☐ <u>Develop a slide presentation.</u> It is recommended, but not required, to use presentation slides for your OCE video presentation. To help you get started, the [OCE Resources](#) page offers a wide variety of additional tools for scientists, including:
   - o [OCE Research Presentation Template](#) (optional)
   - o [OCE Community Slide Introduction](#)
   - o [Sample community-oriented presentation slides](#)
   - o [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 (cc: cfardev@uw.edu), by **May 6, 2022** in order to clarify related issues. (NOTE: In some instances, the CFAR Developmental Core may initiate a request to meet with an applicant to clarify budget issues as needed.)

Optional Items

☐ **Additional CFAR Core/SWG Consultations:** We encourage you to utilize additional CFAR Core and Scientific Working Group (SWG) services early in the pre-submission process to receive consultations on your proposed research plan. CFAR members may request these services at any time. 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 **May 6, 2022** to allow time for completion and integration of feedback into your proposal prior to the May 20, 2022 application deadline.

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

<u>Prior Approvals (use of human participants or animal subjects, international sites)</u>: **Prior to funding, a copy of all Institutional Biohazard, Animal Subject and Institutional Review Board (IRB) approvals (if applicable) must be forwarded** to Linh Newcomb, CFAR Grant and Finance Manager (ltn128@uw.edu). If the project involves human participants and falls under a category that requires additional NIH review, the awardee must submit their protocol and consent forms to Linh for NIH clinical clearance.

Proposals involving either international sites and/or clinical research above minimal risk will require additional clearance from NIH prior to receipt of funding, which requires documenting IRB approval from all participating sites, human participants training certification for all key personnel, and providing the approved protocol/consent form(s). Please note that international projects,

especially those involving human participants, can 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 his or her 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. For international applicants, *CFAR strongly encourages the Awardee to engage at least one in-country mentor (as primary or co-mentor) 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 STD & AIDS 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, *we expect awardees 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). 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* prevention/treatment/cure? 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 – 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)**? Will the proposed mentorship aid in the investigator's career development?

> Does the project take the NIH guidelines on rigor and reproducibility into consideration? (Please also refer to the NIH's Rigor and Reproducibility Guidelines).

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, email a completed OCE Consultation Form to cfaroce@uw.edu. *NIA applicants should also copy cfardev@uw.edu on their request per the detailed instructions above.*

- **Behavioral Science Core**: Provides resources to catalyze new behavioral science research that will contribute to curbing the global HIV epidemic and improve outcomes along the continuum of HIV prevention and care. Applicants proposing a study involving behavioral or qualitative research should complete an online Behavioral Science Research Consultation form to have an expert consult with them regarding their study. *NIA applicants should also email Danielle Terrill, CFAR Program Operations Specialist, at terrill1@uw.edu (cc: cfardev@uw.edu) in order to flag their NIA-related requests within the Core's queue per the detailed instructions above.*

- **Biometrics Core**: Provides a central resource of biostatistical expertise to improve the conception, design, and analysis of HIV/AIDS studies. Any CFAR investigator can consult with Core biostatisticians and quantitative scientists for assistance with study planning and design for grant applications (e.g., sample size and power calculations, development of analytical plans), study implementation (e.g., data management, statistical analysis), or research communication (e.g., drafting of abstracts, posters, or articles). To request a consultation, complete an online Request for Consultation form. *NIA applicants should also email cfardev@uw.edu for support with arranging for pre-submission appointments or written reviews per the detailed instructions above.*

- **Clinical Cohort and Comorbidity Research Core**: Helps researchers access and interpret the comprehensive database of the UW HIV Cohort Study. Applicants proposing a study involving longitudinal data from the UW HIV Clinical Cohort or research datasets from the UW HIV Information System should contact Stephen Van Rompaey (kelpie@uw.edu) to have an expert consult with them regarding their study.

- **Developmental Core**: Provides career development services for UW/FH 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 budget consultation in connection with a UW/FH CFAR award application, please contact Linh Newcomb, CFAR Grant and Finance Manager, at ltn128@uw.edu (cc: cfardev@uw.edu). *NIA applicants are requested to note the detailed budget consultation instructions above.*

- **eHealth SWG**: Promotes multidisciplinary collaborations and provides coordination between CFAR investigators currently working independently in Electronic health (eHealth), mobile health (mHealth), and related digital technologies ("eHealth"). Applicants proposing a study involving eHealth, mHealth, and related technologies should contact Joanne Stekler (jstekler@uw.edu) to have an expert consult with them regarding their study.

- **HIV-Associated Malignancies Core**: Provides assays and data instruments to enable studies of HIV-associated malignancies. Applicants proposing a study involving HIV-associated malignancies should contact Manoj Menon (mmenon@fredhutch.org) to have an expert consult with them regarding their study.

- **Immunology Core:** Provides advanced tools and training for evaluating humoral and cellular responses to HIV infection. Applicants proposing a study involving immunology should contact Stephen De Rosa (sderosa@fredhutch.org) to have an expert consult with them regarding their study.

- **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 cfar@uw.edu for assistance completing the form as needed. *NoA applicants should also email cfar@uw.edu (cc: cfardev@uw.edu) in order to flag their MIIA-related requests within the Core's queue.*

- Retrovirology and Molecular Data Science Core: Assists researchers in viral sequence analysis. Facilities use of frozen blood-derived specimens and data from the Seattle Infection Clinic Cohort. Applicants proposing a study involving sequence-based assays should contact James Mullins (mullspt+cfar@uw.edu) to have an expert consult with them regarding their study.

- 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 Kellie Basham (kmbasham@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 submit your application package in these three steps **by May 20, 2022 11:59 pm PDT**:
(1) *Required*: **Submit your Proposal in one PDF (preferred) or MS Word file to cfardev@uw.edu.**
(2) *Required*: **Complete your online [NIA Application Addendum](#).** The addendum has several fields that are listed below so that you can prepare your answers in advance.
(3) *Optional*: **Complete our online [Investigator Demographic Questionnaire](#)**: 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 <u>do not</u> count toward the 5-page limit for the Research Plan (Specific Aims through Approach). Please see details below.

- ☐ <u>No appendices are allowed</u>.

- ☐ <u>Do not</u> submit Targeted/Planned Enrollment Tables.

- ☐ Submit a detailed budget, and not a modular budget.

<u>**REQUIRED**</u>: **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 (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 <u>primary</u> NIA mentor <u>and any mentors who are located at institutions that are outside of the UW/Fred Hutch CFAR consortium</u> [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: Click here to complete the online NIA Application Addendum, which includes:

☐ 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: Click here to complete the Investigator Demographic Questionnaire, which includes the items listed below. 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, this form enables 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)