Henry M. Jackson FOUNDATION for the ADVANCEMENT OF MILITARY MEDICINE

Human Immunodeficiency Virus (HIV) Research Program

Sponsored By:
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Grant No. - DAMD17-88-Z-8007

FOREWORD

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

John W. Lowe
Deputy Executive Director
March 25, 1991

28 February 1991 Midterm Report (2/25/88 - 8/31/90)

Human Immunodeficiency Virus (HIV) Research (AIDS)

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On February 25, 1988, a $38 million dollar grant was awarded to the Henry M. Jackson Foundation for the Advancement of Military Medicine (HMJF) by the United States Army Medical Research and Development (USAMRDC). This grant was awarded to fund clinical and laboratory research on therapeutic regimens which show promise of ameliorating the effects of HIV infection. Midway through the five year grant, an organizational structure is in place to conduct both basic and applied research of HIV.

Therapeutic; Clinical; AIDS; HIV; RA I; Retroviruses; Therapeutic Trails; Clinical Facility; WRAMC 123

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GENERAL INSTRUCTIONS FOR COMPLETING SF 298

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On February 25, 1988, a $38 million dollar grant was awarded to the Henry M. Jackson Foundation for the Advancement of Military Medicine by the United States Army Medical Research and Development Command (USAMRDC) for research on the Human Immunodeficiency Virus (HIV). With the award of the grant, a funding mechanism was in place that enabled the Department of the Army as the lead agency against HIV to consolidate a tri-service program of applied research within a clinical framework. The past three years of the five year grant have resulted in fulfilling some of the original Workscope and establishing an organization that will continue the process.

I. INTRODUCTION

Nature of the Problem

In late 1980 a few cases of a devastating disease that attacked the body's immune system and its ability to fight disease were identified in the United States. This disease was eventually diagnosed and named acquired immune deficiency syndrome (AIDS). By 1982, the Centers for Disease Control (CDC) were gathering epidemiologic data and case definitions. By 1985 a virus, named at that time HTLV III, had been identified as the infectious agent of AIDS and the transmission of that virus was determined to be through sexual contacts and the exchange of blood products. The impact on the military of this disease and its transmission was recognized early in the disease's history. In 1985 researchers from all three services met to devise a program of testing for the AIDS virus in the military. HTLV III became internationally accepted as the human immunodeficiency virus (HIV) and the testing became the organized and comprehensive HIV testing program of recruits, the reserve and guard units, and active duty members that is in place today.

Attention still needed to be focused on other factors of HIV infection affecting the military. HIV contamination of the blood supply, especially in times of war or overseas duty, the treatment of military personnel already infected with HIV, and new transmission of HIV within the military all were critical to the U.S. troops' deployment and training. Therefore with Congressional support and funding, research on this infectious disease became a military medicine priority.

Background of Previous Work

In 1985 Congress, through the Senate Appropriations Committee Report (SR. No. 99-176), tasked the Army to establish a research program focused on acquired immune deficiency syndrome (AIDS) and recommended funding of $52,600,000. In the following years Congress continued to give guidance for the AIDS research in the Department of Defense and stressed that money earmarked for this research not be used for any other purpose. The Army which had

been designated the lead agency for infectious disease research in the Department of Defense Appropriations Bill, 1982, H.R. No. 97-333, p. 247, was given the task. In 1986 the Assistant Secretary of Defense for Health Affairs provided guidance that reemphasized the Army's role and stressed that the funding should support a balanced program that would not interfere with established medical research and development priorities.

Support from Congress continued with specific direction that the Army's medical research and development be given flexibility in managing the personnel and financial resources for AIDS research. In 1987 researchers within the Walter Reed Army Institute of Research (WRAIR) who had been managing the dollars for HIV research began to look for a method to bring the money not already spent in outside contracts for HIV testing and diagnostics into one program. The establishment of such a program was necessary because money was available for HIV research but personnel were not, except to move them from research on other military relevant diseases. One umbrella program could also direct the research into an applied arena of the clinical setting to supplement and complement the laboratory work.

With the vision and hard work of Colonels Edmund Tramont and Donald Burke and others, the concept of a grant dedicated to HIV research from the United States Army Medical Research and Development Command (USAMRDC) at Fort Detrick in Frederick, Maryland, became a reality. On February 25, 1988, a $38,000,000, five year grant was awarded to the Henry M. Jackson Foundation for the Advancement of Military Medicine (the Foundation). The Foundation had been established by Congress in 1983 to support military medicine and medical research. The award of the HIV research grant fulfilled the legislative intent for both HIV research funding and the Foundation.

Purpose of Present Work

The Jackson Foundation grant proposal of December 31, 1987, states "the objective of this proposal is to conduct clinical trials of therapeutic regimens which show promise of ameliorating the effects of HIV infection. These regimens will consist of drugs or biological or combinations thereof for which a Notice of Claimed Investigational Exemption for a New Drug (IND) has been filed with the Food and Drug Administration. Since we propose to test these regimens in individuals in WR stages 1 and 2 complete virological and immunological support is necessary. This support will be provided by the proposed laboratory described in the Statement of Work. To furnish administrative support to the clinical and laboratory section, we propose to establish a single organization which will accomplish all of the non-scientific aspects of the grant, e.g., hiring, payroll, ordering, receiving, accounting, etc."

The purpose of present work is therefore to conduct clinical trials of therapeutic regimens which show promise **of ameliorating the effects of HIV infection.**

Methods of Approach

With the primary focus of the research effort to ameliorate the effects of HIV infection, the dynamics for an effective research organization within the military were set in place. The framework for conducting that research came first from Congress in August, 1986, when they instructed the research be accomplished in the areas of diagnostics, chemoprophylaxis/chemotherapy, immunology and vaccines, epidemiology and natural history. These areas, with the additions mentioned below, were kept in place.

In March of 1988 John Lowe became the Associate for HIV Research at the Jackson Foundation and began to assemble an organizational structure. From the Foundation headquarters in Rockville, Maryland, he hired staff to develop the clinical research program at Walter Reed Army Medical Center in Washington, D.C. and to build a Jackson Foundation retrovirus laboratory near the WRAIR laboratory in Rockville.

Establishment of physical locations to support the organization moved quickly from that point.

February 24, 1989, the outpatient ward to support the clinical research trials opened at Walter Reed Army Medical Center, Washington, D.C., Building One (the old Walter Reed Hospital).

April 3, 1989, the Henry M. Jackson Foundation Research Laboratory opened at 1500 East Gude Drive, Rockville, Maryland. This state-of-the-art laboratory was planned, designed and built in the first fourteen months of the grant.

October, 1989, the clinical research setting at Wilford Hall U.S. Air Force Medical Center in San Antonio, Texas, opened.

July 20, 1990, the clinical research ward at the National Naval Medical Center in Bethesda, Maryland, opened.

During the First Grant Year approximately **sixty** individuals were hired under the HIV Research Program and **$2,542,000** was spent.

Concurrent with the award of the grant to the Foundation, a Memorandum of Understanding for HIV research among Walter Reed Army Medical Center, Walter Reed Institute of Research, Uniformed Services University of the Health Sciences and Henry M. Jackson Foundation for the Advancement of Military Medicine was signed and implemented.

