

## **Title: Centers for AIDS Research (CFAR) and Comprehensive Cancer Center (CCC) Collaborations in Domestic and International Studies of HIV-associated Malignancies.**

### **PART I – OVERVIEW INFORMATION**

#### **1. Purpose**

The NIH-funded Centers for AIDS Research are pleased to announce a one-year Pilot Grant Awards Program to advance our understanding of the risks, pathogenesis, diagnosis, and treatment of malignancies observed in individuals with human immunodeficiency virus infection. The objectives of this proposal are to utilize two NIH-funded networks, the Centers for AIDS Research (CFARs), <http://www3.niaid.nih.gov/research/cfar/contact.htm>, and the Comprehensive Cancer Centers (CCCs), <http://www.cancer.gov/cancertopics/factsheet/NCI/cancer-centers>, to initiate a cooperative and collaborative program of developmental grant funding that 1) addresses emerging opportunities and scientific needs in the area of AIDS-associated malignancies, 2) builds collaborations between CFAR and CCC members, and 3) utilizes infrastructure provided by the CFAR Network of Integrated Clinical Systems (CNICS) <http://www.cnicsres.ucsd.edu>, the AIDS Malignancy Consortium (AMC), <http://pub.emmes.com/study/amc/public/index.htm>, and the AIDS and Cancer Specimen Resource (ACSR), <http://acsb.ucsf.edu/aboutUs.aspx>. These objectives focus on both the ongoing problems of HIV-associated malignancies in the United States and the expanding epidemic of HIV- and viral-associated cancers at international sites.

There are currently 19 CFARs (18 full CFARs and 1 developmental CFAR), each representing an interdisciplinary group of HIV/AIDS investigators from one or more institutions. All CFARs strive to conduct basic, clinical, behavioral, social science and translational HIV/AIDS research that provides added value to their campuses and targets both domestic and international areas. In addition, all CFARs are located at sites in which there are either NCI-funded Comprehensive Cancer Centers or NCI-funded investigators. As such, CFARs have been and continue to be well positioned to foster collaborations that can apply the expertise of HIV/AIDS and cancer researchers to AIDS-associated malignancies and to respond to the emerging challenges that these cancers pose.

The scientific scope and intended areas of research support for this Pilot Grant Awards Program are summarized in the funding opportunity announcement (FOA) for NIH PA-07-455 (Title: “Research on malignancies in the context of HIV/AIDS”) <http://grants.nih.gov/grants/guide/pa-files/PA-07-455.html>. In brief, this program seeks to encourage new and innovative research in areas such as the study of the etiologic cofactors, pathogenesis, and consequences of HIV-associated malignancies in diverse populations. Research on non-AIDS defining malignancies in the context of HIV infection (e.g., anal, skin, and lung cancers as well as Hodgkin’s disease) is also encouraged, particularly since the incidence of these malignancies may be increasing in the era of Highly Active Antiretroviral Therapy (HAART).

## 2. Key Dates

<b>Release/Posted Date:</b>	<b>December 15, 2007</b>
<b>Letters of Intent Receipt Date(s):</b>	<b>February 1, 2008</b>
<b>Application Submission Receipt Date:</b>	<b>March 15, 2008</b>
<b>Projected Peer Review Date:</b>	<b>April 15, 2008</b>
<b>Earliest Anticipated Start Date:</b>	<b>May 1, 2008</b>

## 3. Overview and General Information

**Mechanism of Support.** Funding for this pilot grant awards program has been made possible by a one-year grant of supplemental funds provided to CFARs by the National Cancer Institute (NCI) and the National Institute of Allergy and Infectious Diseases (NIAID).

**Funds Available, Amount Per Award, and Anticipated Number of Awards.** Funds up to \$75,000 in total costs per application will be available. It is anticipated that 7 – 8 applications will be awarded (see Section 4 of Part II for recommendations and policy regarding indirect [i.e. F&A] costs).

**Eligibility.** Applicants must be full-time faculty members of CFARs or CCCs at CFAR-affiliated institutions. Members of institutionally-designated Cancer Centers at CFAR sites will also be eligible. Non-faculty trainees and instructors are eligible to be included as co-investigators. Priority for funding will be given to applications that establish collaborative research activities between CFAR and Cancer Center members. Collaborations between multiple CFAR sites and/or multiple CCC sites are also encouraged.

**Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are encouraged to apply.

**Number of Applications per applicant.** Applicants may submit more than one application, provided that each application is scientifically distinct.

**Number of PDs/PIs.** More than one PD/PI or multiple PDs/PIs may be designated on the application.

**Application format and materials.** The scientific portion of the application (i.e. Specific Aims, Background & Significance, Preliminary Data, and Experimental Design) should total no more than 4 pages using PHS 398 approved formats and fonts. Preliminary results are not required but may be included. Details relevant to application formatting and submission are listed below (see Section 5 of Part II).

