

Administrative Supplements for P30 Cancer Centers Support Grants (CCSG) to Stimulate Research in Immunotherapy and Tumor Microenvironment in HIV/AIDS Cancer Patients 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

Human immunodeficiency virus (HIV)-infected individuals are at increased risk for developing several cancers. Despite the success of combination antiretroviral therapy (cART) in suppressing HIV and improving patients' quality of life, cART does not lead to eradication of the virus. Cellular immunity is central in controlling HIV replication, and the focus now has shifted more to control of viral replication rather than eradication. Several recent studies have demonstrated the safety and feasibility of immunotherapeutic approaches for successful treatment of some cancers in non-HIV infected individuals. Effective strategies include the use of antibodies to check point inhibitory molecules such as PD-1 and antibodies that targets cytotoxic T-lymphocyte associated antigen-4 (CTLA-4), which are regulators of T cell function. Other reported approaches include the use of chimeric antigen receptor (CAR) T-cells for treatment of adults with relapsed or refractory non-Hodgkin lymphoma patients.

Since HIV adopts numerous strategies to evade immune surveillance, it is of importance to determine if people living with HIV (PWH) will respond to anticancer immunotherapy modalities in a similar fashion to non-HIV infected individuals in the general population. The goal of treating cancer is dependent on a safe and effective immunotherapeutic modality concurrently with enhancing a tumor microenvironment that promotes T cell activation and infiltration into premalignant or cancerous tissue. The success rates of first-generation cancer immunotherapies (e.g., checkpoint inhibitors, genetically engineered T-cells, and new immune activators) have improved remarkably over the past decade resulting in durable, long-term survival, and in some cases, cures for a subset of patients with advanced cancers such as melanoma, blood, and lung cancers. However, little is known about how PWH may respond to immunotherapy; if their tumor microenvironment is more hostile and prevents T cell activation and infiltration; and if they can achieve similar results as the non-HIV infected individuals with cancer.

Purpose and Goals

The National Cancer Institute (NCI) announces an opportunity for supplemental funding to identify and advance immunotherapy translational approaches for HIV/AIDS individuals with cancer. To accomplish this advancement, new, more effective immune-based therapeutic regimens for people with HIV/AIDS-related cancers should be explored through:

- the discovery and characterization of immunotherapeutic targets,
- the development of new immunotherapy treatment approaches, and
- the improved understanding of the immunosuppressive tumor microenvironment

It will be extremely important that the applicant outlines specifically the HIV outcomes for the proposed work. Note that Kaposi's sarcoma-associated herpesvirus (KSHV) studies that are proposed should be in the context of HIV (with HIV outcomes specified) with alignment at 100%. 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.

Specific areas of study may include, but are not limited to, the following examples:

- Discovery of new tumor or tumor microenvironment molecular or immunologic targets
- Development of new molecular targeting agents based on specific signaling pathways activated during the process of tumorigenesis or tumor progression
- Discovery and validation of biomarkers or genetic/epigenetic signatures that may improve cancer diagnosis, and/or prediction of treatment response among diverse racial/ethnic populations to better elucidate and decrease cancer disparities

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 Funding 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: **Immuno/Microenvironment**
- 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, 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.

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.

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.