

Administrative Supplements for P30 Cancer Centers Support Grants (CCSG) to Stimulate Research in Non-AIDS Defining Cancers (NADCs) in Aging Populations

Purpose:

The purpose of this initiative is to stimulate research in non-AIDS defining cancers (NADCs) relevant to aging individuals with HIV infection via support of pilot projects at NCI-designated Cancer Centers (CC). Findings from this supplement are aimed to expand our knowledge of the impact of aging on the pathogenesis of NADCs. The overarching emphasis of this announcement is to explore the (1) pattern, (2) natural history, and (3) optimization of treatment of NADCs occurring in aging HIV-positive individuals.

Background:

The number of older individuals living with HIV/AIDS has risen dramatically over the last decade. From 2001-2008, the proportion of Americans living with HIV who are ≥ 50 years rose to 31% from 17%, and this is expected to rise to over 50% in 2015. The introduction and widespread use of combination antiretroviral therapy (cART) in the mid-1990s has dramatically improved the health outcomes of HIV+ individuals, leading to decreases in AIDS-defining cancers such as Kaposi's sarcoma and non-Hodgkin's lymphoma. However, the longer life expectancy now observed in these individuals has led to the increased incidence of diseases with a longer latency period, such as NADCs. NADCs now account for 50% of all cancers among HIV+ individuals. The incidence and mortality from NADC in HIV+ individuals ≥ 50 years of age have not been extensively studied; however, some studies have shown an increased incidence in liver, bladder, lung, and Hodgkin's lymphoma.

It has become apparent that individuals living with prolonged HIV infection exhibit many of the clinical characteristics commonly observed in aging, such as multiple co-morbidities, polypharmacy, physical and cognitive impairment, functional decline, alterations in body composition, and increased vulnerability to stressors. Moreover, the clinical picture of HIV in older adults may be complicated by many other risk factors, including infections with oncogenic viruses (e.g., human papillomavirus [HPV], Kaposi-sarcoma associated herpesvirus [KSHV/HHV-8], Epstein-Barr virus [EBV], hepatitis B virus [HBV], and hepatitis C virus [HCV]), obesity, and substance abuse including nicotine, alcohol, marijuana, and prescription drugs. Also, HIV-infected patients on cART often have a degree of immunologic impairment and chronic immune activation, even when their CD4 count is normal. Aging itself is associated with immunologic impairment, and it is unclear how these factors interact in aging HIV-infected patients. As such, improved management of older individuals with HIV will require a much deeper understanding of the interface between aging, HIV, associated co-morbid conditions, and concurrent treatment.

Mechanism and Funds Available:

The NCI may allocate up to \$1.6 million dollars per year in total costs depending on funding availability. It is expected that 8 - 9 awards of up to \$200,000 total costs per year will be awarded by September, 2016 to successful applicants; awards will be for one to two years. Funding will be as a supplement to the parent P30 CCSG, with funds restricted to support of pilot studies in non-AIDS defining cancers among aging, HIV+ patients. The selection of the pilot 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 pilot 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 Office of Cancer Centers. The supplement progress report must be included with the CCSG progress report, and a separate annual report is required on the anniversary date of the award.

Eligibility to Apply and Other Requirements

All CCs are eligible to apply. Only one application per CC is permitted. A CC may request funding for one - two years. Any proposal that cannot be completed within the 1-2 year time frame will be viewed as non-responsive. Several examples of research topics are listed below, but these are not inclusive:

- Biology of aging and cancer
- Effects of comorbidities (consequences of the aging process and/or the progression of HIV/AIDS)
- Effects of polypharmacy including antiretroviral therapy on treatment of NADCs; Treatment efficacy and tolerance
- Cancer control for early detection, diagnosis, prevention, treatment, prognosis and survivorship

Receipt Date: February 19, 2016

Allowable Costs: This award is for pilot 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 pilot projects investigators, technicians and reagents.

Application:

1. Cover letter signed by the CC Director

2. Format:

- Requests submitted in response to this opportunity must use the PHS 398 forms (rev. 6/2009; available at <http://grants1.nih.gov/grants/funding/phs398/phs398.html>)
- Use the standard face page of the PHS 398 including all institutional signatures.

3. Provide a 3 -5 page narrative that includes:

- A description of the current HIV/AIDS-related malignancy research portfolio at the CC and the commitment to support HIV-associated malignancy research

- Identification of potential areas of study that would fit the scope of this announcement (**DO NOT SUBMIT** specific pilot projects with your application)
- A commitment to select pilot project(s) that meet the NIH HIV/AIDS Research Priorities listed in NOT-OD-15-137 as high priority. Projects focusing, for example, on EBV, HPV, KSHV, or other oncogenic viruses or HIV alone are not eligible for support under this supplement
- A description of the unique opportunities for developing HIV-associated malignancies research at the CC, including access to special populations or unique resources
- A description of the review committee and the process and criteria for selection of meritorious pilot projects

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 the project leaders.

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 (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

For questions, contact Hasnaa Shafik, MD, PhD via email at shafikh@mail.nih.gov

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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 committee will include members from the NIH Office of AIDS Research and NCI OCC, Office of HIV and AIDS Malignancy, and other NCI divisions. Incomplete and/or non-responsive proposals will be returned without further consideration.