This agreement provided for "coordinating an omnibus clinical and

laboratory research program on Human Immunodeficiency Virus (HIV) Research at Walter Reed in efforts to develop and test effective chemo/immunotherapy and chemo/immunoprophylaxis for soldiers, to evaluate new treatment modalities, to elucidate the pathogenesis of disease, and to provide for an increase in the quality of life of individuals involved in the study." (MOU dated March 14, 1988) **(Appendix D,1.)**

II. BODY

Experimental Methods

From its conception the grant was to be a coordinated effort of clinical trials of therapeutic regimens and applied and basic research efforts in the laboratory. That structure has been greatly refined in the intervening years but not significantly changed.

Mission Area Protocols (MAPS)

In November of 1988 a group of physicians and scientists from the Walter Reed Army Medical Center and the Walter Reed Institute of Research met in Hagerstown, Maryland, to develop a 5 year planning document for military retroviral research. The report contained objectives under seven functional areas derived from the 1986 Congressional appropriations bill; Diagnostics, Natural History, Epidemiology, Chemotherapy, Viral Immunology and Vaccine Development, Animal Models and International Health.

These functional areas became Mission Area Protocols or MAPS under which all basic and applied research fall. Two additional MAPS, Behavioral Medicine/Education and Opportunistic Infections, have been added. Each MAP has been assigned a "Mapmaker", a scientist with expertise in that particular area who is responsible for its coordination. In addition to the objectives outlined for each MAP at the Hagerstown Conference, the Mapmaker and other researchers in that area meet on a regular basis to update and document their current research goals and objectives.

Although the MAPS define the general areas of basic research, each scientist has his or her own work submitted under a protocol or research plan. This protocol specifically outlines the theories, experimental design, and administrative details necessary to its completion. Before the protocol can be undertaken, the researcher's peers must critically analyze it for scientific design and merit and it must fit within the overall HIV Research Program.

One step of the peer review process is the USAMRDC RETROVIRUS CLINICAL RESEARCH COMMITTEE which has been established to review, disapprove, or defer, all clinical research protocols. The committee members certify the protocol's scientific excellence and insure adequate laboratory resources are available to support the

study. All clinical protocols must be approved by this committee before support is given under the HIV Research Program. The precursor to the present tri-service committee was the Army's RETROVIRUS SCIENTIFIC PLANNING COMMITTEE.

Protocols

All research within the HIV Research Program is governed by protocols and will remain so as long as aggressive treatment of HIV and AIDS is primarily experimental. The number and complexity of the protocols have increased with the growth of the HIV Research Program. As of August 7,1990, **54** protocols were in the review process. **(Appendix A)**

Protocols which involve human beings must be approved by the Institutional Review Board (IRB) or Human Use Committee at the medical treatment facility where the research is undertaken. Because many of the HIV protocols are performed at multicenters simultaneously, this review process can be lengthy and difficult to coordinate. Therefore the ARMY SURGEON GENERAL'S HUMAN SUBJECTS RESEARCH REVIEW BOARD was augmented with six voting members from the Navy, Air Force, and USUHS to review the HIV research protocols that are multicentered and tri-service. The individual medical facility commanders may refuse to participate in a particular protocol but they cannot change the protocol after approval by the Board. This insures the standardization of these protocols and the data derived from them. **(Appendix B)**

Interagency Agreements

In addition to the basic and clinical research within the scope of the grant, research is being done through agreements between USAMRDC and institutes of the National Institutes of Health (NIH). These agreements provide money to study areas of HIV infection that are not unique to the military but are important to the overall mission. To date three agreements are in place.

1. An agreement for **$4.7 million** with the **National Institute of Child Health and Human Development** to "study the epidemiology and natural history of HIV infection in all pediatric beneficiaries less than six years of age who reside in a household where at least one parent is infected with HIV."

2. An agreement for **$1.7 million** with the **National Institute of Dental Research** to "conduct a study of oral manifestations of HIV infection in a U.S. military population."

3. An agreement for **$758,000** with the **National Institute of Arthritis and Musculoskeletal and Skin Diseases** to "conduct clinical and epidemiological studies of cutaneous manifestations associated with HIV infection..."

Administrative Methods

Oversight

When the grant was awarded from USAMRDC, the granting agency established an USAMRDC MANAGEMENT AND OVERSIGHT COMMITTEE to be responsible for the progress, administrative plans, current financial status and future financial requirements of the grant. Its chairman is the Research Area Director of Military Infectious Disease Hazards (RAD I) at USAMRDC and its members are selected representatives from appropriate disciplines within MRDC and DoD. **(Appendix C)**

Memoranda of Understanding

In addition to the original Army Memorandum of Understanding (MOU) to establish the HIV Research Program, **(Appendix D,1.)** three other MOUs were signed to expand the Program's scope and include the other two services.

1. In September, 1989, a MOU between the National Naval Medical Center (NNMC), US Naval Health Sciences Education and Training Command (HSETC), US Army Medical Research and Development Command (USAMRDC), Uniformed Services University of the Health Sciences (USUHS), and the Henry M. Jackson Foundation for the Advancement of Military Medicine (HMJFAMM) was signed to include the Navy in the HIV Research Program. **(Appendix D,2.)**

2. In January, 1990, a MOU was signed between Wilford Hall US Air Force Medical Center (WHMC), the US Air Force Surgeon General (AFSG), USAMRDC, USUHS, and HMJFAMM to include the Air Force in the Program. **(Appendix D,3.)**

3. The most recent MOU added the Naval Hospital in San Diego. It was signed in July, 1990, with the Naval Hospital in San Diego, HSETC, USAMRDC, USUHS, and HMJFAMM. **(Appendix D,4.)**

Grant Modifications

Since February 25, 1988, the date of the original grant, modifications to the HIV Research Grant have been necessary to amend the document and to add additional dollars. As of August 31, 1990, fourteen modifications had been completed. **(Appendix E)**

Financial Reporting

After the award of the grant to the Jackson Foundation, extensive work went into creating an accounting system to track in detail the money spent for the program. Paralleling this effort, is and was the budgeting process needed to structure the program's growth and

correspond with the influx of additional program requirements and spending authority from the government. In the first grant year, **$4,885,246.33** was spent. In the second grant year, the total was **$9,874,983.10** and for the first six months of the third year, the expenditures were **$9,798,758.64**. Detailed reports are attached in **Appendix F**.

Personnel

The largest area of expenditure each of the past three years has been for salaries and benefits. The HIV Research Program has required a varied mix of all disciplines; clinical, administrative, scientific, and technical. The program has attracted and retained competent and dedicated individuals interested in combating HIV in all its stages. A list of the employees, their locations, and job titles is attached in **Appendix G.**

III. CONCLUSION

The awarding of the HIV research grant to the Henry M. Jackson Foundation and the subsequent organizational structure has major implications for the path of HIV infection in the military population and civilian world. The work that has been done in each of the MAPS mentioned above all contribute to these implications.

The work done with experimental vaccines promises to result in effective vaccines against HIV infection.

Through the behavioral medicine MAP, researchers are working on large scale surveys of military members' knowledge concerning HIV which will provide material to develop educational programs to stop the spread of this virus.

The animal models using simian immunodeficiency virus (SIV) in primates will give answers to potential HIV vaccines in humans.

