MIPR NO: 92MM2549

TITLE: PROSPECTIVE COLLECTION AND BANKING OF LYMPHOCYTES AND CLINICAL DATA ON HIV INFECTED INDIVIDUAL TAKING ANTIRETROVIRAL AGENTS

PRINCIPAL INVESTIGATOR: Richard Harris, LTC, MS

CONTRACTING ORGANIZATION: Fitzsimons Army Medical Center (HSC) Department of Clinical Investigation Aurora, Colorado 80045-5001

REPORT DATE: April 15, 1994

TYPE OF REPORT: Annual Report

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Prospective Collection and Banking of Lymphocytes and Clinical Data on HIV Infected Individuals Taking Antiretroviral Agents

Richard Harris, LTC, MS

Fitzsimons Army Medical Center (HSC)
Department of Clinical Investigation
Aurora, Colorado 80045-5001

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FAMC has enrolled a total of 633 patients in the natural history study since its beginning. Currently, the FAMC Data Base for patient history and plasma/serum/cell collection is being integrated into the central MMCA data base in coordination with Program area 5. We are initiating a collaboration with Dr. Vahey, Program area 5 in coordination with Wilford Hall (Dr. Meicher). FAMC Data Base files have been sent to the Area 5 Data Manager. We are planning a coordinated evaluation of the FAMC plasma/serum/cell bank for evaluation of surrogate markers in long term HIV patients.

FAMC is cooperating with Denver's Community Programs for Clinical Research on AIDS (CPCRA) by acting as an additional enrollment site for five (5) HIV related drug studies.

FAMC is also conducting a study referred to us by the Henry M. Jackson Foundation (FAMC is not a Jackson site) for the prevention of Mycobacterium avium complex in our severely immunodeficient HIV patients. We are preparing the application to the IRC for an additional study recommended to us by HMJ.

Drug Resistance, HIV, Agents, BL3, Chemotherapy, RAD 1

Unclassified

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In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and Use of Laboratory Animals of the Institute of Laboratory Resources, National Research Council (NIH Publication No. 86-23, Revised 1985).

For the protection of human subjects, the investigator(s) adhered to policies of applicable Federal Law 45 CFR 46.

In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

In the conduct of research utilizing recombinant DNA, the investigator(s) adhered to the NIH Guidelines for Research Involving Recombinant DNA Molecules.

In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.

Principal Investigator's Signature Date

[Signature]
4-26-94
ANNUAL REPORT

1. MIPR No. 92MM2549

2. Report Date: 15 April 1994

3. Reporting Period from: 1 April 1993 to: 31 March 1994

4. P.I.: Richard Harris, LTC, MS

5. Phone #: (303) 361-4045 / DSN 943-4042

6. Agency/Address: Fitzsimons Army Medical Center
HSHG-CI
Aurora, CO 80045-5001

7. Project Title: Prospective Collection and Banking of Lymphocytes and Clinical Data on HIV Infected Individuals Taking Antiretroviral Agents. FAMC Protocol # 91/300

8. Current Staff, with percentage of effort on each project:

   Richard Harris, LTC, MS
   Erin Palestro, R.N. 100%

9. MIPR Expenditures to date:

   Personnel $ 79,206. Supplies $257,858.
   Travel $31,397. Other $3,321.

   Total $420,678.