

CFAR DEVELOPMENTAL AWARDS PROGRAMS

PILOT AWARD PROGRAM FOR INVESTIGATORS NEW TO HIV/AIDS – APPLICATION GUIDELINES 2018

Funding is available through the UCSF-Gladstone Center for AIDS Research (CFAR) Developmental Program to develop the next generation of HIV/AIDS researchers, with the potential to secure future extramural funding.

A. Overview

The **Pilot Award Program for Investigators New to HIV** is aimed for Investigators New to HIV (assistant or associate faculty, including clinical) without past or current HIV/SIV funding with an innovative research idea in translational, clinical, and/or behavioral-epidemiological, HIV/AIDS research. Pilot awards are typically used to initiate a project or to gather preliminary data and findings leading to a future grant application. **International research projects are allowed.** Some topics of current high interest include HIV and aging-inflammation, latency, cure, vaccines, co-infections, implementation science, HIV in women, and research related to health disparities in HIV-infected and HIV-impacted Bay Area populations.

Of high interest to CFAR are investigations ranging from basic pathogenesis to clinical outcomes in the research areas of HIV/aging and inflammation, latency, cure, vaccines, co-infections, HIV in women, and research related to health disparities in HIV-infected and HIV-impacted Bay Area populations. Our [CFAR Science Cores](#) and Working Group are available to assist you in your research.

NOTE: Projects must be within NIH's HIV/AIDS research high or medium priority areas.

CLINICAL TRIALS: [NIH has revised the definition of Clinical Trials in 2018](#): 'If your study involves one or more **human subjects**, involves one or more **interventions**, **prospectively assigns** human subjects to **interventions** and has a **health-related biomedical or behavior outcome**.' If yes, Please contact **Lauren Sterling** or **Brenda Sanchez** with a brief description of your study (brenda.sanchez@ucsf.edu, cc: lauren.sterling@ucsf.edu) to determine whether your proposed project would be eligible for funding through CFAR.

B. Funding Opportunity

The award level for this program is **\$50,000** in direct costs (may include personnel salary and benefits). The funding period is one year. The number of grants awarded is determined by funding available. Any carry forward of funding will require pre-approval and must be fully justified. If this application is awarded, indirect costs at appropriate rates will be added to the total direct costs. (Please note under the RAP funding portal your award could be co-funded by two or more agencies, each requiring separate accounts and documentation).

C. Eligibility

Faculty members at the level of Assistant or Associate Professor level at UCSF or our affiliated partner institutes (<http://cfar.ucsf.edu/about/partners>) may apply. Faculty members may apply only if they are *newly* entering the field of HIV research. **Investigators are not eligible for CFAR Pilot Funding if they have received any past HIV research funding from any agency.** Current faculty at the assistant professor or clinical instructor level (including acting positions) who have not yet received an R01-equivalent award in HIV/AIDS. Non-faculty series or Professional Research Series including Specialist Series. Investigators in these series must make a strong case for their plan for becoming independent researchers.

Who is Not eligible: Postdoctoral fellows and full professors; staff

NOTE: Eligibility requirements need to be met *as of date of submission*; *no waivers are allowed*.

D. Special Consideration for Current NIH T32 and K Awardees

Current T32 awardees can apply for CFAR funds provided NO salary/stipends are taken from the CFAR award. CFAR allows current K awardees to provide complementary effort on their CFAR award **without** salary within their remaining 25% effort, if they also maintain the 75% required on the K. However, K-awardees should consult with their NIH K-award program officer to confirm this exception will be allowed on the K award side.

For additional questions contact Lauren Sterling, CFAR Managing Director at Lauren.Sterling@ucsf.edu.

E. Designation of Research Mentor

All pilot award applications from individuals at the Assistant Professor level or below require an HIV research mentor, and faculty at the Associate Professor level are recommended to find an HIV research mentor or collaborator. **CFAR requires your research mentor's support to advise and guide the research portion of your application before submitting it to RAP.** The mentor should be recognized as an accomplished investigator in AIDS research, and should be able to demonstrate past success in training/mentoring independent investigators. The mentor's role is to provide

oversight on the planning, direction, and execution of the proposed research. In addition, the mentor must commit to mentoring the applicant's throughout the duration of the research project.

