2020 Request for Applications (RFA)
New Investigator Awards (NIAs)

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Please read the entire RFA.
New Investigator Awards (NIAs)

1) Overview

**Purpose**
The purpose of this award program is to encourage junior investigators (at a senior stage of training or recently independent) to conduct independent research, acquire preliminary data to use for exogenous grant submissions, publish, receive mentorship, and write one or more grants to obtain funding to continue their HIV/AIDS research careers.

**Applicant Eligibility**
1. Current UW junior faculty (including acting positions) who have not had an R01 grant in HIV/AIDS
2. Senior post-doctoral fellows or scientists initiating a new area of research that will form a basis for their independent program
3. Junior faculty being recruited to the UW faculty or affiliated institutions
4. Investigators with comparable appointments at UW-affiliated institutions (e.g., Fred Hutch, Infectious Disease Research Institute, Seattle Children’s, University of Hawai’i, and UW/Fred Hutch CFAR affiliated international institutions)

Note that applicants are required to have an MD or PhD or equivalent terminal degree in order to be eligible to apply. Applicants from non-U.S. institutions must have a primary mentor at a U.S. based CFAR institution (University of Washington, Fred Hutch, Seattle Children’s, Infectious Disease Research Institute, University of Hawai’i at Mānoa). NIH K awards do not impact 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. Resubmission of revised projects by previous applicants that address critiques of prior proposal is allowed (see application instructions). Applicants are only allowed to submit one application to this program per cycle. We do not allow Co-PIs to apply; only single PIs are eligible to apply. CFAR values diversity among its awardees and encourages individuals from underrepresented groups to apply.

**Types of Projects**
HIV-related research is defined broadly and includes basic science, clinical, epidemiological, behavioral, and health services research.

We can only accept applications in the NIH’s HIV/AIDS research high or medium priority areas.

We cannot fund research with investigational drugs or clinical trials (see NIH’s definition of a Clinical Trial). If you are considering a study involving approved drugs and/or standard-of-care, please contact Ann Collier (acollier@uw.edu, cc: cfardev@uw.edu) to determine whether your proposed project would be eligible for funding through CFAR.

**Mentoring**
It is strongly recommended that applicants identify a mentor while preparing their application. If needed, please contact Dr. Collier to provide suggestions for possible mentors. An applicant may have co-mentors, but a statement from the applicant’s primary mentor that they have read and discussed the application with the applicant must accompany the application (can be included in the letter of support from the mentor). Please note that successful applicants will form a Mentoring Committee to provide guidance for their career development and to assess progress of each NIA awardee 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. 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 that the CFAR does not have funds to cover additional institutional indirect costs and has negotiated indirect cost waivers from Fred Hutch, Seattle Children’s, and University of Hawai’i.
2. Projects with an international subcontract must include the 8% indirect cost rate as part of their direct cost total of $45,000/year or $55,000/year. A detailed and complete budget and budget justification must be provided for foreign subcontracts.

3. 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).

4. 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.

5. Tuition, fees and stipends for graduate students are allowable within the following guideline: Total compensation (salary, fringe, and tuition/fees) cannot exceed $50,004. (NOT-OD-19-036)

6. 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.

7. 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 allowable. Please follow the link below to section 7.2 cost principles section of the NIH Grants Policy Statement for more information.

Other Information

Interdisciplinary Proposals: Multidisciplinary projects are encouraged and are defined as involving 2 or more investigators or mentors that have differing areas of expertise or different research focuses, e.g. applicant and a co-investigator with differing areas of expertise or applicant plus 1-2 co-mentors with at least one of the co-mentors having different expertise than the applicant (at least one mentor must be faculty at UW or a UW affiliated institution). The applicant must provide a rationale during the online submission process as to why the applicant considers the project to be interdisciplinary.

Human Subjects and Animal Care Approvals: Animal Care and Institutional Review Board approvals, if applicable, must be obtained prior to receipt of award funding, but are not required to submit an application.

2) Pre-Submission Process

Letter of Intent: Email a non-binding "email of intent" listing proposed Principal Investigator, Project Title, Mentor(s), and names of collaborators to cfardev@uw.edu by January 29, 2020.