The natural history and epidemiological data already accumulated has provided the course for the researchers to concentrate their efforts.

The original grant was given for five years and $38 million dollars. In the near future the ceiling on the grant will be raised to $74 million to support the program's growth. The time frame will possibly be extended to continue the program after the fifth year. This will be done to fulfill the Workscope's purpose of **ameliorating the effects of HIV infection.**

7 August 1990

HIV Research Protocols

RV	WU	TITLE	PI
1	8804	Natural History	Dr. Oster
2	8803	Core DX (Adults)	Dr. Burke
	Addendum - HIV Infx of Human Eosinophils		Dr. Lucey
3	8802	Early Rx AZT	Dr. Oster
4	7128	Neurobehavorial	Dr. Salazar
5	8805	Dental Natural History	Dr. Konzelman
6	1151	Urinary (Inactive)	Dr. Link
7	1948	Fansidar (Closed)	Dr. Wright
8	1951	Cryo preserved Lymph (Closed)	Dr. Rhoads
9	1953	Monoclonal Ab.	Dr. Drabick
10	9269	HIV Mark, Mono cells (Hold)	Dr. Baker
11	1958	Langherhans Cells	Dr. Hoover
12	8801	Semen	Dr. Rhoads
13	6220	Peds Natural History	Dr. Fischer
		Peds Natural History (Bethesda)	Dr. Moriarty
		Peds Natural History (San Diego)	Dr. Waecher
14	7139	Phase 1 Poly IC Rx	Dr. Salazar
15	3342	Skin Testing	Dr. Birx
16	6222	Core DX (Children)	Dr. Fischer
17		Saliva (withdrawn)	Dr. Ballou
18	8812	Derm Natural History	Dr. Smith
19	6218	Peds Eval HIV Proteins	Dr. Fischer
20	8807	Cimetidine Rx	Dr. Drabick
21A	8806	Recombinant GP160	Dr. Redfield
21B		Recombinant GP160 Phase II	Dr. Redfield
22	1952	Retrospective Review	Dr. Oster
23A	8809	ST4 (CD4)	Dr. Hawkes
23B	8809	ST4 (CD4) Infusion	Dr. Hawkes
24	8810	Spouse Study	Dr. Rhoads
25	4805	Pathology	Dr. Anderson
26	7243	Psych Natural History	Dr. Rundell
27	8808	Pharmacokinetic - AZT	Dr. Bjornson
28	8814	Pharmacology Database	Dr. Bjornson
29		Macrophage	Dr. Gendleman
30		DTH/Skin Biopsy	Dr. Birx
31	8813	Megestrol Acetate Rx	Dr. Davis
32		P24	Dr. Redfield
33		CASTA	Dr. Birx
34		Skin Test/PG160/p24	Dr. Birx
35	8811	Derm Microflora	Dr. Smith
36		Neuroendocrine	Dr. Bernton
37	8815	Pharmacology (PCP)	Dr. Bjornson
38		Retrospective Study: Suicide	Dr. Rundell
39		Pediatric AZT/DDI Therapy	Dr. Fischer
40		Pediatric CD4 Therapy	Dr. Fischer
41	6264	Perinatal HIV Infection	Dr. Pettett
42		Psychopharmacologic Meds	Dr. Rundell
43	8818	Prospective Emergence/AZT	Dr. Mayers

44	8817	HIV/Syphilis	Dr. Johnson
45		Sleep Study	Dr. Hendrix
46		Propylthiouracil	Dr. LaCivita
47		HIgh/Low Dose AZT (Peds)	Dr. Fischer
48		Changes in blood/skin test	Dr. Henry
49		Dipyridqmole/AZT	Dr. Hendrix
50		Detection...CNS	Dr. Burke
51		rGP120	Dr. Redfield
52		Perinatal Tissue Bank	Dr. Pettett
53		Neurodevelopment	Dr. Nannis

PROTOCOL SUMMARY - 18 SEPTEMBER 1990

RV1 The Natural History of HIV Infection and Disease in United States Military Beneficiaries.

PI: Dr. Charles N. Oster
Status: Ongoing

OBJECTIVES:

A. To systematically document the natural disease progression in individuals with HIV infections in a general military population.

B. To form a study cohort which will be eligible for participation in treatment protocols and for other studies related to specific aspects of the descriptive elements (natural history) of HIV infection.

RV2 Core Diagnostics for HIV Developmental Diagnostics in Adults.

PI: Dr. Donald S. Burke
Status: Ongoing

OBJECTIVES:

A. To develop and evaluate new and/or improved laboratory methods for establishing the diagnosis of HIV, and to correlate detectable HIV virus, HIV antigen, and/or HIV nucleic acid in blood with clinical status.

B. To develop and evaluate new and/or improved laboratory methods for assessing the virus-specific immune response to HIV infection, and to correlate detection of virus-specific antibody or cell mediated immune responses with clinical status.

RV3 VA Cooperative Study No. 298, Treatment of AIDS and AIDS Related Complex Part I: treatment of patients with ARC (AZT versus Placebo.

PI: Dr. Charles N. Oster
Status: Ongoing

OBJECTIVES:

A. Primary:

1. To determine the clinical effect of azidothymidine (AZT) compared to placebo in terms of time to progression to AIDS (i.e., occurrence of major opportunistic infections, dementia, and malignancies) or death. Initial drug assignment will be changed to open label AZT for patients who experience a sustained decline in CD4 lymphocyte concentration to $<200/mm^3$, but analysis will be based on initial treatment assignment.

2. To determine the immunologic effect of AZT compared to placebo in terms of time to drop in CD4 lymphocyte concentration of $\geq$ 25% from baseline assessment.

3. To determine the combined immunologic and clinical effect of AZT in ARC patients by comparing patients receiving AZT with those receiving placebo in terms of time to the first occurrence of any of the following endpoints:

a. Sustained absolute CD4 lymphocyte concentration of $< 200/mm^3$

b. Progression to AIDS

c. Death

4. To determine the anti-viral effect of AZT compared to placebo in eradicating of suppressing HIV.

B. Secondary:

1. To determine the effect of AZT compared to placebo on the immune status of HIV-infected patients by comparing lymphocyte profiles and indices.

2. To determine the long-term toxicities of AZT compared to placebo in terms of abnormalities in blood, hepatic function, renal function, skin,gastrointestinal system and central nervous system.

3. To describe the natural history of ARC in placebo patients in terms of initial CD4 lymphocyte concentration and the Walter Reed Staging System.

RV4 Neurobehavioral Consequences of HTLV-III Brain Infection and AIDS Encephalopathy.

PI: Dr. Andres Salazar
Status: Ongoing

OBJECTIVES:

A. To prospectively characterize the neuropsychological and neurological manifestations of the Acquired Immune Deficiency Syndrome (AIDS) dementia, both in regard to its earliest detectable manifestations and its progression.

B. To establish the timing, localization and progression of HTLV-III infection of the CNS and its relation to clinical signs and symptoms. To investigate host, virus, infection, and epidemiologic factors affecting this progression.

C. To develop a screening instrument to detect the early onset of cognitive and affective changes in HTLV-III infected individuals.

D. To establish a structure for the systematic testing and evaluation of patients to help expedite clinical drug trials and behavioral therapeutic interventions.

