REQUEST FOR COOPERATIVE AGREEMENTS APPLICATIONS: RFA

NIH-NCI-DCT-CTRP-82-13

STUDIES OF ACQUIRED IMMUNO-DEFICIENCY SYNDROME (KAPOSI'S SARCOMA AND OPPORTUNISTIC INFECTIONS)

NATIONAL CANCER INSTITUTE

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I. BACKGROUND INFORMATION

The National Cancer Institute (NCI) invites applications for Cooperative Agreements to support "Working Group" research projects into the etiology and treatment of patients with Kaposi's sarcoma (KS), unexplained opportunistic infections (OI) or other manifestations of acquired immunodeficiency. Since June, 1981, the Centers for Disease Control in Atlanta have learned of an increased occurrence of KS, Pneumocystis carinii pneumonia, and other serious OI's concentrated among homosexual men in the United States. Investigation to date has identified an apparently new syndrome which has reached epidemic proportions. In addition to the association with homosexuality there is an underlying state of profound immunosuppression characterized by marked suppression of peripheral blood inducer/helper T-lymphocytes. Affected patients have very often presented with a symptom complex of chronic fever, weight loss and lymphadenopathy as a prodrome to the development of KS or serious OI. To date epidemiologic studies have failed to reveal an etiology, although abuse of certain drugs (especially nitrites) and previous or concomitant infection with certain viruses and other agents have been common.

This serious public health problem deserves intensive investigation. In addition, research into this epidemic could yield important new information on the etiology of cancer in man. The purpose of this RFA is to encourage such research by providing support to institutions possessing an interest in the problem, as well as a population of affected patients and/or laboratory facilities and personnel appropriate to the conduct of such research.

It is intended that this research will be conducted in the context of a "Working Group," i.e., a group of institutions carrying out various research projects funded as a result of this RFA or other mechanisms. NCI staff will serve as a resource of information and will work to facilitate exchange of information and material

This program is described in the Catalog of Federal Domestic Assistance No. 13.395, Cancer Treatment Research. Awards will be made under the authority of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended; 42 USC 282) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

between involved investigators. It is NCI's assessment that such collaboration between investigators will permit achievement of the goals of this RFA - i.e., definition of etiology, treatment and prevention - in the most rapid and efficient manner possible.

II. RESEARCH GOALS AND SCOPE

Studies to be proposed should stress innovative approaches to this problem and should include any or all of the following three components:

1) Epidemiologic studies designed to identify risk factors in patients with KS, the acquired immunodeficiency syndrome or prodromal conditions, along with appropriate control populations.

2) Laboratory research projects in etiology and pathophysiology. These would inclue both in vitro and in vivo studies in such areas as immunology, microbiology, virology, and toxicology, and would comprise studies of the immunodeficiency syndrome, prodromes, Kaposi's sarcoma and opportunistic infections.

3) Innovative treatment and prevention research projects involving patients with Kaposi's sarcoma, unexplained opportunistic infections, other manifestations of acquired immunodeficiency, or prodromes to this syndrome. Most appropriate would be therapy studies linked to etiologic hypotheses or observations.

Encouraged, but not required, are applications from institutions or consortia possessing resources and expertise in all areas. All applicants should clearly document access to an adequate patient population base (either directly or through explicit collaboration) since a major criterion for review will be an ability to complete meaningful studies in a reasonable period of time.

The NCI plans semi-annual meetings of the Working Group. It is hoped that these meetings will provide an opportunity for the development of collaborative arrangements between investigators performing complementary research. At this time it is impossible to explicitly outline the nature of such arrangements since the scope of projects to be funded is unknown. An example, however, would be the provision of biological specimens from patients enrolled in epidemiologic studies to investigators performing in vitro studies of immune function. It is NCI's assessment that this cooperation will hasten the resolution of the important questions relevant to this epidemic and will result in a more efficient allocation of funds. It is anticipated that NCI staff will play a key role in coordinating and facilitating such collaboration as various research activities evolve. Further details of this involvement are outlined below under "Terms of Award."