NOTE: Mentor cannot have supervisory authority over the applicant(s) under any circumstance part-time or full-time during the project period. If the applicant works in your lab and you are his/her supervisor, you are required to find another person to act as a Research Mentor for the applicant's project. If questions arise, please contact Lauren Sterling, at Lauren.Sterling@ucsf.edu, CFAR Managing Director.

F. Criteria for Review/Evaluation of Applications

Completed applications which meet eligibility requirements will be evaluated for scientific and technical merit by an appropriate review committee convened by the UCSF Resource Allocation Program in accordance with NIH review criteria: 1. Significance, 2. Approach, 3. Innovation, 4. Investigator, 5. Environment. Each of these criteria will be addressed and considered in assigning the overall application score:

1. **Significance:** Does this study address an important problem applicable to the NIH HIV/AIDS research priorities? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field? If the aims of the project are achieved, how will the applicant's research career be enhanced?
2. **Approach:** Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well-reasoned and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? Are the administrative plans for the management of the research project appropriate, including plans for resolving conflicts? Is the research hypothesis-driven or hypothesis-generating?
3. **Innovation:** Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?
4. **Investigators:** Is the work proposed appropriate to the experience level of the applicant? How will this award enhance the applicant's career development? Do the letters of support document a strong commitment to help the applicant develop his/her career?
5. **Environment:** Does the scientific environment(s) in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

G. Research Resources

Awardees are encouraged to use one or more support services from our CFAR research resources:

1. **Implementation Science Scientific Working Group** – Applicants proposing a study in the field of implementation science are encouraged to have an expert from the new Implementation Science Working Group consult with them regarding their study. Send an email with a brief study description to Elvin Geng, SWG Director (elvin.geng@ucsf.edu)
2. **Clinical and Population Sciences Core** - Steven Deeks, MD & Jeff Martin, MD, MPH, Directors (SDeeks@php.ucsf.edu; martin@psg.ucsf.edu)
3. **Immunology Core** - Jeffrey Milush, PhD, Director (Jeffrey.Milush@ucsf.edu)
4. **Virology Core** - Joseph Wong, MD, Directors (joseph.wong2@va.gov)
5. **Specimen Bank Core** - Richard Jordan, DDS, PhD & Yvonne DeSouza, MS, Directors (richard.jordan@ucsf.edu, Yvonne.DeSouza@ucsf.edu)
6. **Pharmacology Core** - Francesca Aweeka, Director (FAweeka@sfghsom.ucsf.edu)
7. **Health Disparities Core** – Applicants proposing to conduct research with human subjects, especially local and/or underserved communities, are encouraged to consult with the Health Disparities Core. Send an email with a brief study description to Lauren Sterling, Managing Director (lauren.sterling@ucsf.edu) to receive this consultation.

H. CHR/IRB Approvals

All NIH-funded research requires IRB approval and human subjects training certification. All awardees whose research involves **human subjects** (e.g., patients or cohorts or the use of specimens/samples/medical record data) will be required to apply for and obtain approval for their research from the UCSF Committee on Human Research (CHR).

Note: Funding for research projects involving human subjects will not be released until a CHR approval or CHR waiver letter (citing the awardee's name) and proof of human subjects training have been received and forwarded to the NIH program office. If you have any questions regarding the CHR approval process, please contact the MSO for your department. New investigators should visit the *UCSF CHR* website for details on when and how to apply for *CHR approval* at <http://irb.ucsf.edu>. Information on training, including online training resources, can be found on the CHR website at <http://irb.ucsf.edu/citi-human-subjects-training>.

At no point can CHR approval or waiver expire during the project. Should CHR approval expire before the study is

completed, all study research must be stopped immediately, and cannot be recommenced until CHR approval has been obtained.

