



Memorandum

DARROW

Date May 5, 1983

From Director,
Center for Infectious Diseases

Subject Request for Clearance to Use Cooperative Agreement Instrument to Assist and Collaborate With the San Francisco City-County Health Department in Conducting Epidemiologic Studies of the Acquired Immune Deficiency Syndrome (AIDS)

To William H. Foege, M.D.
Director, Centers for Disease Control
Through: David K. Rowe *DKR*
Director, Procurement and Grants OfficeI. INTRODUCTION

The Center for Infectious Diseases requests clearance to use the cooperative agreement instrument of award to support the development and implementation of AIDS epidemiologic studies among homosexual men in San Francisco. The request complies with the provisions of HHS Grants Administration Manual Chapter 1-01, PHS Grants Administration Manual Chapter 1-01 and 1-02 (Draft). No deviation from PHS or Health and Human Services grants administration policies is involved in this request other than being a single source action (San Francisco City-County Health Department).

II. BACKGROUND

From June 1981 to May 2, 1983, the Centers for Disease Control (CDC) received reports of 1,366 persons diagnosed with diseases caused by an underlying Acquired Immune Deficiency Syndrome (AIDS). About 27% of these persons had Kaposi's sarcoma (KS), 51% had Pneumocystis carinii pneumonia (PCP), 8% had both KS and PCP, and 14% had other opportunistic infections. About 95% of these cases have been diagnosed in males, and over 75% of these males have had sexual contact with other males before developing AIDS. Of those followed for at least two years after diagnosis, 75% have died. Over 150 cases of AIDS have been reported from each of two cities in the United States: New York and San Francisco.

From 1977-1981, the CDC collaborated with five clinics in the United States in a multi-stage study of hepatitis B infections among homosexual men. As a participant in these studies, the San Francisco Health Department enrolled over 6,800 men during these years. Over 1,300 were systematically interviewed for behavioral risk factors and serologic testing for hepatitis was performed at CDC on the entire group. Serum specimens, collected serially over time, are stored from most of these men in CDC's Division of Hepatitis and Viral Enteritis. Preliminary information suggests that over 50 cases of

AIDS have developed among these 6,800 men, with the age specific incidence approaching two percent in some age categories. Over one-third of the cases of AIDS in San Francisco have occurred among this cohort, identifying them as the highest incidence group for this disease.

The natural history of AIDS is poorly understood. Information on the incidence of prodromal signs and symptoms, such as generalized lymphadenopathy, is lacking. Close followup of this cohort is the most efficient means to learn the population-based incidence of these conditions, and their relationship to previously identified risk factors and subsequent AIDS. The previously collected risk factor information and banked sera will allow assessment of susceptibility factors as well.

In a case-control study conducted in New York City, San Francisco, Los Angeles, and Atlanta by CDC in October-November 1981, certain aspects of homosexual lifestyles were found to be related to AIDS. Large numbers of different sexual partners, sexual exposures in bathhouses, and earlier age of initiation of regular sexual activity with other men were among the most important risk factors identified among the homosexual men studied.

Although the case-control study conducted in 1981 showed many differences between cases and matched controls, some questions could not be answered with the data available at the time. For example patients with KS could not be compared with patients with PCP or other opportunistic infections because so many of the latter had either died or were too ill to be interviewed by the time CDC physicians were able to reach them. The cross-sectional data collected from homosexual males in 1981 portrayed the cases clearly different in their lifestyle from control groups of homosexual men. More recently reports suggest that AIDS is now being found in those who do not report large numbers of different sexual partners, do not use recreational drugs, and do not have histories of syphilis, hepatitis and other sexually transmitted diseases (STD). Close followup of the previously mentioned cohort could assist in determining whether AIDS is becoming more common among homosexual men with fewer partners. Close monitoring of incidence in this group by age and category of previously identified risk factors is possible.

This cooperative agreement is to support a study of the natural history and incidence of AIDS among homosexual men as well as additional risk-factors in order to clarify the dynamics of this illness. Clues derived from these studies should contribute to further definition of risk factors, and lead to refinements in the recommendations for the prevention of AIDS. Specimens obtained will assist in the search for the agent responsible for AIDS. *

III. AUTHORIZING LEGISLATION

- A. Section 301(a) of the PHS Act, as amended by PL 95-626, states:
"The Secretary shall conduct in the Service, and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research investigations, experiments, demonstrations, and studies relating to the cause, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man including water purification, sewage treatment, and pollution of lakes and streams."
- B. The Federal Grant and Cooperative Agreement Act of 1977 (PL 95-224) authorized the use of a cooperative agreement when the principal purpose of the relationship is the transfer of money, services, or anything of value to a recipient to accomplish a public purpose of support authorized by Federal statute and substantial involvement is anticipated between the Government and the recipient during the performance of the contemplated activity.

IV. PURPOSE AND COOPERATIVE ACTIVITIES

A. Purpose

The purpose of this cooperative agreement is to assist the San Francisco City-County Health Department in designing and conducting epidemiologic studies of AIDS in homosexual men in San Francisco in order to clarify the dynamics of this illness, assist in the search for agent(s) responsible for AIDS, and to develop further recommendations for the prevention of AIDS.