Required for All Applicants

Biostatistical Consultation: All applicants are required to discuss their proposal with one of CFAR’s biostatisticians prior to/during the preparation of their application. This consultation is best done early in the preparation process but must occur before February 14, 2020. Sometimes this requirement is waived for those with biostatistical expertise, involvement in the project, or because biostatistical consultation is not relevant for the project.

- If you are a Seattle-based investigator, please contact cfardev@uw.edu (subject: NIA Biostats Consultation) before January 29, 2020 to schedule your biostatistical review or to request a waiver. There will be a limited number of time slots available for you to schedule your in-person consultation. You will be required to submit a draft of your methods 48 hours before your consultation. If possible and appropriate, this draft should contain a statement of your scientific hypothesis and proposed outcomes which will be used to confirm or reject your hypothesis.
- If you are an international investigator or not based in Seattle, please send a copy of your draft methods by January 29, 2020 to cfardev@uw.edu and we will arrange your written consultation with a CFAR biostatistician.
Budget Consultation: Applicants from all institutions (including UW) are required to consult with Linh Newcomb about their budgets to clarify budgetary issues before February 14, 2020. Please send a draft copy of your budget and justification to Linh Newcomb (lt128@uw.edu).

CFAR Membership: All applicants are required to be CFAR Members. Information about membership can be found at http://depts.washington.edu/cfar/get-involved/cfar-membership.

Required for Some Applicants

International Applicants: International applicants must obtain approval that they are eligible to apply prior to development of their proposal. They should send an up-to-date NIH biosketch or curriculum vitae for review to cfardev@uw.edu (cc: acollier@uw.edu; Subject: NIA International Applicant Eligibility Check) no later than January 29, 2020.

Institutional Approval for non-UW Applicants: Applicants from other institutions should prepare and submit a NIH SF 434 R&R form (R.200), with concurrence from their institution’s business official. UW applicants do not need departmental, school, or Office of Sponsored Programs signatures. For more information, contact cfardev@uw.edu prior to the development of their proposal and no later than February 14, 2020.

Optional Assistance (Consultations with CFAR)

Use of CFAR Resources: We encourage you to utilize services from the CFAR Community Action Board, Cores, and/or Scientific Working Groups early in the preparation of your NIA application. The Community Action Board, Cores, and Scientific Working Groups have explicitly offered their consultations services (see Appendix A: Consultation Information). More information about CFAR Cores and services can be found at http://depts.washington.edu/cfar/discover-cfar/cores. These consultations must be completed no later than February 14, 2020.

3) Post-Award Requirements (if funded)

Prior Approvals (use of human or animal subjects, international sites): Prior to funding, a copy of all Institutional Biohazard, Animal Care and IRB approvals (if applicable) must be forwarded to cfardev@uw.edu. If the project involves human subjects and the institutional IRB has deemed the study “greater than minimal risk”, the awardee must submit a Clinical Research Checklist to Linh Newcomb, CFAR Grant and Fiscal Manager (lt128@uw.edu) before funding is released. Proposals involving either international sites or clinical research above minimal risk will require additional clearance from NIH prior to receipt of an award, which requires documenting IRB approval from all participating sites, human subjects training certification for all key personnel, and providing the approved consent form(s). Please note that international projects, especially those involving human subjects, can take several months to obtain all required approvals and therefore applicants should incorporate this into their study timeline.

Mentoring Committee and Agreement: Awardees will draw up a brief written agreement with their mentor and identify members of their mentoring committee.

Reporting and Presentation Requirements: Awardees will be required to submit yearly progress reports to the CFAR and 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 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 Fiscal Manager (ltin128@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?

- **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 and AIDS?

- **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?

- **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?

- **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? If relevant, is an appropriate level of collaboration with an appropriate community partner described?

- **Impact of Project on Pathway to Independence** – Will the project help prepare the applicant for a career as an independent HIV/AIDS researcher? Will the proposed mentorship aid in the investigator’s career development? (Address this in section A of applicant’s biosketch.)

