

## 2009 Request for Applications (RFA)

### HIV-Associated Malignancy Research Pilot Awards

RFA Schedule

<b>RFA Release Date.....</b>	<b>September 11, 2009</b>
<b>Pre-Application Consultations:</b>	
Eligibility for International Applicants.....	October 1, 2009
Biostatistical Consultation.....	October 1, 2009
Non-UW Applicants Budgetary Consultation.....	October 1, 2009
<b>Application Due Date .....</b>	<b>November 2, 2009</b>
<b>Estimated Review Date.....</b>	<b>December 2009</b>
<b>Estimated Start Date.....</b>	<b>January 2010</b>

## **HIV-Associated Malignancy Research Pilot Awards**

### Purpose

The main purpose of this award program is to stimulate research that will expand our knowledge of the pathogenesis of HIV-associated cancers. Through this award the funder (NCI) seeks to foster multidisciplinary collaborations between Cancer Centers and CFAR investigators. It is anticipated that this research will lead to the development of novel diagnostic, preventive and therapeutic strategies for both AIDS-defining and non-AIDS-defining malignancies. Awardees should plan to use pilot-grant derived data as the basis for subsequent applications to other funding sources.

### Eligibility

- 1) Current FHCRC members and UW faculty (including acting positions)
- 2) Scientists completing fellowships
- 3) Senior post-doctoral fellows initiating a new area of research that will form a basis for their independent program
- 4) Faculty being recruited to the FHCRC, UW faculty or affiliated institutions
- 5) Investigators with comparable appointments at FHCRC or CFAR-affiliated institutions (e.g., Seattle Biomedical Research Institute, Seattle Children's, and affiliated foreign institutions)
- 6) Minority investigators at the University of Hawaii with comparable positions

Note that applicants are required to have an MD or PhD or equivalent degree in order to be eligible to apply and must have a collaborative relationship with an investigator (or have membership) at Fred Hutchinson Cancer Research Center. NIH K awards do not impact on 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.

### Types of Projects

Pilot studies may include basic, epidemiologic, translational and clinical research on the etiology, pathogenesis, prevention and management of HIV-associated malignancies. Proposed studies can also target diverse populations across the spectrum of age and gender in national and international settings. Applicants are also encouraged to address health disparities, including women and minorities in their proposals.

Examples of research topics are listed below but are by no means inclusive:

- Role of oncogenic viruses and/or HIV in the induction of AIDS-related malignancies.
- Impact of prolonged immunosuppression on the development of AIDS-related malignancies.
- Impact of incomplete or failed responses to HAART on the development of AIDS-related malignancies.
- Host genetic susceptibility to AIDS-related malignancies in patients with HIV infection.

Per NIH, we cannot fund clinical trials of investigational drugs, but we can fund behavioral interventions. If you are considering a study involving approved drugs and/or standard-of-care, please contact Corey Casper (ccasper@fhcrc.org, cc: krelliot@uw.edu) to determine whether your proposed project would be eligible for funding through this mechanism.

### Funding Available

The Fred Hutchinson Cancer Research Center has received a two-year supplement from the National Cancer Institute to fund these awards. These funds are set aside specifically for the purpose detailed above.

Funding is available for awards up to \$63,450 per year (direct costs) for up to two years. Indirect costs are allowable (FHCRC applicants should follow FHCRC indirect cost guidelines; UW on-campus applicants may request up to 46% (off-campus applicants request 26%); applicants from other institutions may request up to 46% or their institution's negotiated rate (if lower than 46%)). Awards can be used for salary, technical support, laboratory supplies, equipment, and travel costs related to the project. Be sure to read our [Computer Policy](#) if you would like to budget for a computer [Go here: [http://depts.washington.edu/cfas/cfar/funding/grant\\_new\\_invest.html](http://depts.washington.edu/cfas/cfar/funding/grant_new_invest.html) ].

Requests for Second Year of Funding: Second year funding is contingent upon demonstration of satisfactory progress during year one.

### Pre-Submission Requirements

**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 no later than **October 1, 2009**. Contact Sarah Holte at [sholte@fhcrc.org](mailto:sholte@fhcrc.org) and copy Kristen Elliott ([krelliot@fhcrc.org](mailto:krelliot@fhcrc.org)).

**Use of Cancer Center and CFAR Resources:** We encourage applicants to use FHCRC Shared Resources, CFAR Cores or link to CFAR Scientific Programs, especially the AIDS-Associated Infections and Malignancies (AIDS-AIMS) Scientific Program (see <http://depts.washington.edu/cfas/cfar/center/> for more information).

**Collaborative Proposals:** Multidisciplinary projects are encouraged and are defined as involving 2 or more investigators 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 FHCRC, UW or affiliate). In a cover letter, the applicant must provide a rationale as to why the applicant considers the project to be interdisciplinary. Ideally, the PI would be new to the field of HIV-associated malignancy research, as defined by a lack of NIH peer-reviewed grants on which they serve as PI in the field and no publications in the field in the medical literature.

**Mentoring:** It is strongly recommended that **junior** faculty applicants identify a mentor. A statement from the applicant's primary mentor that they have read and discussed the application with the applicant must accompany the application (can take the form of a letter of support – see 'Mentor Statement' in Application Instructions below).