B. Cooperative Activities

1. San Francisco City-County Health Department Activities

- a. Design and conduct studies in collaboration with CDC directed to define the history, incidence and risk factors for AIDS in homosexual men in San Francisco. The focus of these studies should be a cohort of more than 6800 homosexual men previously identified by the health department (1977-81) through hepatitis studies. Defined epidemiologic and serologic data available from this group of men provides a unique basis to study precisely the incidence and risk factors for AIDS. The protocol should include

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procedures for contact and interview of cases and controls and obtaining biological specimens, as needed. Specimens will be subjected to serologic and virologic tests at CDC. The previously collected clinical, serologic, and epidemiologic information on the hepatitis cohort should be used for comparative purposes.

- b. Collaborate in the analysis, presentation, and publication of findings.

2. CDC Activities

- a. Collaborate in the development and review of the study protocol for epidemiologic studies including: definitions of cases and controls, sampling procedures, questionnaire design, interviewer selection and training, monitoring interview results and specimen collection, analysis, presentation, and publication of research findings.
- b. Provide criteria for case determination and the selection of controls.
- c. Assist the San Francisco Health Department in evaluating risk factors and incidence trends, and determining the natural history of AIDS.
- d. Perform serologic, immunologic and virologic tests in support of the above studies.

V. SCHEDULING AND REPORTING

The San Francisco Health Department will submit progress reports on a quarterly basis for the first year and semi-annually thereafter. The duration of the agreement is anticipated to be 3 years.

VI. APPLICATION INFORMATION

Further information on this program may be obtained from:

Technical:

- ① James W. Curran, M.D., M.P.H.
(404) 329-3472
- ② Harold W. Jaffe, M.D.
(404) 329-3162
- Acquired Immune Deficiency Syndrome (AIDS) Activity
Center for Infectious Diseases
Centers for Disease Control
Atlanta, Georgia 30333

Business:

Leo A. Sanders
Chief, Grants Management Branch
Procurement and Grants Office
Centers for Disease Control
255 East Paces Ferry Road, N.E.
Atlanta, Georgia 30305

The original and two copies of the application should be sent to the Procurement and Grants Office at the above address.

VII. REVIEW OF THE APPLICATION.

Review of the application will be conducted in accordance with PHS Grants Administration Manual Chapter PHS: 1-507, Objective Review of Grant Applications. An Ad Hoc Committee will be convened to determine the scientific merit of the application. The application should include the following:

- A. A brief statement of the San Francisco Health Department's understanding of the problem and the purpose of the cooperative agreement.
- B. A summary of the health department's current activities in AIDS surveillance and research.
- C. The details of how the health department will develop and implement epidemiologic studies among homosexual men, including a brief description of existing collaborations with other AIDS investigators in the San Francisco area.
- D. The size, qualification, and time allocation of the proposed staff, and the availability of facilities for health department and CDC staff to be used during the study.
- E. How the project will be administered.
- F. A proposed schedule for accomplishing the activities of the cooperative agreement including time frames.

VIII. PERIOD OF CLEARANCE

It is requested that the period of clearance to award a cooperative agreement for this project be three (3) years.

IX. ESTIMATED COST

The estimated cost of the program is up to \$100,000 for the first year. Subject to the availability of additional funds this fiscal year the project may be expanded. Second and third year funding is estimated at \$500,000 each, subject to the availability of funds.

X. REASON FOR PROPOSING SAN FRANCISCO CITY-COUNTY HEALTH DEPARTMENT AS RECIPIENT OF THIS COOPERATIVE AGREEMENT

There are several reasons for awarding the cooperative agreement to the San Francisco City-County Health Department. San Francisco is second only to New York City in the number of AIDS cases reported to CDC. Of these two cities, only San Francisco participated in studies of hepatitis among homosexual men which were conducted by CDC. These

studies have previously (1977-1981) identified a cohort of over 6,800 homosexual men in San Francisco with defined serologic and epidemiologic information which could be extremely valuable in additional studies of AIDS. In addition, a working group has been organized in San Francisco to study the clinical and epidemiologic aspects of AIDS in homosexual men. This group consists of staff of the Health Department, University of California-San Francisco, and the Kaposi's Sarcoma Foundation. This collaborative environment provides an opportunity to conduct additional epidemiologic studies with input from public health officials, academicians, and the community.

If additional AIDS funds are provided this fiscal year the San Francisco project will be expanded to the degree needed to conduct a study of the size commensurate with the problem in San Francisco. It also may be possible that the study then would be expanded to other cities which have similar problems. A decision will be made at that time whether the additional cities would be funded on a competitive basis.

XI. CONCLUSIONS AND RECOMMENDATIONS

Based on the nature of collaboration between the San Francisco Health Department and CDC and since it will be essential for CDC personnel to maintain active involvement with the San Francisco Health Department in the development and implementation of AIDS epidemiologic studies in homosexual men, it is concluded that the funding mechanism most appropriate for this program is the Cooperative Agreement as authorized by P.L. 95-224. It is recommended that this request be approved.


Walter R. Dowdle, Ph.D.

OMB Clearance (is) (is not) required.

Project Clearance Officer, OPPE

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APPROVED:

William H. Foege, M.D.
Director, CDC

DISAPPROVED

William H. Foege, M.D.
Director, CDC