E. To use the AIDS encephalopathy model to study basic brain structure-function relationships which can contribute to the understanding of behavior and performance in normal subjects.

RV5 Natural History of Oral Manifestations of HIV Infection in a U.S. Military Population.

PI: Dr. Joseph Konzelman
Status: Ongoing

OBJECTIVES:

A. To document oral manifestations of HIV infection, along with their associated risk factors, in relation to the onset and progression of systemic disease. Specific attention will be given to HIV-related periodontal pathologies, candidal infections, and viral and immunologic components of saliva.

RV6 Evaluation of Renal function, Protein Excretion and the Urinary Sediment in Patients with Antibody to the Human Immunodeficiency Virus (HIV).

PI: Dr. Christine Link
Status: Inactive

OBJECTIVES:

A. To prospectively document renal function, protein

excretion, and the urinary sediment in patients who have been determined to be positive for the antibody to HIV and present to WRAMC for evaluation and staging.

B. To determine the prevalence of, and describe, the renal abnormalities in this population.

C. To determine if there is a relationship between the extent of disease as measured by a standard staging evaluation and the type and/or severity of renal abnormalities.

RV7 A Double Blind Randomized Placebo Controlled Trial of Fansidar Prophylaxis in Patients with HTLV-III Disease.

PI: Dr. D. Craig Wright
Status: Closed

SUMMARY:

The study suggested that Fansidar prophylaxis prevented pneumosystic carinii infection.

RV8 Human Immune Response to HTLV-III Infection.

PI: Dr. Joanne L. Rhoads
Status: Closed

OBJECTIVES:

A. To establish a large pool of cryopreserved lymphocytes obtained from donors who are in an early stage of HTLV-III infection (WR-2). These lymphocytes will be used for two purposes: first, to establish cell lines of mononuclear cells infected with HTLV-III for use in cytotoxic killing assays, and, second, to determine if HTLV-III virus specific, HLA restricted, cytotoxic lymphocyte activity occurs naturally in HTLV-III infected people.

RV9 The Generation of Human Monoclonal Antibodies to the HIV.

PI: Dr. Joseph Drabick
Status: Ongoing

OBJECTIVES:

A. To generate human monoclonal antibodies to commercially available recombinant HIV antigens from the lymphocytes of patients infected with HIV.

RV10 Evaluation of Human Immunodeficiency Virus (HIV)-Related Proteins on the Surface of Lymphocytes from Patients with Evidence of HIV Exposure or HIV Illnesses.

PI: Dr. James Baker
Status: On Hold

OBJECTIVES:

A. To use monoclonal antibodies developed against HIV-related proteins (P120, P24 and P15-17) to identify HIV-infected lymphocytes by Fluorescent Activated Cell Sorter (FACS) analysis to determine whether patients with early stages of HIV-related illness (WR Stage 1-4) who demonstrate evidence of heavy viral load (many cells expressing viral proteins) are more likely to develop frank AIDS. In addition, to see if the identification of virally-infected cells might be used to screen patients who are negative on other types of immunologic screening (antibody tests) or require viral culture.

RV11 In Situ Hybridization for Detection of HIV in Langerhans Cells of HIV-Infected Patients.

PI: Dr. David Hoover
Status: Ongoing

OBJECTIVES:

A. Confirm whether Langerhans cells are infected with HIV.

B. Determine the fraction of infected cells in the sampled population.

C. Correlate intensity of skin infection with clinical and laboratory evidence of progression of HIV infection

D. Compare the intensity of infection of blood mononuclear cells with Langerhans cells.

RV12 Identification and Characterization of Human Immunodeficiency Virus in Human Semen.

PI: Dr. Joanne L. Rhoads
Status: Ongoing

OBJECTIVES:

A. Identify and quantitate HIV-infected cells in the semen of men infected with HIV.

B. Determine if HIV attaches to the spermatozoa in HIV infected semen.

C. Quantify and characterize antibodies to HIV in the seminal plasma of HIV infected men.

D. Determine whether free (non-cell associated) HIV exists in seminal plasm.

RV13 Epidemiology of HIV in Pediatric and Perinatal Patients: A Natural History Study.

PI: Dr. Gerald Fischer
Status: Ongoing

OBJECTIVES:

A. To develop a Pediatric AIDS center (PAC) that will identify and prospectively follow children who are military beneficiaries with HIV infection. All high risk infants will be followed for at least two years to determine if infection has occurred and those with HIV infections will be followed thereafter.

B. Identify all pediatric beneficiaries < 6 years of age who reside in a household where at least one parent is infected with HIV and develop a pediatric HIV registry.

C. Determine the HIV infection status of each high risk child in these families (utilize CDC classification).

D. Identify source of HIV infection and characterize family environment and socioeconomic status.

E. Prospectively follow high risk and infected children every 3-4 months to determine infection status and analyze the natural history of pediatric HIV infection

F. Identify all spouses of HIV positive active duty personnel and HIV positive active duty women to retrospectively analyze obstetrical status

G. Identify pregnancies in high risk and infected women.

RV14 Intramuscular Poly-ICLC and Zidovudine in the Management of HIV Infection: An Open Pilot Trial.

PI: Dr. Andres Salazar
Status: Ongoing

OBJECTIVES:

A. Determine the safety or toxicity of Poly-ICLC plus Zidovudine in patients with advanced HIV infection, based on historical controls.

B. Study the human immune response to Poly-ICLC plus Zidovudine in patients with AIDS.

C. Explore the potential therapeutic efficacy of the biological response modifier Poly-ICLC plus Zidovudine in the management of HIV infection, based on historical controls. By necessity in a pilot trial such as this, only relatively large beneficial effects maybe apparent.

RV15 Delayed-Type Hypersensitivity Skin Testing: Correlation of Intradermal Injection vs. Epicutaneous Antigen Placement with CD4 Number in Normals and HIV Seropositive Subjects.

PI: Dr. Deborah L. Birx
Status: Ongoing

OBJECTIVES:

A. Correlate antigen reactivity by intradermal and epicutaneous injection to circulating CD4 number.

B. Compare subject reactivity to each of the antigens: tetanus toxoid, Candida albicans, and trichophyton, as determined by simultaneously placed intradermal and epicutaneous injection.

C. Correlate anergy, as determined by intradermal injection vs epicutaneous antigen placement, with evidence of HIV disease progression and development of AIDS.

D. Develop a standardized anergy panel for clinical staging of HIV subjects in the Armed Forces hospitals.

RV16 Evaluation of Diagnostic Assays for Human Immunodeficiency Virus (HIV) in Children with Evidence of HIV Exposure or HIV Illness.

PI: Dr. Gerald Fischer
Status: Ongoing

OBJECTIVES:

A. To analyze laboratory assays for detection of HIV

infection in children, and to correlate the results with the clinical status of the child.

RV17 Human Saliva (withdrawn)

RV18 The Investigation of the Cutaneous Manifestations of HIV Infection in Relation to the Onset, Severity and Progression of Disease.

PI: Dr. Kathleen Smith
Status: Ongoing

OBJECTIVES:

A. To estimate the incidence, prevalence and natural history of skin disease of all types in each Walter Reed stage of HIV infection.

B. To investigate the association between the use of specific dugs with drug eruptions in patients with immune dysfunction and the relationship to anergy and T-cell depletion.

