

CFAR DEVELOPMENTAL AWARDS PROGRAMS
PILOT AWARD PROGRAM IN HIV/AIDS – APPLICATION GUIDELINES

Funding is available through the University of California, San Francisco–Gladstone Institute of Virology & Immunology 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 is aimed toward junior investigators (*assistant faculty, three years or less*), and senior postdoctoral fellows 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 effort. **International research projects are allowed.** Some topics of current high interest include HIV and aging-inflammation, latency, cure, vaccines, co-infections, HIV in women, and research related to health disparities in HIV-infected and HIV-impacted Bay Area populations.

B. Funding Opportunity

The award level for this program is **\$40,000** 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 Professor (*three years or less*) or post-doctoral fellows at UCSF or at our affiliated partner institutes (<http://cfar.ucsf.edu/cfar?page=about-01-00>) may apply. More senior faculty members may apply only if they are *newly* entering the field of HIV research.

D. Designation of Research Mentor

All pilot award applications from individuals at the Assistant Professor level or below require the designation of 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 strongly recommends seeking 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.

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:

- CHR date of approval
- CHR 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-G] excluding literature cited)

- a. Aims (list **two** aims)
- b. Background and Significance
- c. Preliminary studies
- d. Experimental Design and Methods (include time-table)
 - i) Hypothesis, ii) Rationale, iii) Experimental approach, iv) Interpretation of results
- e. Explain how this pilot project is important for your career goals (e.g., lead to major funding, etc. max 5 lines of text)
- f. Human Subjects: describe patients, specimens, and/or human subject data that will be used in your research, and describe the methods that will be used to protect subjects and/or information
- g. Understanding of and commitment to following security and confidentiality guidelines for all Protected Health Information (PHI)
- h. Literature cited (not included in the page limit)

K. Budget

The award level for this program is \$40,000 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. For all awards, appropriate indirect costs will be added to the total direct costs. Any required subcontracts will be negotiated at a maximum indirect rate of 26%. Travel, along with other costs, must be fully justified. **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 Pilot Award Program:

Pilot 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. SRA; Lab. Technician)	X	
Patient Care		X
Indirect Costs (26%)	X	
Other Expenses**	X	

* 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).

**Refer to UCSF *Charging Practices* for examples of allowable expenses

http://controller.ucsf.edu/fin_compliance/files/CAS_Appendix_A.pdf

***Refer to UCSF *Charging Practices* for examples of unallowable expenses

http://controller.ucsf.edu/fin_compliance/files/CAS_appendix_B.pdf

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" and/or T32 award (it is unallowable).

L. Budget Justification: justify all costs fully

M. Background of Principal Investigators

BioSketch of Principal Investigator, co-investigators, and UCSF Faculty Mentor(s): Use NIH 398/2590 Biographical Sketch format page (<http://grants.nih.gov/grants/funding/phs398/biosketch.doc>).

N. Letter of Support

Please provide a letter of support from the department chair or other unit head. For all applicants, department chair/unit head should indicate support for the application with signature. In addition, for junior investigators, department chairs/unit heads should comment on the independence of the applicant and availability of lab space and other resources for the proposed research.

O. Criteria for Review/Evaluation of Applications

Applications that are complete and 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? 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 cores:

- 1. Clinical and Population Sciences Core** - Steven Deeks, MD & Jeff Martin, MD, MPH, Directors (SDeeks@php.ucsf.edu; martin@psg.ucsf.edu)
- 2. Immunology Core** - Elizabeth Sinclair, PHD, Director (esinclair@sfg.ucsf.edu)
- 3. Virology Core** - Teri Liegler, PhD; Joseph Wong, MD, Directors (TLiegler@sfg.ucsf.edu, joseph.wong2@va.gov)
- 4. Specimen Bank Core** - John Greenspan, PhD & Yvonne DeSouza, Directors (John.Greenspan@ucsf.edu, Yvonne.DeSouza@ucsf.edu)
- 5. Pharmacology Core** - Francesca Aweeka, Director (FAweeka@sfgsom.ucsf.edu)

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). See the *CHR Overview of the Application Process*:

<http://www.research.ucsf.edu/chr/Guide/AppCommRevGI.asp#General>. New investigators should visit the UCSF CHR website for details on when and how to apply for CHR approval at

<http://www.research.ucsf.edu/chr/NewInv/chrNewInv.asp>. Information on training, including online training resources, can be found on the CHR website at <http://www.research.ucsf.edu/chr/Train/chrTrain.asp>.

Research that is NOT considered human subject research per CHR Guidelines, (refer to <http://www.research.ucsf.edu/chr/Guide/chrExemptApp.asp#NotHuman>). Under limited circumstances, research involving **only** unidentifiable or coded private information or specimens is not considered 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://www.research.ucsf.edu/chr/guide/HSDecisTree.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://www.research.ucsf.edu/chr/guide/chrExemptApp.asp>

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. *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 can not be recommenced until CHR approval has been obtained.*

R. Studies with Foreign Components

If the study has an international component requiring a subcontract to a foreign institution, IRB approvals (both local and foreign), foreign institute FWA#, and human subjects training certifications (for local and foreign investigators) will be required for NIH approval before the release of any funding. [See NIH checklist form at:

<http://www.niaid.nih.gov/LabsAndResources/resources/cfar/Documents/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: 1) a foreign budget listing all its expenses with 8% indirect cost factored in, and 2) a 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 should cite CFAR as the funder as follows:

This research was supported by a grant from the National Institutes of Health, University of California, San Francisco–Gladstone Institute of Virology & Immunology Center for AIDS Research, P30-AI027763.

U. Progress Reporting

Progress reports will be due to the CFAR program office after the first six months and at the end of the project period. Progress reports are provided to the CFAR Directors and the NIH program office.

V. Program Contact

Should you have any questions regarding submission or reporting procedures, please contact Brenda Sanchez, CFAR Program Analyst, at brenda.sanchez.ucsf.edu. Additional information related to application for funding can be found on the CFAR website: <http://cfar.ucsf.edu/cfar?page=funding-00-00>.