**Application submission.** Applications, supporting materials, and institutional letters (if provided) should be submitted electronically as two (2) PDF files **no later than March 15, 2008** to Olivia Loskoski at the University of Pennsylvania CFAR <[oliviaj@mail.med.upenn.edu](mailto:oliviaj@mail.med.upenn.edu)>

## **PART II - FULL TEXT OF ANNOUNCEMENT**

### **Section I. Funding Opportunity Description**

#### **1. Research Objectives**

The Background, Scientific Priorities, and Specific Research Objectives for this Pilot Grant Awards Program are as specified NIH PA-07-455, <http://grants.nih.gov/grants/guide/pa-files/PA-07-455.html>.

In brief, a wide range of research projects that foster collaborative activities between CFAR and CCC members is sought for this Pilot Grant Awards Program. New and innovative areas are encouraged, and priority for funding will be given to projects that, as a result of this award, can lead to subsequent NIH funding mechanisms (e.g. R21, RO1, etc.). Areas of scientific emphasis include:

- (1) Developing and utilizing relevant models to study disease pathogenesis of the prevalent viral agents (i.e., KSHV/HHV-8, EBV, HPV) found in AIDS-defining cancers;
- (2) Discovering and characterizing new viral and microbiological agents that act as co-factors in tumor promotion and/or progression;
- (3) Developing and utilizing predictive models for the preclinical evaluation of new therapies against HIV-associated malignancies;
- (4) Developing therapeutic strategies for HIV-associated malignancies based on the roles of infectious agents in the pathogenesis;
- (5) Developing preclinical applications to translate basic knowledge of HIV-associated malignancies towards the development of new treatments for patients with these diseases in a national or international setting;
- (6) Defining the molecular epidemiology of HIV-associated cancers and their pre-neoplastic conditions;
- (7) Discovering, developing, and utilizing biomarkers of cancer risk, progression, and/or response to treatment, including immunologic and epigenetic markers and markers that change during the course of disease (e.g., cytokines or viral load);
- (8) Discovering new modifiable factors contributing to the disease development; and
- (9) Identifying biological relationships between HIV/AIDS-associated malignancies and immune reconstitution inflammatory syndrome (IRIS).

Applications directly linking pathogenesis in the context of HIV infection to molecular target identification and interdisciplinary approaches are particularly encouraged. Such approaches may include effort integration among oncologists/hematologists, infectious

disease specialists, virologists, microbiologists, molecular biologists, chemists, tumor biologists, immunologists, biochemists, pharmacologists, and/or investigators in other disciplines appropriate to the proposed research.

Studies of HIV-associated malignancies in international settings of high HIV incidence and prevalence, including India, South East Asia, Eastern Europe, Central/South America, and Africa are encouraged, as these sites may offer unique research opportunities.

This Pilot Grant Awards Program is not designed to support clinical trials of treatment for HIV-associated malignancies. However, some aspects of clinical research may be incorporated in projects proposed in response to this program. Depending on a specific project proposed, such aspects may include: analysis of samples and data collected from clinical trials, analysis of identified costs for patient visits, or specimen shipping and handling. Utilization of existing NIH-funded resources including the CFAR Network of Integrated Clinical Systems (CNICS), <http://www.cnicsres.ucsd.edu>, the AIDS Malignancy Consortium (AMC), <http://pub.emmes.com/study/amc/public/index.htm>, and the AIDS and Cancer Specimen Resource (ACSR), <http://acsb.ucsf.edu/aboutUs.aspx>, are encouraged.

## **2. Strategic Priorities**

In addition to scientific areas of emphasis noted above, a goal of this award is to foster collaborations between CFAR and Cancer Center members to address emerging challenges in basic, clinical, behavioral, social and translational areas of the recognized and emerging HIV-associated malignancies. It is expected that such collaborations will apply the considerable expertise encompassed by individuals in at these sites. Collaborations between multiple CFAR sites and/or multiple CCC sites are also encouraged and prioritized.

## **3. Eligible Individuals**

Applicants must be full-time faculty members of CFARs or CCCs at CFAR-affiliated institutions. Members of institutionally-designated Cancer Centers will also be eligible. Non-faculty trainees and instructors are eligible to be included as co-investigators. Priority for funding will be given to applications that establish collaborative research activities between CFAR and Cancer Center members. Collaborations between multiple CFAR sites and/or multiple CCC sites are encouraged.