Research that is NOT considered human subject research per CHR Guidelines: Under limited circumstances, research involving **only** unidentifiable or coded private information or specimens is not considered human subjects research (refer to <http://irb.ucsf.edu/not-human-subjects-research>) . This can be determined and certified by the Principal Investigator based on the diagram *Determining Whether Human Subjects are Involved in Research When Obtaining Private Information (data) or Biological Specimens*, <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/decision-tree-human-subjects.pdf>. If only coded/unidentifiable samples or data will be used in the proposed research, a CHR waiver or self-certification will be required, refer to *Exempt Certification and Non-Human Subject Research Application* <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/self-certification-form.pdf>

STUDIES ABOVE MINIMAL RISK: The NIH requires additional review (clinical checklist) for all studies above minimal risk. <https://www.niaid.nih.gov/sites/default/files/cfarguideclinresstud.doc>. IRB approvals, consent docs, protocol will be required. **Once all paperwork has been filed with the NIH, approval takes approximately 8–12 weeks.**

I. Studies with Foreign Components

If the study has an international component requiring a subcontract to a foreign institution. Additional NIH approval and review is required (both local and foreign) foreign-institute FWA#, and human subjects training certifications (for local and foreign investigators) will be required before the release of any funding. [See NIH checklist form: <https://www.niaid.nih.gov/research/cfar-research-project-guidelines>. **Once all paperwork has been filed with the NIH, approval takes approximately 8–12 weeks.**

NOTE: International research proposals should provide two separate budgets: 1) a foreign budget listing all its expenses with 8% indirect cost factored in, and 2) domestic budget listing all its expenses with 26% indirect cost factored in.
Rule of thumb: If the expense is done at UCSF or affiliated institution, then it is a domestic expense; conversely if it's a foreign expense, it must occur at the foreign location. Funding will last for up to one year. Any carry forward of funding will require pre-approval and must be fully justified. **All CFAR-funded research conducted in an international setting must have both UCSF and international institution CHR approval and must be approved by the NIH before funding will be released to the awardees institution via subcontract at UCSF.** (The number of grants awarded is determined by funding available).

J. Research Involving Stem Cells

Research involving human stem-cells, you will need to supply the GESCR date and approval number.

K. Publications

All studies and publications resulting from funded projects are required to be compliant with PMCID Public Access regulations and must cite CFAR support as follows: This research was supported by from the NIH-funded UCSF-Gladstone Center for AIDS Research (P30 AI027763).

L. Progress Reporting

Progress reports will be due to the CFAR program office by the month of May (CFAR progress reporting) and at the end of project period. Progress reports are provided to the CFAR Directors and the NIH program office.

TO APPLY (instructions):

STEP 1) Complete the RAP [electronic application form](#)

STEP 2) Upload your proposal as a **SINGLE PDF** that includes all the things listed in numeric order in the instructions below

Instructions for Proposal PDF

Please write your proposal following the instructions listed below and create one single PDF file.

Proposal Length: Maximum 6 pages, including figures and tables, excluding table of contents and literature cited. **Format Requirements:** Arial font; 11 pt; minimum 0.5 inch for all margins; no appendices; include page numbers and table of contents.

Resubmissions

Definition: Same research topic with an amended application or research plan rather than a new research topic and new research plan.

Requirements: Please use up to one extra page to introduce your revised proposal, addressing the issues raised in the review, and any additional changes to your proposal. A new letter from the Chair is not required if the resubmission is within 2 cycles (one skipped cycle max). You will include the old letter and state your resubmission is within 2 cycles

and new letter is not required. Make sure the new changes are highlighted in bold or italic font so the reviewers can easily see where and how the proposal has changed. Do NOT use track changes.

1) Investigator Name (no multiple PIs); only one application is permitted per cycle.

- Country of citizenship
- Country of permanent residence

2) Project Title

3) Foreign Country. Supply the following (if applicable):

- Country
- Project field site
- Foreign institution FWA number
- Foreign IRB date of approval and approval number (specify if pending)

4) Human Subjects - Indicate if human subjects will be used or not. Supply the following:

- IRB date of approval
- IRB approval number
- Specify if pending

5) Animal Subjects - Indicate if Animal subjects will be used or not. Supply the following:

- IACUC date of approval
- IACUC approval number
- Specify if pending

6) Abstract - (one paragraph only, max 300 words summary of project including objective, design, duration of study, and statistical analysis of data).

