Administrative Supplements for P30 Cancer Centers Support Grants (CCSG) to Stimulate Research in HIV/AIDS Cancer Research Projects at NCI-designated Cancer Centers

Purpose:

The purpose of this initiative is to stimulate research in AIDS defining and non–AIDS defining cancers at the NCI-designated Cancer Centers (CC). This effort is aimed to expand the knowledge base of HIV/AIDS malignancy pathogenesis and etiology, early detection, treatments, and cures. The research proposal should address questions that can be tested by using biospecimens and/or cohort data. It is intended that discoveries from this effort will inform and guide the development of novel diagnostic, preventive and therapeutic strategies for AIDS-defining and/or non-AIDS defining cancers.

Background:

Mortality among people living with HIV/AIDS decreased substantially with the introduction of combination antiretroviral therapy (cART). However, treatment might not fully reverse the effect of early immune suppression and immune dysfunction, and chronic inflammation can persist among people receiving cART. Individuals with HIV infection are now living longer and cancer is a leading cause of mortality among them. There is a substantial decrease in the incidence of AIDS defining cancers (ADCs: Kaposi sarcoma, non-Hodgkin lymphoma, cervical cancer), and an increasing incidence of non-AIDS defining cancers (NADC), such as Hodgkin disease, lung, liver and anal cancers. Additionally, with prolonged survival of the HIV population, the effect of HIV-related immunosuppression in an aging population is unclear.

As of the end of 2015, there were approximately 36.7 million people worldwide living with HIV. In the USA, 1.1 million people are living with HIV. The new HIV infections have declined to approximately 40,000 new cases a year, most occur among a few groups such as African American and Hispanic/Latino gay and bisexual men, and African American heterosexual women living in the Southern United States.

Mechanisms and Funds Available:

The NCI may allocate a total of $2.0 million dollars per year in total costs depending on funding availability. It is expected that 8 - 9 awards of up to $250,000 total costs per year will be awarded by September 2018 to successful applicants; awards will be for one to two years. The NCI intends to provide supplemental funds to the Cancer Center Support Grant at the NCI-designated Cancer Centers (CC) in support of projects that utilize biospecimens from the AIDS and Cancer Specimen Resource (ACSR) (http://acsr.ucsf.edu) inventory (or another certified biorepository); data from existing cohorts; and/or biospecimens and clinical data from the Cancer Center itself, including international partnerships of the Center. The NCI-funded ACSR is a national/international repository of specimens that have been collected from HIV-infected individuals and HIV-negative controls. The specimens and associated data are made available to the research community-at-large at NO COST. For more details please visit ACSR inventory explorer at https://acsr.ucsf.edu/inventory-explorer/
The selection of the projects will be through the established cancer center internal review process. The internal review committee should include members from the cancer center, and ad hoc reviewers with relevant expertise as needed. More than one research project may be selected for funding. All projects must have documentation of approval from the CC’s Protocol Review and Monitoring System and the institutional IRB, as appropriate. CCs must select pilot projects that are eligible for high priority AIDS funding according to NOT-OD-15-137. Titles and abstracts of selected pilot projects must be sent to the Office of Cancer Centers (OCC) prior to activation to ensure this requirement has been fulfilled.

Progress of research projects will be monitored by the NCI Office of Cancer Centers. The supplement progress report must be included with the CCSG progress report. A full annual report is required on the anniversary date of the award.

