CC-AMC Pilot Awards in HIV-Associated Malignancies

**Project award amount:** $75,000

**Description**

The focus of the awards program is to stimulate research collaborations on HIV-associated malignancies between investigators at the Helen Diller Family Comprehensive Cancer Center (HDFCCC) and NCI-supported AIDS Malignancy Consortium (AMC) investigators at UCSF by providing pilot funding to HDFCCC investigators. The purpose of the NCI supplemental funds is to foster pilot projects within the HDFCCC that have the potential to develop into larger independent research projects funded by the NIH or other organizations.

Malignancies constitute a substantial source of morbidity and mortality among HIV-infected persons, even in the era of anti-retroviral therapy. AIDS-defining malignancies (Kaposi’s sarcoma, non-Hodgkins lymphoma, cervical cancer) continue to develop in HIV-infected persons, particularly in developing countries, and the incidence of non-AIDS defining malignancies is growing among HIV-infected men and women.

Funding is available through the HDFCCC via the NCI Supplement. The HDFCCC will support pilot projects focused on HIV and cancer. Examples of research topics include:

- Role of inflammation in cancer development in HIV-infected patients
- Predictors of survival in patients with AIDS-defining and non-AIDS defining cancer, nationally and internationally
- Role of oncogenic viruses and/or HIV in the induction of HIV-associated malignancies
- Impact of prolonged immunosuppression on the development of HIV-associated malignancies
- Impact of incomplete or failed responses to HAART on the development of HIV-associated malignancies
- Host genetic susceptibility to HIV-associated malignancies in patients with HIV infection
- Strategies for the prevention of cancer in the HIV-positive population
The HDFCCC will look to support projects that utilize data or specimens within the HDFCCC and/or AMC, leverage research capacity development supported by NCI in Africa, expand upon relevant new knowledge generated in the HDFCCC that can be immediately applied to HIV-associated cancers, promote the development of systematic tools for future inter-HDFCCC collaborations on HIV-associated cancers, and address health disparities. Applicants are encouraged to use the AIDS and Cancer Specimen Resource (ACSR).

Note: Studies involving clinical trials are not allowed.

**Details:**

1. The award level for this program is $75,000 in direct costs (may include personnel salary and benefits).

2. The number of grants awarded is determined by funding available.

3. The funding will last for a one-year period.

4. Any carry forward of funding will require approval and must be fully justified.

5. Progress reports will be due to the HDFCCC Programs Office at the midpoint and at the end of the project period. Reports should reference subsequent funding acquired, research goals met, posters, publications, etc.

6. Awardees will be strongly encouraged to participate in the UCSF HIV-related Malignancies Research Group (HMRG) and the Andy I. Choi Mentoring Program of the UCSF-GIVI Center for AIDS Research. The HMRG is part of the HDFCCC Cancer, Immunity, and Microenvironment Program [1] and awardees are also strongly encouraged to participate in this program’s activities.

7. If applicable, CHR and IACUC approval and must be obtained before funding will be released to the awardee.

8. This award does not support travel or equipment.

9. Studies involving clinical trial trials are not allowed.

**Eligibility:** Researchers with academic appointments at all levels are eligible. Post-doctoral fellows are not eligible.

Investigators must be a member or be sponsored by a member of the HDFCCC. A list of HDFCCC Members and Associate Members and membership application information can be found at http://cancer.ucsf.edu/people/membership/ [2].

An AMC member must serve as a co-investigator on the pilot project application.

**Criteria for Review and 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 the review criteria employed by the NIH which include five core areas: 1. Significance, 2. Approach, 3. Innovation, 4. Investigator, 5. Environment. Each of these criteria will be addressed and considered in assigning the overall score weighing them as
appropriate for each application.

Useful web-links

For information about the AIDS Malignancy Consortium program:
Joel Palefsky M.D. (HPV-related malignancies, non-AIDS-defining malignancies): joel.palefsky@ucsf.edu [3]
Lawrence Kaplan, M.D. (Lymphoma): lkaplan@medicine.ucsf.edu [4]
Toby Maurer, M.D. (Kaposi’s sarcoma): maurert@derm.ucsf.edu [5]

For information about the Helen Diller Family Comprehensive Cancer Center:
http://cancer.ucsf.edu/ [6]
The CFAR Andy I. Choi Mentoring Program:

For a list of Cancer Center faculty:
http://cancer.ucsf.edu/people/membership/ [2]

For information on the Cancer Center’s Cancer, Immunity and the Microenvironment Program:
http://cancer.ucsf.edu/research/programs/immunity [1]

TO APPLY:

STEP 1) Complete the electronic application form [8]
STEP 2) Upload your proposal PDF

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 literature cited.

Format Requirements: Arial font; 11 pt; minimum 0.5 inch for all margins; no appendices.

