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

2018 Request for Applications (RFA)
New Investigator Awards (NIAs)

RFA Release Date	**March 26, 2018**
Email of Intent Due Date	**April 20, 2018**
<u>**NIA Pre-Application Consultation Deadlines:**</u>	
Biostats Review Scheduling Deadline..	April 27, 2018
International Applicant Eligibility Check.....................................	April 27, 2018
Required Biostatistical Consultation Deadline......................	**May 11, 2018**
Required Budget Consultation Deadline...............................	**May 11, 2018**
Optional CFAR Consultations..	May 11, 2018
NIA Application Due Date	**May 25, 2018**
Estimated Review Date	**August 2018**
Estimated Award Date	**September 2018**

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.

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, Center for Infectious Disease Research, Infectious Disease Research Institute, Seattle Children's, University of Hawai'i, and 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. 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. 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 unsure as to whether your proposed study would be a clinical trial, please contact Ann Collier (acollier@uw.edu, cc: cfardev@uw.edu) to determine whether your proposed project would be eligible for funding through CFAR.

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, Center for Infectious Disease Research, Seattle Children's, and University of Hawai'i.

2. Projects with a foreign 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 (PHS 398 Form pages 4-5) 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 $47,484. (NOT-OD-17-003)

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 allowability. Please follow the link below to section 7.2 cost principles section of the NIH Grants Policy Statement.

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 in the online submission as to why the applicant considers the project to be interdisciplinary.

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.

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.

Use of CFAR Resources: We encourage all applicants to use or contact CFAR Cores or Scientific Working Groups. All Cores and Scientific Working Groups have explicitly offered their consultations services (see Consultation Information below). Information about CFAR cores and services can be found at http://depts.washington.edu/cfar/find-a-service.

2) **Pre-Submission Process**

Required for All Applicants

Letter of Intent: Email cfardev@uw.edu a non-binding "email of intent" listing proposed Principal Investigator, Project Title, Mentor(s), and names of collaborators by **April 20, 2018**.

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 May 11, 2018**. 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 local investigator, please contact cfardev@uw.edu (subject: NIA Biostats Consultation) before **April 27, 2018** 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, please send a copy of your draft methods by **April 27, 2018** 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 Nguyen about their budgets to clarify budgetary issues before **May 11, 2018**. Please send a draft copy of your budget and justification to Linh Nguyen (ltn128@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 April 27, 2018.**

Institutional Approval for non-UW Applicants: Applicants from other institutions should prepare and submit a NIH 398 face page, 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 May 11, 2018**.

Optional Assistance (Consultations with CFAR)

We encourage you to utilize CFAR services early in the preparation of your NIA application. **Consultations must be completed no later than May 11, 2018**.

Community Action Board Consultation: All applicants **are strongly encouraged** to consult with the Community Action Board (CAB), especially applicants proposing research with local and/or underserved communities. Contact Vanessa Leja (lejav@uw.edu) to organize a consultation with the CAB. The CAB can advise on research question development, study recruitment, the acceptability and feasibility of research methods, and research dissemination strategies. More information: http://depts.washington.edu/cfar/discover-cfar/cores-and-programs/cfarcfas-community-action-board-research-consultations

CFAR Core Consultations

Clinical Epidemiology and Health Services Research Consultation: Applicants proposing a study involving longitudinal data on 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 from the Clinical Epidemiology and Health Services Research Core consult with them regarding their study.

Clinical Research Consultation: Applicants proposing clinical, translational or basic research projects that require access to local research subjects, clinical specimens/procedures or viral assays such as droplet PCR, 2LTR, single copy RNA tests and proviral DNA measurements should contact Nina Kim (hyangkim@uw.edu) to have an expert from the Clinical and Retrovirology Research Core consult with them regarding their study.

Computational Biology and Molecular Profiling Consultation: Applicants proposing a study involving sequence-based assays should contact Martin McIntosh (cfarcompbio@fredhutch.org) to have an expert from the Molecular Profiling and Computational Biology Core consult with them regarding their study.

Health Economics Consultation: Applicants proposing a study using Health Economic Methods should contact Julia Dettinger (jcdettin@uw.edu) to have an expert from the Health Economics Impact Study Team (HEIST) consult with them regarding their study.

HIV-Associated Malignancies (HIVAM) Consultation: Applicants proposing a study involving HIV-associated malignancies should contact Anna Larsen (alarsen@fredhutch.org) to have an expert from the AIDS-Associated Infections and Malignancies Core consult with them regarding their study.

Immunology Consultation: Applicants proposing a study involving immunology or other basic research should contact Lindsey Kirkham (ldk2317@uw.edu) to have an expert from the Immunology Core consult with them regarding their study.

International Consultation: International applicants should contact Julia Dettinger (jcdettin@uw.edu) to have an expert from the International Core consult with them regarding their planned study design.

Sociobehavioral Consultation: Applicants proposing a study involving behavioral or qualitative research should contact Lindsey Kirkham (ldk2317@uw.edu) to have an expert from the Sociobehavioral and Prevention Research Core consult with them regarding their study.

CFAR Scientific Working Group (SWG) Consultations

Adolescent Health Consultation: Applicants proposing a study involving adolescent health should contact Renee Heffron (rheffron@uw.edu) to have an expert from the Adolescent Health SWG consult with them regarding their study.

Cure Consultation: Applicants proposing a study in HIV cure should contact Tom Andrus (tandrus@fredhutch.org) to have an expert from the Curative Therapies for HIV SWG consult with them regarding their study.

eHealth Consultation: Applicants proposing a study involving eHealth, mHealth, and related technologies should contact Joanne Stekler (jstekler@uw.edu) to have an expert from the eHealth SWG consult with them regarding their study.

Implementation Science Consultation: Applicants proposing a study in the field of implementation science should contact Kenny Sherr (ksherr@uw.edu) to have an expert from the Implementation Science SWG consult with them regarding their study.

Substance Abuse Consultation: Applicants proposing a study in the field of substance abuse should contact Dennis Donovan (ddonovan@uw.edu) to have an expert from the Substance Abuse and HIV/STI SWG consult with them regarding their study.

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 the CFAR Program Manager 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.

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 CFAR Program Manager. 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?

- 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?

APPLICATION INSTRUCTIONS

After completing all pre-submission requirements, submit the following in one PDF (preferred) or MS Word file by 5:00 p.m. PDT May 25, 2018 to https://depts.washington.edu/cfar/find-funding/new-investigator-awards/submission-form. Please note that there are several questions on the submission form that you will need to answer in order to submit your application. They are listed below the proposal information below so that you can prepare your answers ahead of time.

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 sections 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. Face Page: (PHS 398 Form page 1 - Download: MS Word or PDF) Institutional sign-off for non-UW applicants 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 mentors located at a non-Seattle institution (Either PHS 398 Format or SF424 format acceptable)

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. Biosketches are not requested for collaborators.)

Additional Information Requested 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)
- Demographics