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the PD/PI is invited to work with his/her organization to develop an application for support. There is no limit to the number of awards an individual institution can submit. Individuals from underrepresented racial and ethnic groups, as well as individuals with disabilities, are always encouraged to apply for NIH support.

## **4. Funds Available and Indirect Costs**

The administering entity for the Pilot Grant Awards Program is the University of Pennsylvania. The program, which is co-sponsored by NIAID and NCI, has received funding in the amount of \$550,000 total costs for one year.

Under this mechanism, funding will be available for individual grants up to a maximum of \$75,000 in total costs. It is anticipated that 7 - 8 awards will be made. In order to maximize the benefit of these one-time awards, and to show institutional commitment to this program, several participating CFARs, including the University of Pennsylvania, Duke University, and Case Western Reserve University have agreed that if an application from their institutions is awarded, the equivalent of the entire award (Direct Costs and F&A) will be available to the project for expenditure as direct costs. In addition, the University of Pennsylvania has agreed that in administering the award it will subvent all F&A associated with providing these funds through subcontracts to the recipient institutions. In line with this, we encourage all applicant institutions to consider and directly address this same approach in any award request.

## **5. Application and Submission Information**

Applicants should use the former PHS 398 forms (last updated 4/06) previously used for the non-electronic R21 funding mechanism (see below in this Section).

PDs/PIs should work with their institutions/organizations to make sure they are registered in the eRA Commons.

1) Organizational/Institutional Registration in [Grants.gov/Get Registered](https://grants.gov/GetRegistered) and registration in the eRA Commons.

Because applicants will be from CFARs and/or Cancer Centers at institutions that house CFARs, it is expected that these institutions will be fully registered with NIH Central Contractor Registration (CCR) and have an existing Data Universal Number System (DUNS) number, and a Taxpayer Identification Number (TIN) or Employer Identification Number (EIN). It is also expected that these institutions will be Commons-registered.

Direct questions regarding the Commons registration to:

eRA Commons Help Desk

Phone: 301-402-7469 or 866-504-9552 (Toll Free)

TTY: 301-451-5939

Business hours: M-F 7:00 a.m. – 8:00 p.m. Eastern Time

Email: [commons@od.nih.gov](mailto:commons@od.nih.gov)

2) Project Director/Principal Investigator (PD/PI) Registration in the NIH eRA Commons: Refer to the [NIH eRA Commons System \(COM\) Users Guide](#).

- The individual(s) designated as PDs/PIs on the application must also be registered in the NIH eRA Commons. In the case of multiple PDs/PIs, all PDs/PIs must be registered **and be assigned the PI role** in the eRA Commons prior to the submission of the application.
- Each PD/PI must hold a PD/PI account in the Commons. Applicants should not share a Commons account for both an Authorized Organization Representative/ Signing Official (AOR/SO) role and a PD/PI role; however, if they have both a PD/PI role and an Internet Assisted Review (IAR) role, both roles should exist under one Commons account.
- When multiple PDs/PIs are proposed, all PDs/PIs at the applicant organization must be affiliated with that organization. PDs/PIs located at another institution need not be affiliated with the applicant organization, but must be affiliated with their own organization to be able to access the Commons.

### 3) Content and form of submitted application.

Applications will be submitted electronically as two (2) PDF files. Forms will be the previously PHS 398 forms (last updated 4/06).

#### **PDF “1” includes:**

- Face Page
- Abstract and Key Personnel
- Form Page 4 (Year-One Budget)
- Budget Justification
- NIH Biographical Sketches for PI, Co-PI, and Key Personnel
- Resources and Environment

#### **PDF “2” includes:**

- Research Plan (maximum of 4 Pages for the 4 sections below)
  - Specific Aims
  - Background and Significance
  - Preliminary Results (not required)
  - Experimental Plan
- Literature Cited
- Human Subjects
- Vertebrate Animals
- Consortium/Contractual Arrangements
- Letters of Support
- Institutional Letter- indicating policy regarding indirect costs for application.

4) PHS 398 forms available at <http://grants.nih.gov/grants/funding/phs398/phs398.html>

5) Submission information:

Letters of Intent (due February 1, 2008) and applications (due March 15, 2008) should be submitted electronically as PDF files to:

**Olivia Loskoski**  
**Administrative Coordinator, Penn CFAR**  
[oliviaj@mail.med.upenn.edu](mailto:oliviaj@mail.med.upenn.edu)  
**Telephone: 215-746-2754**

### **PART III - CONTACTS**

Questions of an administrative nature may be addressed to:

Evelyn Olivieri  
Associate Director, Penn CFAR  
email: [oliviere@mail.med.upenn.edu](mailto:oliviere@mail.med.upenn.edu)  
Telephone: 215-573-7354

Questions of a scientific nature may be addressed to:

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