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 view, 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. P.I. Name(s) (must be a Cancer Center member) optionally, you may apply with two PIs. If funded, PI1 will be the primary contact for the award set up and management. PI2 must be a Cancer Center or AMC member. If the proposal has multiple PIs, both PI1 and PI2 need to meet the eligibility criteria listed for this grant mechanism.

2. Project Title

3. Proposal (maximum 6 pages, including figures and tables, excluding literature cited)
   - Aims (list two aims)
   - Background and Significance
   - Preliminary studies
   - Experimental Design and Methods (include time-table)

i) 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.) - max 500 words
   - Mentoring Plan: Please describe the plan for oversight of this project by your mentor(s), including the specific role of your primary mentor named in this application.
   - Literature cited (not included in page limit)

4. 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. Is CHR approval required? Please see the note below regarding human and animal research. If approval has already been granted, please include the CHR approval letter with your application

5. Animal Subjects: Is IACUC approval required? Please see the note below regarding human and animal research. If IACUC approval has already been granted for this project, please include the IACUC approval letter with your application.

6. Co-Investigator Names (max five) to be entered in the fields of the electronic application form. Need to have a faculty appointment (one is required and must be an AMC Member)

7. Detailed Budget ($75,000 maximum total costs per proposal for domestic and foreign projects) 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. Add the network recharge rates to your budget.

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Mailing | X
Tuition | X
Travel | X
Research Staff Support (e.g. SRA; Lab. Technician) | X
Patient Care | X
Others | X

*NIH base salary cap. Partial investigator salary support may be requested. Generally PI salary support should not exceed 10% of the budget, anything over 10% must be well justified. Multiple PIs can decide how to distribute that 10% salary support among themselves (e.g., 5%/5% or 6%/4%).

**Refer to UCSF Charging Practices for examples of allowable expenses: http://controller.ucsf.edu/fin_compliance/cas_guidelines.asp [10]

Note: If you are receiving salary support from an NIH "K" award, please disclose this information.

8. **Budget Justification:** Clearly and fully justify all costs.

9. **Bio-sketch of Principal Investigator(s) and Co-Investigator(s):** (5 pages maximum) Use form (http://grants.nih.gov/grants/funding/424/SF424R-R_biosketchsample_VerC.docx [11]) with other support pages. Include active, pending, and planned proposals. Include percent effort, total direct costs (current year) and potential overlap with the current proposal. Include bio-sketch for both PIs of a multi-PI application.

10. **Letter(s) 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. Include the letter of support at the end of your PDF proposal and address it to the RAP Committee. If there are multiple (two) PIs, a letter of support is required for both PIs. If PIs are in the same department, the chair can vouch for both PIs in a single letter.

11. **In-country institutional letter of support:** Please provide a letter of support from the project
site/institution with signature. The site/institution should comment on the independence of the applicant and availability of lab space and other resources for the proposed research.

**Note to all applicants: If your proposal is selected for funding, the following will be required:**

**Human Subjects.** 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/AppCommRevG1.asp#General [12]. 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 [13]. Online training for human subject certification can be found on the CHR website at http://www.research.ucsf.edu/chr/Train/chrTrain.asp [14].

**Research that is NOT considered human subject research per CHR Guidelines,** (refer to http://www.research.ucsf.edu/chr/Guide/chrExemptApp.asp#NotHuman [15]). 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 [16]. If only coded/identifiable 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 [17].

**Animal Research.** All NIH-funded research at UCSF requires UCSF Institutional Animal Care and Use Committee (IACUC) approval and animal research training certification. All personnel conducting procedures on live animals must be appropriately trained and qualified in those procedures per UCSF guidelines. Refer to the **IACUC Education and Training Policy** [18] for additional information: http://www.iacuc.ucsf.edu/Policies/awPolTrng.asp [18]. All awardees whose research involves live animals will be required to apply for and obtain approval for their research from IACUC. See the **IACUC Overview of the Application Process:** http://www.iacuc.ucsf.edu/HowTo/awHowApply.asp [19] New investigators should visit the **UCSF IACUC** website for details on when and how to apply for **IACUC approval** at http://www.iacuc.ucsf.edu/New/awNewuser.asp [20]. Training and animal use certification information can be found on the IACUC website at http://www.iacuc.ucsf.edu/Training/awTrain.asp [21].
For projects with a foreign component. 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 the NIH checklist form at:\(^{[22]}\)] http://www3.niaid.nih.gov/research/cfar/docs/CFAR_International_Studies_Checklist.doc Once all paperwork has been filed with the NIH, approval takes approximately 6?8 weeks.

**Note:** Your proposal should reflect 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 incurred 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 two years. Any carry forward of funding will require approval and must be fully justified. **All research conducted under this funding mechanism 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).