Please also refer to the NIH’s Rigor and Reproducibility Guidelines: Does the project take the NIH guidelines on rigor and reproducibility into consideration?
The proposal should be written on PHS 398 forms and should follow a modified NIH investigator initiated grant application (R01) format. The Research Plan (Specific Aims through Approach) is limited to 4 pages (Bibliography and References Cited section do not count toward the page limit). No appendices are allowed. Do not submit Targeted/Planned Enrollment Tables. Submit a detailed budget, not a modular budget.

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 (PHS 398 Format - Download: MS Word)

   a. Please use section A to answer the question: How will the CFAR NIA prepare you for a career as an independent HIV/AIDS investigator?

7. Biographical Sketch for primary NIA mentor and any other mentors located at a non-Seattle institution

8. Resubmission Information (if applicable; maximum 1 page) Use PHS 398 Continuation Format pages (Download: MS Word or PDF).

   a. Previous application title and date submitted
   b. Major changes from the prior application
   c. Your response to the reviewers’ comments from your prior submission
   d. Any other information relevant to the submission

9. Research Plan (Maximum 4 pages for a-d below). Use PHS 398 Continuation Format pages (Download: MS Word or PDF).

   a. Specific Aims (suggested length ½ page)
   b. Significance (suggested length 1 page)
   c. Innovation (suggested length ½ page)
   d. Approach (suggested length 2 pages)

10. Bibliography and References cited (as needed)

11. Protection of Human Subjects (if applicable; maximum 1 page)

12. Vertebrate Animals (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 (Only allowed from mentor(s) of the proposed project and also from community-based collaborators (if relevant). Biosketches are not requested for collaborators.)

Additional Information Required in the Online Submission Form:
- Topic Key Words (5-10)
- Justification for Interdisciplinary Award (if applicable)
- Lay Language Summary
- Suggested Reviewers (Required: 2 non-Seattle-based, non-conflicted senior investigators)

Additional Information Requested in the Online Submission Form but Optional
- Demographics (including gender)
APPENDIX A: CONSULTATION INFORMATION

Community Action Board Consultation: All applicants are strongly encouraged to consult with the Community Action Board (CAB) as early as possible in the development of your proposal, especially applicants proposing research with local (Washington State-based) and/or underserved communities. Contact cfarcab@uw.edu by January 29, 2020 to schedule a consultation with the CAB. The CAB can advise on research question development, study recruitment, the acceptability and feasibility of research methods (not just clinical issues), and research dissemination strategies. More information: http://depts.washington.edu/cfar/discover-cfar/cores-and-programs/cfar-cas-community-action-board-research-consultations.

CFAR Core Consultations

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 contact Danielle Terrill (cfar@uw.edu) to have an expert consult with them regarding their study.

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.

Translational Research Science Sub-Core: The Translational Research Subcore (formerly the Clinical Retrovirology & Research Core) helps investigators perform clinical studies by supporting enrollment of HIV-infected patients, 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 subjects, and/or clinical specimens/procedures should contact Kate Thanel (kthanel@uw.edu) to have a professional 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 Katie Maggard (kmaggard@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 and Ana Gervassi (sderosa@fredhutch.org and ana.gervassi@seattlechildrens.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 contact Danielle Terrill (cfar@uw.edu) to have an expert consult with them regarding their study.

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.

CFAR Scientific Working Group (SWG) Consultations

Adolescent Health SWG: Catalyzes innovative research by bringing together investigators with interest and experience in addressing the unique issues facing adolescents in HIV treatment, cure, and prevention, including development of biomedical HIV prevention approaches, optimized models for care and treatment, and relevant behavioral and laboratory science. Applicants proposing a study involving adolescent health should contact Renee Heffron (rheffron@uw.edu) to have an expert consult with them regarding their study.

Cure SWG: Provides infrastructure that fosters new ideas, engages the community, and promotes the development of novel curative treatments for HIV and develops new intra-/inter-CFAR projects and funding applications on curative therapies for HIV. Applicants proposing a study in HIV cure should contact Tom Andrus (tandrus@fredhutch.org) to have an expert consult with them regarding their study.

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.