

Instructions for Applying for Administrative Supplements to Funded EDRN and Alliance U01 and U24 Cooperative Agreements

Supplement Title: Supplement for Biomarker Studies on AIDS-Associated Malignancies

Request Receipt Deadline: July 10, 2008

First Possible Award Date: September 1, 2008

Eligibility Requirements

Requests for administrative supplemental funding may be submitted by National Cancer Institute (NCI)-funded U01 or U24 grantees, as long as the following conditions are met:

1. The parent grant award is within the Early Detection Research Network (EDRN) or the Alliance of Glycobiologists for Detection of Cancer and Cancer Risk and must be valid for one year from the start date of the supplement;
2. There are no funds in the parent award to pay for the proposed research effort;
3. The Principal Investigator (PI) for the supplement must be the PI of the parent grant.

Research Objectives

These supplements are intended to provide 1-year funding to investigators funded in the EDRN or Alliance and who wish to conduct research on HIV/AIDS-related malignancies. Projects related to AIDS-defining malignancies (Kaposi's sarcoma, non-Hodgkin's lymphoma, or cervical cancer) or malignancies that occur with higher prevalence in the HIV-infected population (anal, colorectal, lung, oropharyngeal, liver, renal, and vaginal cancers, melanoma and Hodgkin's lymphoma) are particularly encouraged. Projects may also focus on malignancies showing equal prevalence between infected and non-infected populations in relation to comparisons of biomarker signatures between both populations. Examples of research objectives for the supplements may include but are not limited to: 1) Discovery of new biomarkers relevant to cancers that occur in the HIV-infected population. 2) Determination of whether biomarkers associated with cancers of the HIV-infected population have similar specificity and sensitivity in histologically identical cancers of the non-infected population. 3) Study strategic screening processes to define risks for developing cancers in the HIV-infected population. 4) Develop biomarkers for viral associated cancers that often occur in HIV-infected populations. 5) Studies identifying biomarkers that may be used to assess progression or treatment outcome of HIV-associated malignancies.

Funds Available

An applicant may request a project period of one year and a budget for direct costs of up to \$100,000 per year. Applications specifically designed to provide data for larger, future investigator initiated grants are particularly encouraged. Although the financial plans of the NCI provide support for this program, administrative supplement awards pursuant to this initiative are contingent upon the availability of funds and the receipt of a sufficient number of meritorious requests.

Application Procedure

Only one proposal from a grantee is permitted.

All requests must include the following:

- a. Cover letter listing the eligible parent grant signed by the PI, and any collaborating investigators at the same institution as the PI, and the appropriate official from the grantee institution. The cover letter should also include:
 - o If applicable, state intent to submit a request for a no-cost extension.
 - o Include the following statement: "Per supplement instructions, a detailed budget request is enclosed."
- b. A letter of Intent to collaborate from each collaborating investigator located at an institution different from that of the PI, cosigned by the appropriate official from the grantee institution. Collaborators need not be part of the parent grant thus availing PIs to additional scientists and clinicians who work with the HIV-positive population.
- c. A biosketch for the PI and each collaborating investigator
- d. PHS 398 Cover page:
 - o Item 1: The request must have the same title as the parent grant. Please include the number of the parent grant.
 - o Item 2: Identify as "Administrative Supplement."
 - o Item 3: The request must have the same PI as the parent grant.
 - o Item 4: Request no more than a single year of support. There must be an active parent grant during the entire funding period.
- e. Detailed Budget of Initial Budget Period (PHS 398, Form 4)
 - o All applicants can request up to \$100,000 in direct costs and must provide a detailed budget.
- f. Research Plan
Provide a description of the pilot work or proposed research plan and how it relates to the area of cancer in the HIV-infected population. If pertinent, indicate how the research supported by this supplement will benefit the work from the parent grant. This description should include an introduction, preliminary research findings if any justifying the need for supplemental funding, proposed strategies and methodology, future plans to sustain the area of research once the supplement funding period has ended (not to exceed 10 pages).

Requests should contain enough detail to allow assessment of the scientific merit of the proposed research plans for future support of the research activity and the appropriateness of the request for supplemental funding. All requests require an itemized budget and must be signed by the grantee institution's business office. Requests for administrative supplements under this program must comply with NIH policies for inclusion of women, minorities, and children in research involving human subjects.

The earliest anticipated award date for this program will be September 1, 2008. Inquiries related to this notice should be addressed to one of the NCI Program Directors listed below. Applicants are encouraged to discuss the relevance of their administrative supplement request with one of the NCI Program Directors listed at the end of this document.