C. To determine the frequency, prognostic and diagnostic value of tubuloreticular inclusion bodies (seen on EM) for each Walter Reed stage.

D. To determine the role of the skin for diagnosing subclinical systemic infections.

RV19 Evaluation of Human Immunodeficiency Virus (HIV)-Related Proteins on the Surface of Lymphocytes from Children with Evidence of HIV Exposure of HIV Illnesses.

PI: Dr. Gerald Fischer
Status: Ongoing

OBJECTIVES:

A. To use monoclonal antibodies developed against HIV-related proteins (p120, p24 and p15 - 17) to identify HIV-infected lymphocytes by Fluorescent Activated Cell Sorter (FACS) analysis to determine if HIV infected lymphocytes can be detected in children with HIV infection. In addition, we would like to determine if the number of HIV infected cells increase as the child gets older.

RV20 The Use of Cimetidine for Immuno-augmentation in HIV Seropositive Patients.

PI: Dr. Joseph Drabick
Status: Ongoing

OBJECTIVES:

A. To determine is Cimetidine, an H2 antagonist known to inhibit T-cell suppression, can affect the cellular immunity of immunosuppressed HIV infected patients in a positive manner, resulting in partial immune restitution.

RV21A Active Immunization of HIV Infected Patients with Recombinant GP160 HIV Protein Phase I Study of Immunotherapy, Immunogenicity and Toxicity.

PI: Dr. Robert R. Redfield
Status: Ongoing

OBJECTIVES:

A. To evaluate the immunogenicity and toxicity of the recombinant human immunodeficiency virus (HIV) envelope glycoprotein GP160 candidate vaccine, in patients with early HIV Infection (Walter Reed Stages 1-2).

RV21B Active Immunization of Early HIV Infected Patients with Recombinant GP160 HIV Protein: Phase II Study of Immunotherapy, In vivo Immunoregulation and Clinical Efficacy.

PI: Dr. Robert R. Redfield
Status: In Review (WRAMC HUC 25 Sep 90)

OBJECTIVES:

A. To conduct a phase II trial of the recombinant human immunodeficiency virus (HIV) envelope glycoprotein, gp160 candidate vaccine, in patients with early HIV infection (WR Stage 1-2). Specific objectives include: (1) to continue to evaluate the immunogenicity and toxicity of this product; (2) to determine the parameters predictive of immunoresponsiveness; and (3(to determine the clinical efficacy of immunization with gp160 in the treatment of early HIV infection. This will be accessed by determining alteration in the natural history of HIV infection both in terms of in vivo HIV regulation and clinical disease progression.

RV22 The Clinical Presentation of HIV Infected Patients at Walter Reed Army Medical Center.

PI: Dr. Charles N. Oster
Status: Ongoing

OBJECTIVES:

A. To present demographic and clinical information on patients with Human Immunodeficiency Virus infection (HIV) seen at the Infectious Disease Clinic at Walter Reed Army Medical Center.

RV23A/B Phase I and II Study of the Use of Soluble CD4 Protein in Human Immunodeficiency Virus Infection.

PI: Dr. Clifton A. Hawkes
Status: 23A (Study complete) 23B (On hold)

OBJECTIVES:

A. PHASE I and IIA

1. Determine the safety and pharmacokinetics of single intravenous infusions of ST4 in Walter Reed Stage 3,4,and 5 patients.

2. Determine the safety,pharmacokinetics, and anti-viral and immunologic effects of multiple intravenous infusions of ST4 in Walter Reed Stage 3-6 patients.

3. Determine the safety and pharmacokinetics of single intravenous infusions of ST4 in Walter Reed Stage 1 and 2 patients.

4. Determine the safety, pharmacokinetics, and anti-viral and immunologic effects of multiple intravenous infusions of ST4 in Walter Reed Stage 1 and 2 patients.

B. PHASE IIB

1. Determine the safety, anti-viral and immunologic effects of extended therapy with soluble CD4 in Walter Reed Stage 3,4,5 and 6 patients, if no significant untoward effects are seen in earlier trials, and bolus infusion therapy is feasible.

2. Determine the anti-viral and immunologic effects of extended therapy with St4 in Walter Reed Stage 1 nd 2 patients if no significant untoward effects are seen in earlier phases of this study, and bolus infusion

therapy is feasible.

RV24 Factors Affecting Heterosexual Transmission of Human Immunodeficiency Virus.

PI: Dr. Joanne L. Rhoads
Status: On hold

OBJECTIVES:

A. Determine the factors, both host- and virus-specific,which affect heterosexual venereal transmission of human immunodeficiency virus (HIV).

RV25 Pathological Manifestations of HIV Infection at Autopsy.

PI: Dr. David Anderson
Status: Ongoing

OBJECTIVES:

A. To enable research on the etiopathogenesis of HIV-associated immunodeficiency by the timely performance and routine processing of complete autopsies on patients with HIV disease.

B. To provide pathologic assessment of disease processes causing morbidity and mortality in patients enrolled in WRAMC HIV research protocols.

C. To obtain fresh tissue for research immunohistochemical phenotyping of immune cells and immunohistochemical detection of viral infections in organ sections from patients with HIV disease as well as in control sections immunocompetent autopsy patients without HIV disease.

D. To conduct a trial comparison of the relative sensitivity and specificity of immunochemistry and in situ hybridization for detection of retroviral (HIV) and herpes viral (EBV and CMV) infection of disease in freshly frozen tissue from major organ systems of HIV patients.

E. To obtain fresh tissue from major organ systems to be stored in a tissue registry in the following states of preservation: unfixed at -70^{0}C, preserved for future electron microscopic studies, and formalin fixed, paraffin-embedded. This tissue registry will constitute a resource for subsequent research.

RV26 Psychiatric Natural History.

PI: Dr. James Rundell
Status: In Review (USUHS HUC - 10 Sep 90)

OBJECTIVES:

A. Consolidate clinical neuropsychiatric and psychosocial data in a form with lends itself to analysis and incorporate this into the general HIV natural history database.

B. Develop analogous database at tri-service study sites that use identical measures.

C. Identify and refine useful clinical measures that can be used to predict transmission risk and risk for neuropsychiatric or psychosocial morbidity.

D. Develop, pilot and validate a new instrument and methodology being developed that relates sexual behavior data and HIV transmission risk.

E. Develop, pilot, and validate a new instrument for collection of psychosocial and life events data that relates to HIV transmission and psychiatric morbidity.

F. Develop databases for the following natural history study areas:

1. Neuropsychiatric and psychosocial factors associated with HIV transmission risk behaviors.

2. Areas of focus for psychiatric interventions most likely to significantly impact on the spread of infection.

3. Factors that prevent suicidal and/or other behavioral risks (e.g. excessive drinking or drug use) discovered to be primarily or secondarily associated with HIV transmission.

4. Evaluation of the role of psychosocial phenomena such as social supports, coping and methods of modifying stress in reducing transmission, diminishing morbidity in HIV-infected persons, and facilitating subjects' participation in treatments and research protocols.

G. Document the significance of neuropsychiatric and psychosocial factors (i.e. psychopathology, substance abuse, neuropsychopathology, personality traits and disorders, impact of stressful events, coping mechanisms, and social

supports) as they occur in and influence the course of the natural history of HIV infection and associated diseases and to examine how these factors influence observed military/occupational performance capacity.

