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

Key Dates

Release Date: January 18, 2024
Request Receipt Due: April 5, 2024
Earliest Anticipated Start Date for Awards: July 8, 2024

Background
Mortality among people living with HIV (PWH) 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. PWH are now living longer, and cancer is a leading cause of mortality among them. Among the cancers that PWH develop are AIDS-defining cancers (Kaposi sarcoma, non-Hodgkin lymphoma, cervical cancer) and non-AIDS-defining cancers (Hodgkin disease, lung, liver, and anal cancers). Additionally, with the high life expectancy among PWH, the effect of HIV-related immunosuppression in an aging population is unclear.

There were approximately 39 million people across the globe with HIV/AIDS in 2022. An estimated 1.3 million individuals worldwide became newly infected with HIV in 2022. In the USA, there is an estimated 1.2 million PWH. The new HIV infections in the United States have declined to approximately 32,000 new cases a year (2022). 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 HIV-associated cancers. 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.
The research proposal should address questions that can be tested by using biospecimens and/or cohort data.

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 living 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

This NOFO is not designed for support of clinical trials.

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 $250K total costs for 1 year or $500K for 2 years
- Cancer Centers whose P30 Cancer Center Support Grant will be on an extension at the time of the award in Fiscal Year 2024 are not eligible
- Based on availability of funds, it is anticipated that awards for this supplement opportunity will be made in July 2024
- 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 **April 5, 2024**. *For tracking purposes, please notify*

Ms. Molly Maher (molly.maher@nih.gov) by email at the time of submission, but do not send the application itself.
Submissions should follow the instructions in the Notice of Opportunity (NOFO) including the following:

1. Research Plan (6 pages) must include the following elements:

- Make sure to add to the title of the supplement, in parenthesis: ***Biospecimen/Cohort***
- Description of the background, preliminary data (if available), relevant cancer center infrastructure, data sources, and specific aims for the proposed research
- Inclusion of diverse populations across the spectrum of age, gender, and race. Inclusion of underserved and marginalized groups, including but not limited to Black/African American and Latino/Latina communities, women, people who use drugs, men who have sex with men, transgender women, and other sexual and gender minority populations are encouraged
- Leadership of projects by junior or mid-level investigators is encouraged
- Inclusion of a **statement** of how the proposed project is aligned with NIH HIV/AIDS Research Priorities as described in NOT-OD-20-018
- Outline specifically the HIV outcomes for the proposed work. As such, if the NIH Office of AIDS Research (OAR) does not deem an application as 100% aligned, the NCI Office of Cancer Centers (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 all 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.

Letter of Intent
A letter of intent is not required for this supplement.

Evaluation Criteria
Supplements will be administratively evaluated by NCI Program staff with appropriate scientific expertise. The applications will be evaluated based upon access to the appropriate patient populations and patient data, feasibility of completing aims, and overall responsiveness to the NOFO, including whether it fits within the scope of the parent grant. 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: 240-276-5622; Email: shafikh@mail.nih.gov) for questions related to the supplement.