Submission of Administrative Supplement Request

Submit a signed, typewritten original of the request, as well as required accompanying program materials, publications, biosketches, and letters of support in one package. Please send the original paper copy and an electronic PDF file of the package to:

Donald Johnsey
 Program Specialist
 6130 Executive Boulevard, MSC 7362
 Rockville, Maryland 20892-7362 (for U.S. Postal Service express or regular mail)
 Rockville, MD 20852 (for express/courier delivery)
johnseyd@mail.nih.gov

REQUESTS HAND-DELIVERED BY INDIVIDUALS TO THE NATIONAL CANCER INSTITUTE WILL NOT BE ACCEPTED. This policy does not apply to courier deliveries (i.e., FEDEX, UPS,

DHL, etc.) (<http://grants.nih.gov/grants/guide/notice-files/NOT-CA-02-002.html>). Do NOT send applications to the NIH Center for Scientific Review (CSR).

Review Considerations

Upon receipt, requests will be reviewed for completeness and for responsiveness by the NCI. Incomplete and/or non-responsive requests will not be considered.

Administrative supplement requests that are complete and responsive to the supplement announcement will be evaluated for scientific, feasibility and technical merit by NCI and NIH program staff (and other appropriate persons and selected outside consultants) who have expertise in the subject area in accordance with the review criteria stated below. Only those requests that describe research deemed to have the highest scientific merit will be considered for funding.

Review Criteria

The goal of these NCI-supported (administrative) supplements is to foster basic, translational and clinical research in cancer biomarkers of HIV-infected/AIDS associated population. Projects related to malignancies occurring in higher prevalence with the HIV-infected population are of higher priority than malignancies that show equal prevalence between infected and non-infected populations. The staff and consultants will evaluate the following aspects of the administrative supplement requests in order to judge the likelihood that the proposed project will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered by the reviewers, weighing them as appropriate for each request. The administrative supplement request does not need to be strong in all categories in order for it to receive a favorable evaluation. For example, an investigator may propose to carry out important work that, by its nature, is not innovative, but is essential to move a field forward.

The five categories of review criteria to be used in the evaluation of these administrative supplement requests are listed below.

1. *Significance*. Does the proposed research address an important cancer problem in the HIV population? If the aims of the proposed project are achieved, how will the results drive this field? Does the pilot work show promise for future long term support?
2. *Approach*. Are the research studies adequately designed, Are proposed methods, and analyses appropriate to the aims of the proposed objectives. Does the applicant acknowledge potential problem areas and consider alternative tactics? How appropriate are the plans to sustain research area once the supplemental funding period has ended? Is the pilot work likely to result in a subsequent proposal?
3. *Innovation*. Does the proposed study employ novel concepts, approaches, or methods? Are the aims original and innovative? Does the study challenge existing paradigms or develop new methodologies or technologies? Is the pilot likely to develop an innovative line of research?
4. *Investigator*. Is the investigator appropriately trained and qualified to carry out this work? Evidence of Relevant letters of support from key collaborating personnel.
5. *Environment*. Does the environment in which the work will be done contribute to the probability of success? Do the proposed approaches take advantage of unique features of the research environment or employ useful, collaborative arrangements? Is there evidence of institutional support?

The initial review also will examine the administrative supplement requests for demonstration of the following items: the appropriateness of proposed project budget and duration; and where appropriate the adequacy of plans to include both genders, minorities and their subgroups, and children as appropriate for the goals of the research. Finally, the provisions for the protection of human subjects and the safety of the intervention environment will be examined.

Award Criteria

Requests for administrative supplements submitted to the Division of Cancer Prevention, NCI, will be considered for award based upon the following considerations: (a) scientific and technical merit; (b) program relevance; (c) future funding potential; (d) availability of funds.

Required Federal Citations

ALL REQUIRED FEDERAL CITATIONS for PHS grants as stated in the parent U01 or U24 award apply to this administrative supplement. A statement assuring compliance with applicable NIH policies, e.g., human subjects, animal welfare, data sharing should be included.

A final report is due at the conclusion of this supplemental funding.

Inquiries

Direct inquiries concerning the supplements and administrative review matters to:

Karl Krueger

Program Director

Cancer Biomarkers Research Group

Division of Cancer Prevention

6130 Executive Boulevard, MSC 7362

Rockville, Maryland 20892-7362 (for U.S. Postal Service express or regular mail)

Rockville, MD 20852 (for express/courier delivery)

voice: 301-594-1044

fax: 301-402-8990

kruegerk@mail.nih.gov

Direct scientific inquiries regarding AIDS associated malignancies to:

Geraldina Dominguez

Program Director

Office of HIV and AIDS Malignancy

National Cancer Institute

6120 Executive Blvd, MSC 7204 (for U.S. Postal Service express or regular mail)

Rockville, Maryland 20852 (for express/courier delivery)

voice: 301-496-3204

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