H. Correlate the manifest psychiatric morbidity and comorbidity with the stage of HIV infection and the somatic and neurologic pathophysiology measured during follow-up.

I. Compare neuropsychiatric and psychosocial findings in HIV-infected military personnel with non-infected military personnel.

J. Conduct tests to insure the comparability of laboratory, clinical, and behavioral data across sites.

K. Utilize both neuropsychiatric and psychosocial data at six-month intervals to develop intervention strategies to address both HIV transmission behaviors and psychiatric morbidity:

1. Facilitation of responsible sexual behavior.

2. Cooperation with medical treatment.

3. Psychoactive substance use disorders treatment.

4. Psychopharmacologic medications.

5. Management of neurocognitive disorders.

RV27 A Pharmacokinetic Study to Investigate a Possible Association Between Zidovudine (AZT)/Glucuronyl (GAZT) Blood Levels and Drug Toxicity and Efficacy in HIV Infected Patients.

PI: Dr. Darrel C. Bjornson
Status: Ongoing

OBJECTIVES:

A. Develop a database to gather useful information to help us describe the relationship between plasma Zidovudine (AZT) and GAZT concentrations and drug toxicity.

RV28 A Pharmacoepidemicologic Study to Develop a Database to document Variations in the Outcome of Illness Which May Be Due To Drug Effects, Both Beneficial and Adverse, (e.g., side Effects, Compliance) and To Document Patterns of Drug Use in HIV Infected Patients.

PI: Dr. Darrel C. Bjornson
Status: Ongoing

OBJECTIVES:

A. This protocol will be the Master Protocol to build a database in conjunction with the HMJF HIV Network database that will serve as a format for both retrospective and prospective observational studies on marketed and investigational drugs. Subsequent addendums will be submitted that define specific drug studies that relate to side effects, compliance, and clinical outcomes. The objective of this study then, will be to develop a database to study outcomes of illness due to drug effects (beneficial and adverse) and to gather useful information on drug use patterns of HIV infected patients.

RV29 Clinical, biochemical and molecular and studies of human immunodeficiency virus-macrophage interactions.

PI: Dr. Howard Gendleman
Status: In Review (RC2 Administrative Hold)

OBJECTIVES:

A. Determine the optimal conditions for maintaining blood and tissue monocytes in vitro for the isolation and propagation of HIV.

B. Determine the utility of monocyte viral isolation techniques for diagnosis and/or confirmation of HIV infection.

C. Investigate the role of MCSF in the susceptibility of monocytes to virus infection.

D. Define a possible heterogeneity of response of donor monocytes to HIV infection.

E. Study the role of cytokine/lymphokines and DNA viruses and other opportunistic pathogens in affecting virus replication and monocyte function.

F. Determine if the CD4 epitope is the receptor for HIV on monocyte/macrophages and to investigate other possible viral receptors.

G. Determine the biochemical and molecular nature of monocyte-HIV tropism(s) and cytopathic effects.

RV30 Delayed-Type Hypersensitivity Skin Testing: Correlation with skin biopsy and in vitro lymphocyte testing in HIV seropositive patients and HIV seronegative normals.

PI: Dr. Deborah L. Birx
Status: In Review (HIVSUBC then HUC)

OBJECTIVES:

A. Development of optimal criteria for evaluation of delayed-type hypersensitivity (DTH) skin testing with regard to specificity and sensitivity in both HIV(-) and HIV(+) subjects.

B. Correlation of biopsy results (the gold standard) with Walter Reed staging (that utilizes cutaneous reactivity alone) for HIV disease.

C. Correlation of in vivo ski testing and biopsy with in vitro functional lymphocyte studies.

D. Correlation of in vivo DTH skin testing, biopsy, and in vitro functional lymphocyte assays with HIV disease progression.

RV31 The Effect of Megestrol Acetate on the Cachexia of Human Immunodeficiency Virus (HIV) Disease: A Randomized, Placebo-Controlled, Double-Blinded Study.

PI: Dr. Charles Davis
Status: Ongoing

OBJECTIVES:

A. To assess the efficacy of megestrol acetate in the treatment of the anorexia and weight loss associated with HIV disease.

B. To conduct a detailed, longitudinal analysis of nutritional, biochemical, anthropomorphic, and psychosocial parameters in HIV patients receiving megestrol acetate.

C. To assess the effect of megestrol acetate on the cell-mediated and humoral immune response.

D. To assess the effect of megestrol acetate on HIV activity.

E. Assess the effect of megestrol acetate on zidovudine serum levels.

RV32 Active Immunization of HIV Infected Patients with Recombinant P24 HIV Protein: Phase I Study of Immunotherapy: Immunogenicity and Toxicity.

PI: Dr. Robert R. Redfield
Status: In Review (WRAIR SR then HIVSUBC)

OBJECTIVES:

A. To evaluate the immunogenicity and toxicity of the recombinant human immunodeficiency virus (HIV) structural protein p24 candidate vaccine in patients with early HIV infection (Walter Reed Stage 1-2).

RV33 Pilot Study to Compare CASTA to New Standardized Candida albicans from Greer Laboratories to current Candida albicans from Hollister-Steer Laboratories.

PI: Dr. Deborah L. Birx
Status: In Review (WRAIR SR then HIVSUBC)

OBJECTIVES:

A. Comparison of CASTA (noval candida albicans skin test antigen) as a standardized skin test antigen both in vitro and in vivo in HIV-infected and normal HIV(-) subjects to our current non-standardized candida albicans from Hollister Steer.

RV34 Pilot Investigation of Recombinant HIV Proteins (gp160 and p24) as Delayed-Type Hypersensitivity Skin Test Antigens and In Vitro Lymphocyte Proliferation.

PI: Dr. Deborah L. Birx
Status: In Review (Tabled at RC2 12 Jan 89)

OBJECTIVES:

A. Development of the optimal criteria for evaluation of DTH skin testing with HIV specific proteins HIV-1 gp160 and p24.

B. Correlation of in vivo DTH skin testing with HIV specific proteins HIV-1 pg160, p24 with in vitro functional lymphocyte studies to HIV specific proteins to the clinical stage of HIV positive patients.

RV35 The Investigation of the Cutaneous Microflora Found in HIV Infected Patients as it Relates to the Onset, Severity and Progression of Disease.

PI: Dr. Kathleen Smith
Status: Ongoing

OBJECTIVES:

A. Determine the cutaneous microflora and the relationship of the microbial skin flora to the stage of immune suppression and to document the carriage of potential pathogens.

RV36 Neuroendocrine Adaptation to Stress: Immune Function and HIV.

PI: Dr. Edward Bernton
Status: In Review (Delayed Approval RC2 9 May 89)

OBJECTIVES:

A. To study and describe the natural history of changes in serum DHEA, DHEA-sulfate, and cortisol in patients with HIV, with particular reference to of correlations of abnormalities in the secretion of these hormones with clinical stage of disease and with deterioration of immune function.