7) Proposal - (maximum 6 pages, including figures and tables, [a-e below] excluding literature cited, mentoring plan, and additional human-subjects information [f-i below])

- Aims (list at least two aims)**
- Background and Significance**
- Preliminary studies**
- Experimental Design and Methods (include time-table)**
 - Hypothesis**
 - Rationale**
 - Experimental approach**
 - Interpretation of results**
- Explain how this pilot project is important for your career goals, e.g., lead to future funding, etc.**
- Mentoring Plan.** Describe the plan for oversight of this project by your mentor(s) including the specific role of your primary mentor named in this application. (not included in the page limit)
- Literature cited** (not included in the page limit)
- Protection of Human Subjects description** (if applicable)
- Inclusion/Enrollment Table** (if applicable for studies proposing human subjects, including existing resources)
<https://grants.nih.gov/grants/forms/phs-inclusion-enrollment-report.htm>

8) Budget - The award level for this program is \$50,000 in direct costs for a one-year project period. (Direct expenses must = \$50,000). Direct costs may include personnel (salary and fringe benefits), consultant costs, equipment, supplies, travel to perform the study or to present findings from the study, and other expenses. Travel, along with other costs, must be fully justified. For all awards, appropriate indirect costs will be added to the total direct costs.

Note: Any foreign subcontracting institution is limited to 8% indirect costs. All applicants applying from other institutions besides UCSF should contact [Frank Fernandez](#), cc [Brenda Sanchez](#) for assistance developing your budget with the appropriate allowable indirect costs.

Please use the NIH PHS 398 form "Page 4: Detailed Budget for Initial Budget Period"

(<http://grants.nih.gov/grants/funding/phs398/fp4.doc>) to prepare your budget. The grid below describes the budget items which are allowable/not allowable for the Mentored Award Program:

Pilot Award Program Budget	Allowable	Not Allowable
PI Salary	X	
Post Doc Salary	X	
Administrative Support		X
Program Supplies	X	
Equipment	X	
Software	X	
Personal Computers*	X	
Mailing	X	
Tuition	X	
Travel**	X	
Research Staff Support (e.g. RSA; Lab. Technician)	X	
Patient Care		X
Indirect costs***	X	
Others Expenses****	X	

* Computers are only allowable when essential to the conduct of the proposed research. If the computer is planned to be used for other projects / responsibilities in addition to the CFAR project, we require that the cost of the computer be shared with those other project budgets, in accordance with the amount of use anticipated by each project.

** Travel for awardees is allowed only if required to conduct the study or to present findings from this study at a conference (not simply to attend a conference).

*** Budget should include your fully allowable federally-negotiated indirect costs

**** Refer to the *UCSF Charging Practices and Guidelines* of allowable Expenses

<https://controller.ucsf.edu/quick-reference/contracts-grants-accounting/cost-accounting-standards-cas-guidelines>

Note: If chosen for an award, applicants must adhere to NIH policy specifying that the collection of salary support from CFAR NIH funds while simultaneously collecting salary support from an NIH K award is unallowable.

9) Budget Justification: Clearly and fully justify all costs including benefit rates and indirect costs. Please contact us for assistance with your budget and/or sub-contract if you have any questions.

10) NIH Bio-sketch of Principal Investigator(s); Mentor(s), and Co-Investigator(s) (5 page maximum). Bio-sketch of Principal Investigator, UCSF/affiliate Faculty Mentor(s), and co-investigator (s): Use NIH SF424 Biographical Sketch Format page (<http://grants.nih.gov/grants/forms/biosketch.htm>).

11) Letters of Support – Department Head and Mentors

- a) Department Head / Unit head (should indicate support for the application)
- b) Mentor/Collaborator's Letter of Support: Include a letter of support from your research mentor or HIV Collaborator that includes the information outlined below:
 - i. Specific areas in which HIV research will be provided
 - ii. Mentor/collaborator's background in HIV research
 - iii. Describe how the project fits with the mentor's research agenda and mentees career development (optional)
 - iv. Describe mentor/collaborator's working relationship (previous and/or current) with applicant

12) Institutional Letter of Support (If Non UCSF)

Please provide a letter of support from the project site institution with signing official signature. The site/institution should comment on the independence of the applicant and availability of space and other resources for the proposed research.

Program Contact - Should you have any questions regarding submission or reporting procedures, please contact [Brenda Sanchez](#), CFAR Developmental Core Manager. *If you are considering a study involving any clinical or behavioral intervention, please contact (brenda.sanchez@ucsf.edu) or (lauren.sterling@ucsf.edu) with a brief description of your study to determine whether your proposed project would be eligible for funding through CFAR.*