



Memorandum

Date **SEP 20 1983**

From Human Subjects Review Coordinator
Office of the Director, CDC

Subject Protocol #639, "Acquired Immune Deficiency Syndrome in a Cohort of
Homosexual Male Clinic Patients" -- APPROVAL

To William W. Darrow, Ph.D.
AIDS Activity, CID

Thank you for submitting your revised protocol and memorandum dated September 15. Your response has been reviewed by the Chairperson of the IRB, who agreed that you have addressed the concerns raised by the IRB. The revised protocol is approved. The approval period is for one year. If activity is to continue beyond that time, the protocol will have to be re-approved (as required by regulation).

A handwritten signature in cursive script, reading "Deena A. Koniver", is positioned above the typed name.

Deena A. Koniver

cc:
Assistant Director for Medical Science, CID

Instructions: Submit this form, along with 7 copies of the protocol and any supporting documents, to the Designated Staff Office. (See CDC Manual Guide -- General Administration No. CDC - 11, Protection of the Individual as a Research Subject.) Be sure to include an abstract and to complete all applicable items.

Title of Protocol:

Acquired Immune Deficiency Syndrome in a Cohort of Homosexual Male Clinic Patients

Name of CDC Employee Serving as Principal Investigator, Project Officer, etc.

William W. Darrow, Ph.D.

William W. Darrow

Telephone

329-3162

CDC Organizational Component (Identify Center/Institute/Office and Division)

Center for Infectious Diseases, AIDS Activity

Type of Request:

- Policy Review New Protocol Amendment Continuation, No Change
 Other (Explain) _____

Existing Protocol Number, if any, and Approval Date

Check below if Protocol is Believed to be Exempt.

Exempt (Specify Reasons): _____

Estimated Number of Subjects

830

Proposed Dates for Project

Beginning October 3, 1983 Ending June 29, 1984

Type of Project (Check all that are applicable)

- Intramural FDA Regulated Clinical Investigation Grant Special Foreign Currency Program (P.L. 480) Interagency Agreement (Money Transferred from CDC)
 Collaborative Contract Cooperative Agreement Interagency Agreement (Money Transferred to CDC) Other (Specify) _____

COMMENTS (This space may be used to expand on or clarify any items)

This observational study will be conducted in cooperation with the San Francisco Department of Public Health. Participants will be volunteers who consent to be studied.

ASSURANCE OF CONFIDENTIALITY

Has formal authorization been given to assure confidentiality? No Yes (If yes, provide copy of approved authorization request)

ABSTRACT

This study of acquired immune deficiency syndrome (AIDS) in homosexual male patients is designed to (1) determine the incidence of AIDS and related conditions in a clearly defined cohort, (2) correlate morbidity and mortality with evidence of AIDS among members of the cohort, and (3) associate AIDS and other adverse outcomes with possible risk-factors for AIDS. Participants will be volunteers who consented to be studied in earlier investigations of hepatitis B infections. After giving voluntary, written, informed consent for this study, participants will provide clinical, laboratory and interview data. The results from this study will provide an estimate of incidence and better understanding of the natural history of AIDS.

APPROVALS (Signature and Position Title)

Date

Remarks

Harold W. Jaffe
Harold W. Jaffe, M.D., Chief, Epidemiology Section, AIDS

8/18/83

James W. Curran
James W. Curran, M.D., M.P.H., Director, AIDS Activity

8/18/83

DIRECTOR, CENTER/INSTITUTE/OFFICE
John V. Bennett
John V. Bennett, M.D., Asst. Director for Medical Science

8/22/83

SPACE BELOW RESERVED FOR USE OF IRB, ETC.