B. To determine if depressed levels of DHEA-S and/or hypercortisolism in asymptomatic seropositives (WR-1) or immunologically-intact symptomatic seropositives (WR-2) is a prognostic marker predictive of more rapid disease progression. A positive correlation showing more rapid disease progression in a subgroup with the most suppressed DHEA-S levels or elevated Cortisol/DHEA-S ratios could provide a preliminary rationale to identify such patients and treat with DHEA.

C. To attempt to determine if abnormalities in the above hormones in HIV patients without opportunistic infections represent a physiologic response to infection with HIV or a psychophysiologic response in susceptible individuals to the chronic stress of being diagnosed as having this disease.

RV37 Pneumocystis carinii pneumonia (PCP) in HIV patients: A Cohort study to estimate the protective effect of prophylactic pentamidine inhalation in compliant versus non-compliant patients.

PI: Dr. Darrel C. Bjornson
Status: Ongoing

OBJECTIVES:

A. To determine if patients who are compliant with the use of pentamidine inhalation have a decreased risk of developing PCP when compared to those who ar non-compliant. This project will be a pharmacoepidemiologic observational study to test the following research hypothesis: HIV patients who are treated prophylactically with pentamidine inhalation and are compliant have less of a risk of developing PCP than those who are treated prophylactically with pentamidine but are not compliant. The null hypothesis would state that there is no difference in the risk of PCP between patients who are compliant and those non compliant.

RV38 Retrospective Study of Factors which Influence Suicide, Suicide Attempts, and Suicide Ideation Among and HIV Positive Military Population: Walter Reed Army Medical Center.

PI: Dr. James Rundell
Status: In Review (WRAIR SR then HIVSUBC - on admin hold per PI)

OBJECTIVES:

A. To collect,via a retrospective records review, data which relates to suicide potential among all patients admitted to WRAMC during calendar year 1987 with an HIV positive diagnosis.

B. To compare these data with similar data already collected for the same period at Wilford Hall.

C. To analyze those factors which are similar or different between categories of patients based on stage of disease, clinical psychiatric diagnosis, and demographics.

RV39 A Randomized Trial to Evaluate the impact of Maintaining Steady-State Concentrations of Azidothymidine (AZT) versus those by an Intermittent Schedule o Delivery in Children with Symptomatic HIV Infection.

PI: Dr. Gerald Fischer
Status: In Review (HIVSUB then HUC)

OBJECTIVES:

A. To determine whether the pharmacokinetic profile of AZT influences its efficacy on HIV infection in children.

1. To evaluate whether a continuous infusion of AZT will have an impact on improving the neurodevelopmental deficits associated with HIV disease in children when compared to a comparable total daily dose of AZT that is administered on a standard divided dosage schedule (e.g., every six hours).

2. To assess whether a steady-state pharmacokinetic profile can be attained with an oral sustained release formulation of AZT that will mimic that achieved by the continuous intravenous administration of AZT.

3. To determine whether an oral sustained release formulation of AZT will achieve comparable clinical efficacy as the continuous intravenous route of delivery of AZT at the same bioequivalent daily dosage, and to assess whether either or both of these steady-state formulations are superior to that achieved with an intermittent dosage schedule.

a. To determine whether there are differences in the time to neurodevelopmental improvement among the three regimens as measured at the 3, 6, and 9 month follow-up evaluations.

b. To determine whether there is an overall difference in the degree of neurodevelopmental improvement among the three regimens after 3, 6, and 9 months of therapy.

c. To determine whether patients failing to improve or giving evidence of a progressive loss of neurodevelopmental function after a minimum of six months intermittent AZT can improve when crossed over to continuous infusion of sustained release AZT administration.

d. To determine whether there are differences in the organ specific response (i.e., improvement in neurodevelopmental deficits versus other clinical or laboratory abnormalities associated with HIV infection) in children receiving AZT on an intermittent versus steady-state administration schedule.

B. To determine whether there are differences in the tolerance and side-effects associated with AZT when administered on an intermittent schedule versus a steady-state schedule.

1. To assess whether there are differences in the

morbidity of treatment. For example, do patients on continuous intravenous therapy require more impatient therapy because of catheter associated complications.

2. To determine whether there are differences in the rate and degree of hematologic or non-hematologic toxicities associated with an intermittent versus oral sustained release verses the continuous intravenous administration of AZT.

3. To determine whether there are differences in patient or parent (guardian) compliance between the three treatment regimens.

C. To determine the extent of interpatient variation in AZT levels and whether there is a correlation of plasma and CSF levels with the degree of therapeutic efficacy.

D. To determine whether there are differences in the response of children who acquire HIV infection perinatally versus those who acquire HIV infection by transfusion.

RV40 A Phase I Safety Study of Recombinant CD4 (rCD4) in Infants and Children and in Pregnant Women and Newborns with HIV Infection.

PI: Dr. Gerald Fischer
Status: In Review (WRAIR SR then HIVSUBC)

OBJECTIVES:

A. To determine the safety profile of rCD4 therapy in infants and children with AIDS or AIDS-related complex, asymptomatic seropositive infants and children, and infants born to seropositive mothers, and who are proven to be HIV positive.

B. To determine the safety profile of rCD4 in high risk newborns and in seropositive pregnant women at the onset of labor.

C. To obtain a preliminary indication of the antiviral effects of rCd4 in infants and children with AIDS or AIDS-related complex, asymptomatic seropositive infants and children, and infants born to seropositive mothers, and who are proven to be HIV positive.

D. To measure steady state serum levels or rCD4 following continuous infusion therapy.

E. To selectively measure the effect of rCD4 on the immune

function of neonates, infants, and children.

RV41 Perinatal HIV Infection: Epidemiology and Natural History.

PI: Dr. Gary Pettett
Status: In Review (USUHS HUC 10 Sep 90)

OBJECTIVES:

A. The purpose of this project is two-fold: (1) to develop a clinical perinatal center for the diagnosis and management of pregnant women with human immunodeficiency virus (HIV) infection and their newborn infants, and (2) to systematically collect clinical, laboratory and epidemiologic data describing the course and natural history of perinatal HIV infection by focusing on the following specific objectives and questions:

1. Determine the maternal to fetal transmission rate in population of dependent and active-duty pregnant women.

   a. Is there a relationship between the severity of maternal infection and transmissibility?

   b. Are there clinical/laboratory markers of maternal disease which are predictive of perinatal transmission?

2. Determine whether pregnancy adversely affects the course of HIV infection in young women.

   a. Describe the progression, if any, of HIV infection in pregnancy and quantify the risk, if any, of maternal/fetal opportunistic infection.

   b. Are other latent viruses with frequently inhabit the cervix and/or vagina during late pregnancy (CMV, Herpes virus) potentiated by the presence of HIV infection or immune deficiency?

3. Develop criteria for the diagnosis of HIV infection during the early neonatal period.

4. Develop a clinical (pediatric) staging system describing disease progression following perinatal transmission.

5. Establish the existence and/or frequency of fetal embryopathy.

RV42 HIV Transmission and Morbidity: Response to Psychopharmacologic Medications.

PI: Dr. James Rundell
Status: In Review (WRAIR SR then HIVSUBC - on admin hold per PI)

OBJECTIVES:

A. To relate psychopharmacologic treatments in HIV-infected persons to changes in direct and indirect measures of HIV transmission behaviors.

