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

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 (ADCs) - Kaposi sarcoma, non-Hodgkin lymphoma, cervical cancer, and an increasing incidence of non-AIDS defining cancers (NADCs), 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. There were approximately 38 million people across the globe with HIV/AIDS in 2019. An estimated 1.7 million individuals worldwide became newly infected with HIV in 2019. In the USA, 1.2 million people are living with HIV. The new HIV infections in the USA have declined to approximately 34,800 new cases a year (2019), 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.

Purpose and Goals

The National Cancer Institute (NCI) announces an opportunity for supplemental funding in support of projects that utilize biospecimens from the AIDS and Cancer Specimen Resource (ACSR)* 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 primary goal of this initiative is to stimulate research in ADCs and NADCs at the NCI-designated Cancer Centers (CC). This effort is aimed to expand the knowledge base of HIV/AIDS cancer pathogenesis, etiology, early detection, treatments, and cures. 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.

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

Eligibility and Budget

- This opportunity is open to all currently NCI-Designated Cancer Centers.
- Only one supplement request per center will be considered.
- To be considered responsive for supplemental funding, centers must articulate a detailed project plan.
- Supplement requests may not exceed \$500,000 total costs for 2 years.
- Cancer Centers whose P30 Cancer Center Support Grant will be on an extension at the time the award is made in FY22 are not eligible.
- It is anticipated that awards for this supplement opportunity will be made in September 2022.
- Any proposal that cannot be completed within the 2-year time frame will be viewed as non-responsive.
- Allowable costs include funding for the Project Leader of the study (maximum of 20% effort), who must be a member of the NCI-designated cancer center; funding for required expertise to complete this project; and costs for supplies.
- The purchase of large pieces of equipment through this supplement will not be permitted.

Application Submission Format

Applications must be submitted electronically via eRA Commons to the parent award (P30) using PA-20-272 "Administrative Supplements to Existing Grants and Cooperative Agreements (Parent Admin Supplement)" on or before **May 9, 2022**. Your submission should follow the instructions in the funding opportunity announcement, including the following:

- 1. Research Plan (6 pages) including the following elements
- Make sure to add to the title of the supplement in parenthesis Biospecimens/Biocohort
- The research proposal should address questions that can be tested by using biospecimens and/or cohort data.

- Proposed research may include basic, translational, and clinical research on the etiology, pathogenesis, prevention, and management of AIDS defining and non-AIDS defining cancers.
- Description of the background, preliminary data (if available), relevant cancer center infrastructure, data sources, and specific aims for the proposed research.
- Inclusion of target diverse population across the spectrum of age, gender, and race is encouraged.
- Leadership of projects by junior or mid-level investigators is encouraged.
- Inclusion of a <u>statement</u> 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 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.
- Outline specifically the HIV outcomes for the proposed work. Note that KSHV studies
 that are proposed should be in the context of HIV (with HIV outcomes specified) to be
 aligned at 100%. As such, if the NIH Office of AIDS Research (OAR) does not deem an
 application as 100% aligned, OCC will be unable to fund it.
- Details of the qualifications for the identified lead(s) of the supplement. Note: separate SF424 forms will be needed for biosketches.
- 2. Detailed budget and justification for funding and activities requested using SF424 forms.

In addition, the application must include Project Summary/Abstract and Specific Aims as a part of a submission package. No appendix or attachments are allowed.

For tracking purposes, please notify Nga Nguyen (nga.nguyen@nih.gov) when you submit application (but please do not send the application itself).

Evaluation Criteria

Supplements will be administratively evaluated by NCI staff with appropriate expertise. There will not be a secondary review process.

Awards

Awards will be based on responsiveness to the goals of this announcement and the availability of funds.

Reporting Requirements

As part of the annual progress report of the parent NCI Cancer Center Support Grants include information on what has been accomplished via the administrative supplement during the funding period. A copy of the annual progress report for the administrative supplement should also be sent to Dr. Hasnaa Shafik by email at shafikh@mail.nih.gov.

Questions

Please contact Dr. Hasnaa Shafik (telephone: 240-276-5600; Email: shafikh@mail.nih.gov) for questions related to the supplement.

* 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/ 2