**International Applicants:** International applicants **must** obtain approval that they are eligible to apply **prior to development** of their proposal. Send a current NIH format biosketch or curriculum vitae for review to Corey Casper at [ccasper@fhcrc.org](mailto:ccasper@fhcrc.org) (copy Kristen Elliott at [krelliot@fhcrc.org](mailto:krelliot@fhcrc.org)) no later than October 1, 2009.

**Institutional Approval:** All applicants **are required** to consult with the FHCRC Program in Infection-related cancers Administrative Coordinator about their budgets **prior to the development of their proposal and no later than October 1, 2009**, to clarify budgetary issues. Contact Kristen Elliott at [krelliot@fhcrc.org](mailto:krelliot@fhcrc.org) or 206-667-4600.

### Pre-Award Requirements

**Human Subjects and Animal Care Approvals:** These approvals, if applicable, must be obtained prior to receipt of an award, but are not required to submit an application. Proposals involving either international sites or clinical research above minimal risk will require additional clearance from NIH prior to receipt of an award, which includes IRB approval from all participating sites and human subjects training certification for all key personnel.

### Post-Award Requirements

1. Prior to funding, a copy of all Institutional Biohazard, Animal Care and IRB approvals must be forwarded to the FHCRC Program in Infection-related cancers Administrative Coordinator. 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 FHCRC Program in Infection-related cancers Administrative Coordinator before funding is released. If the project is being conducted overseas, prior approval from NIH is required prior to commencement of the study. It is recommended that if your study is minimal risk or below and linked to a non-minimal risk study, you apply for independent approval by the IRB – this will expedite the regulatory approval process.
2. Awardees will be required to submit yearly progress reports to the Cancer Center and CFAR and make an oral presentation at the annual AAIMS symposium.
3. Cancer Center support must be acknowledged in all publications derived from funding. CFAR Core or Program support must be similarly acknowledged.
4. In the event that pending other support is funded which overlaps with or reduces your effort on this project, you must notify the FHCRC Program in Infection-related cancers Administrative Coordinator. Your funding status will be reviewed and if it is determined that you are unable to meet the specific aims of your proposal, the award will be revoked.
5. After project is completed, be available to provide information about publications, collaborations, and future grants related to your project.

### Application Instructions

**After completing all pre-submission requirements, submit the following in one MS Word file by 11:30 p.m. November 2, 2009 to Kristen Elliott ([krelliot@fhcrc.org](mailto:krelliot@fhcrc.org))**

Use the PHS Form 398 (11/07 version) and NIH R01 format with the modifications listed below. No appendices are allowed. Do not submit Targeted/Planned Enrollment Tables. Submit a detailed budget, not a modular budget. The Research Plan (‘Specific Aims’ through ‘Research Design and Methods’) is limited to 10 pages.

1. Cover letter (including reviewer suggestions, description of why your application meets eligibility requirements, and other pertinent information)
2. Face page: (Form page 1)
3. Abstract page: (Form page 2)
4. Detailed budget for 12 month period: (Form page 4)
5. Complete budget and justification: (Form page 5)
6. Biographical Sketch for all key personnel (including research support section C)
7. Resources Page
8. **Research Plan (‘Specific Aims’ through ‘Research Design and Methods’ limited to 10 pages)**
  - Specific Aims (suggested length ½-1 page)
  - Background and Significance (suggested length 1-2 pages)
  - Preliminary Studies (suggested length 2-3 pages)
  - Research Design and Methods (suggested length 3-5 pages)
  - Protection of Human Subjects (if applicable; maximum 1 page)
  - Vertebrate Animals (If applicable; maximum 1 page)
  - Bibliography and References Cited (as needed)
9. Mentor’s Statement (if applicable)
10. Letters of support (Letters of support from collaborators essential to the proposed project must accompany the application)

## **Frequently Asked Questions**

### **Q. Am I eligible to apply?**

A. Consult the Eligibility section on page 1 of this RFA. If you have further questions about eligibility, contact Corey Casper, MD, MPH (ccasper@fhcrc.org).

### **Q. Do I need to be a U.S. citizen to apply?**

A. You do not need to be a U.S. citizen to apply, but note eligibility requirements for international applicants under the Eligibility section.

### **Q. How do I fill out the budget if I am proposing a subcontract?**

A. Each subcontracting institution requires a separate detailed budget page, and scope of work. Detail the justification for the subcontract costs in the overall budget justification. The total direct costs and total costs (direct plus indirect) are then entered on the overall detailed budget page of the application.

### **Q. Does the award allow indirect costs?**

A. Indirect costs are allowable (FHCRC applicants should follow FHCRC indirect cost guidelines; UW on-campus applicants may request up to 46% (off-campus applicants request 26%); applicants from other institutions may request up to 46% or their institution's negotiated rate (if lower than 46%)). Be sure to complete the mandatory budgetary consultation by the deadline stated above to be sure your budget reflects appropriate indirect cost.

### **Q. My application includes a subcontract to a foreign site – how does that affect my budget?**

A. If your proposal involves a subcontract to a foreign site, you should include indirect costs, which are limited to a maximum of 8 percent.