

CFAR DEVELOPMENTAL AWARDS PROGRAMS

MENTORED SCIENCE AWARD PROGRAM IN HIV/AIDS – APPLICATION GUIDELINES 2017

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 **CFAR Mentored Scientist Award** is a grant targeted toward mentoring and training early stage investigators at a senior stage of clinical or postdoctoral training or new faculty at UCSF or affiliated partner institutes to conduct a research project, allowing them to acquire preliminary data and findings leading toward a future grant effort. Investigators with backgrounds in clinical, basic, behavioral-epidemiological, and/or implementation science HIV/AIDS research are all welcome to apply.

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. CFAR has designated funding for at least two awards in both of basic and clinical/epidemiological/behavioral/translational sciences, and one award in implementation science. International research projects are allowed.

Applicants for this award must indicate a faculty research mentor(s) who will commit to guiding the applicant throughout the duration of the proposed project.

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

NIH does not allow CFAR to fund clinical trials or human use of an investigational drug. If you are considering a study involving a clinical intervention (e.g. approved drugs and/or standard-of-care), please contact 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. 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). CFAR commits to funding in two priority research areas as long as scientifically meritorious proposals are received in each:

- Basic Science (Two or more awards)
- Clinical/Translational/Epidemiological/Behavioral Sciences (Two or more awards)

C. Eligibility

Investigators must be at UCSF or affiliated partner institutes (<http://cfar.ucsf.edu/about/partners>).

1. Postdoctoral or clinical fellows in training
2. 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

Special Considerations for Current NIH T32 and K Awardees:

- **Current T32 awardees can apply for CFAR funds provided salary/stipends are NOT from CFAR award**
- Current mentored K awardees can provide complementary effort on the CFAR **without** salary within their remaining 25% effort. The mentored CDA must also maintain the 75% on the K. K-awardees should consult with their program officer on the K to make sure they will allow this exception.

D. Designation of Research Mentor

All Mentored award applications require a faculty research mentor. This should be an individual who has primary responsibility for overseeing the research career development of the applicant—usually assigned through the applicant's department. **CFAR requires your research mentor's support to advise and guide the research portion of your application before submitting it to RAP.** If no such person has yet been named, the applicant must arrange this before submission of the grant proposal.

The mentor's role is to provide oversight on the planning, direction, and execution of the proposed research. 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. 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.

E. Proposal Basics - Provide your project title, the amount of funding you are requesting, your contact information, and the contact information for any co-investigators and finance analyst. Indicate if you have been funded in the past 5 years by one of the following UCSF agencies, (list titles of grants in detail). Include enough information to allow RAP to understand their content. Specify dollar amounts awarded and source of funds, e.g., CFAR).

- SOS
- REAC
- CFAR
- Cancer Center
- Academic Senate
- Departmental Startup Funds
- Other UCSF (explain _____)

F. Proposal Format Requirements - Your proposal should follow the format requirements below:

- Arial, font 11
- 0.5 inch for all margins
- 6-page limit, including figures and tables, excluding literature cited
- **No appendices**

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

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

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

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

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

J. Proposal - (maximum 6 pages, including figures and tables, [a-e below] excluding literature, mentoring plan, cited 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, ii) Rationale, iii) Experimental approach, iv) Interpretation of results
- Explain how this pilot project is important for your career goals (e.g., lead to major funding, etc. Maximum 5 lines of text)**
- 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)
<http://grants.nih.gov/grants/forms/inclusion-enrollment-report.pdf>

K. Budget

The award level for this program is \$50,000 in direct costs for a one-year project period. Direct costs may include personnel (salary and fringe benefits), consultant costs, equipment, supplies, travel, 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. All applicants applying from other institutions besides UCSF should contact (Francisco.Fernandez@ucsf.edu) for help developing your budget and assistance with indirect cost allowability.

Note: Any foreign component is limited to 8% indirect costs, plus 26% on the first \$25,000, for each sub-contracting institution. If your proposal has a foreign component, please see section "**R. Studies with Foreign Components.**"

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 Science Award Program:

Mentored Science Award Program Budget	Allowable	Not Allowable
PI Salary	X	
Post Doc Salary	X	
Administrative Support		X
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 request 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

http://controller.ucsf.edu/pam/cas_guidelines.asp

Note: If chosen for an award, applicants must adhere to NIH policy regarding the collection of salary support from these CFAR NIH funds while simultaneously collecting salary support from an NIH K (PI salary cannot exceed 15% of the budget, anything over 10% should be well justified and NIH base-salary caps applies. For current T32 awards salary/stipends cannot be paid with CFAR funds).

L. Budget Justification: Justify all costs fully

M. Background of Principal Investigators

Biosketch of Principal Investigator, faculty research mentor(s), and co-investigators: Use NIH SF424 Biographical Sketch Format page (<http://grants.nih.gov/grants/forms/biosketch.htm>).

N. Letters of Support

Please provide a letter of support from the department chair or other unit head and from the project mentor. For all applicants, the department chair/unit head should indicate support for the application with signature. In addition, for postdoctoral or junior investigators, department chairs/unit heads must comment on the independence of the applicant, their status as it pertains to consideration for a faculty appointment, and availability of lab space and other resources for the proposed research. The mentor’s letter of support should indicate agreement to serve in the capacities described above in D. and indicate their support for the submission of the application.

O. 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?

P. 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** - Teri Liegler, PhD; Joseph Wong, MD, Directors (TLiegler@sfggh.ucsf.edu, 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.

Q. 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.*

R. 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. IRB approvals (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/sites/default/files/internationalstudieschecklist.doc>]. Once all paperwork has been filed with the NIH, approval takes approximately 8–12 weeks.

NOTE: International research proposals should provide two separate budgets: 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).

S. Research involving Stem Cells

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

T. 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).

U. 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.

Program Contact Should you have any questions regarding submission or reporting procedures, please contact Brenda Sanchez, Core Development Manager, at Brenda.sanchez@ucsf.edu. Additional information related to an application for funding can be found on the CFAR website: <http://cfar.ucsf.edu/funding>.