Eligibility to Apply and Other Requirements:

All CCs (except those which will be on a Type 3 extension in FY19) are eligible to apply. Only one application per CC is permitted. An application could be comprised of one or two projects. A CC may request funding for 1 - 2 years. Any proposal that cannot be completed within the 1-2-year time frame will be viewed as non-responsive. Specific areas of study may include, but are not limited to, the following examples:

- Discovery of reliable molecular and immunological diagnostic and prognostic biomarkers and pathogen markers, useful for early detection, progression, or response to treatment of non-AIDS-defining and AIDS-defining cancers
- Discovery and development of novel targets and efficacious new therapeutic agents, interventional strategies, or improved delivery systems for the treatment of persons afflicted with non-AIDS-defining and AIDS-defining cancers
- Studies to develop biomarker and diagnostic assays from a wide spectrum of AIDS-defining and non-AIDS defining cancers
- Studies to determine the cellular genome, transcriptome, epigenome, proteosome and metabolome of virally induced and other tumors in the context of HIV infections
- Studies to determine the effects of prolonged moderate immunosuppression and/or incomplete or failed responses to cART on the development of either non-AIDS-defining or AIDS-defining cancers
- Studies aimed at understanding the molecular pathogenesis of AIDS defining as well as non-AIDS-defining HIV-associated cancers
- For a given HIV-associated tumor type (e.g. lung cancer), studies aimed at understanding similarities and differences between the tumors arising in HIV-infected and uninfected individuals, understanding differences in their pathogenesis and establishing similarities and differences in various body sites

Proposed studies can also target diverse populations across the spectrum of age and gender. Research may include basic, translational, and clinical research on the etiology,
pathogenesis, prevention, and management of AIDS defining and non-AIDS defining cancers. Leadership of projects by junior or mid-level investigators is encouraged.

**Receipt Date: March 31, 2018.**

**Allowable Costs:**

This award is for research projects only and does not support the purchase of equipment and salary for project leaders. The general areas in which costs are allowable are as follows: salaries for project(s) investigators, technicians and reagents.

**Application Procedure:**

1. Cover letter: signed by the CC Director should accompany each application. Center Director needs to provide the name of the project leader(s) to undertake the project.
2. Format of the Application: SUBMIT your project(s) with your application.
   - Use the standard face page of the PHS 398 including all institutional signatures.
   - Provide 3-5-page narrative that includes (1) rationale, study design, project time line and methods for each project proposed; and (2) facilities/resources at Cancer Center that will be available to the project. Explain how this announcement was made available to the CC investigators; describe the review committee membership and review process; number of applications submitted and number selected for moving forward.
   - A statement of how the proposed project would meet the NIH HIV/AIDS Research Priorities as listed in the NOT-OD-15-137. It should explain which high priority topic or topics it will address and how it will be addressed.
   - General projects focusing, for example, on EBV, HPV, KSHV or other oncogenic viruses or HIV alone are not eligible for support under this supplement award.
3. Overall budget and budget justifications. Clearly detailed costs (Direct and Indirect) along with a narrative justifying each requested cost must be provided. If submitting more than one project, present separate budget pages per project.
4. Statement assuring compliance with applicable NIH policies e.g., human subjects, animal welfare, data sharing, and understanding of the requirements for NIH approvals prior to any international study initiation, etc.
5. A biographical sketch for any key personnel.
6. A completed application checklist, please check "REVISION" to grant number. (This application is for additional funds to supplement a currently funded grant.)
Where to send the Cover Letter and Application:

Do not send applications to the NIH Center for Scientific Review. The cover letter and the application (Word or PDF file) can be e-mailed to:

Dr. Hasnaa Shafik at shafikh@mail.nih.gov

If unable to send via email a hard copy can be sent to:

Hasnaa Shafik, MD, PhD
Office of Cancer Centers
National Cancer Institute
National Institutes of Health
9609 Medical Center Drive
Bethesda, MD 20814-9692
Room: 2-W-210

Application Review Process:

The applications will be administratively reviewed for responsiveness to the eligibility criteria above; relevance of the proposed concept to the CC; and adequacy of the plan, approach and environment. The review committees will include members from the NCI Office of Cancer Centers, Office of HIV and AIDS Malignancy (OHAM) and other NCI divisions. Incomplete and/or non-responsive proposals will be returned without further consideration.

For clarification and/or questions concerning this supplement, contact Hasnaa Shafik MD, PhD by phone at 240-276-5600 or via email: shafikh@mail.nih.gov