B. To document the efficacy of psychopharmacologic agents in treating psychiatric disorders in HIV-infected individuals.

C. To describe frequency and risk factors for developing adverse effects and drug-drug interactions of psychopharmacologic agents at various stages of HIV infection.

D. To establish a database and patient base for use in future planned specific studies of the efficacy of psychopharmacologic treatments.

RV43 Prospective Study of the Emergence of Zidovudine (AZT) Resistance in Patients Infected with the Human Immunodeficiency Virus (HIV) Who Are Treated with AZT.

PI: Dr. Douglas L. Mayers
Status: In Review (USUHS HUC 10 Sep 90)

OBJECTIVES:

A. To determine the time course, frequency and clinical parameters associated with the development of AZT resistance in HIV isolated from patients on AZT.

B. To determine if there exists a level of AZT resistance, measured in vitro, which correlates with clinical deterioration in patients who are receiving AZT.

C. To develop a repository of frozen HIV-infected peripheral blood mononuclear cells (PBMC) with resistant virus for future studies into the molecular basis of didexynucleotide resistance.

RV44 The Effect of HIV Infection on the Initial Manifestations and Response to Treatment of Syphilis.

PI: Dr. Steven C. Johnson
Status: Ongoing

OBJECTIVES:

A. To compare the efficacy of standard therapy for early syphilis with a more intensive antibiotic regimen in patients with and without HIV infection.

RV45 Sleep Disturbances in HIV-Positive Patients, a Descriptive Study.

PI: Dr. RoseMarie Hendrix
Status: In Review (WRAIR SR)

OBJECTIVES:

A. To describe sleep stage distribution and sleep disturbances in HIV-positive patients and an age, sex, and sleep complaint matched HIV negative control gorup.

RV46 Evaluation of Propylthiouracil in the Prevention of Cachexia in AIDS Patients.

PI: Dr. Cathy LaCivita
Status: In Review (Approved RC2, 9 Jan 90)

OBJECTIVES:

A. This study is designed to determine if propylthiouracil (PTU) therapy can decrease weight loss in AIDS patients by decreasing serum levels of triiodothyronine (T3), which is a catabolic thyroid hormone. The pilot study (phase I) will include 20 HIV positive adults with CD4 counts < 400 cells/mm^3. Each subject will be randomized to receive PTU or placebo therapy for five months and will have seven venipunctures to determine changes in thyroid hormone levels, tumor necrosis factor, and serial body weights to assess changes on body weight with therapy. If differences are found in T3 levels and body weights in PTU treated subjects compared to controls, but analysis reveals that larger patient numbers are needed for statistical significance, then phase II a larger double blinded randomized study of the same design will be performed. Risks of study are those of venipuncture, and possible rare side effects of PTU therapy - hypothyroidism, skin rash, myalgias, arthralgias, hepatitis, edema.

RV47 A Randomized Blinded Trial to Evaluate the Safety and Tolerance of High Versus Low Dose Zidovudine Administered to Children with Human Immunodeficiency Virus.

PI: Dr. Gerald Fischer
Status: Withdrawn

RV48 Changes in Peripheral Blood Lymphocyte Counts, Subsets and Activation by Delayed Hypersensitivity Skin Testing in HIV Seropositive and Seronegative Individuals.

PI: Dr. Richard E. Henry
Status: In Review (Approved RC2 9, Jan 90)

OBJECTIVES:

A. We propose to examine the effects of delayed hypersensitivity (DTH) skin testing on the peripheral blood lymphocytes as measured by Coulter Counter, as well as determining the changes in lymphocyte subsets and activation states by fluorescence-activated cell sorting in a population of 12 health, HIV seronegative adults and 25 healthy, HIV seropositive adults (Walter Reed 1 or 2). The study will involve 4 separate peripheral venous blood samplings, two to establish baseline values, the third 48 hours after placement of 5 recall antigens (skin testing for delayed hypersensitivity), and the fourth at 120 hours (5 days post skin testing) to document return of lymphocyte values toward their baseline. Five HIV seropositive and four HIV seronegative subjects will serve as internal controls and undergo the series of blood sampling without receiving the DTH skin testing. The DTH skin testing and one blood sample are standard of care for HIV seropositive individuals. The subjects are at minimal risk from either the venous blood sampling or the single DTH skin testing. The study will continue for 6 months after SGO approval unless the required number of subjects are enrolled before that time. From this study, we hope to show the effects of delayed hypersensitivity skin testing on the values of lymphocyte surface markers in HIV-infected subjects compared with non-HIV infected, healthy subjects.

RV49 The Effect of Dipyridamole on Zidovudine Pharmacokinetics.

PI: Dr. Craig Hendrix
Status: In Review (Approved RC2, 14 May 90)

OBJECTIVES:

A. Determine the effects of DPM on ZDV pharmacokinetics.

B. Determine the highest tolerable oral doze of DPM administered concurrently with ZDV>

C. Determine whether an oral regimen of 100mg every four hours (600mg/day) or greater of DPM will produce plasma concentrations capable of inhibiting nucleoside transport in vitro.

RV50 Detection and Clinicopathologic Correlation of Human Immunodeficiency Virus (HIV-1) Nucleic Acids and Antigens in Reticuloendothelial and Central Nervous System Tissues by Immunohistochemistry, In situ Hybridization, and Polymerase Chain Reaction.

PI: Dr. Allen Burke
Status: In Review (Approved RC2, Jul 90)

OBJECTIVES:

A. Establish a retroviral pathology laboratory for qualitative and semiquantitative detection of HIV-RNA, and HIV antigens in adjacent human tissue sections using immunohistochemistry (IHC), in situ hybridization (ISH) and polymerase chain reaction (PCR).

B. To establish both low molecular weight (unintegrated) and high molecular weight (chromosomally integrated) HIV DNA content in lymphoid and central nervous system (CNS) tissues using differential ultracentrifugation and PCR.

C. To correlate the content and histologic location of HIV antigens, replicating HIV RNA as well as integrated and nonintegrated HIV-DNA in lymphoid tissues (tonsils, lymph node, spleen) with clinical disease state.

D. To provide a tissue-based reference service to DOD and other researchers for detection of HIV in human tissues.

RV51 A Phase I Study of the Safety and Immunogenicity of rgp120/HIV-1_{IIIB} Vaccine In HIV-1 Seropositive Adult Volunteers.

PI: Dr. Robert Redfield
Status: In Review (WRAMC HUC 25 Sep 90)

OBJECTIVES:

A. To evaluate the safety (clinical and immunologic) of rgp120/HIV-1_{IIIB} immunization in asymptomatic HIV-1 infected volunteers.

B. To compare the immune response of a 0, 1, 4, 8, 16 week schedule to a 0, 8, 16 week schedule.

C. To determine whether rgp120/HIV-1_{IIIB} immunization causes a significant immune response as defined by one or more of the following:

1. induction of neutralizing antibodies to the IIIB isolate of HIV-1

2. increased cross-neutralization titers to HIV-1 isolates other than IIIB

3. increased titers of antibodies to the principal neutralizing determinant of HIV-1_{IIIB}

4. increased titers of antibodies to HIV-1 epitopes other than the principal neutralizing determinant

5. gp120 antigen specific lymphocytic proliferation.

RV52 Perinatal HIV Tissue Bank.

PI: Dr. Philip G. Pettett
Status: In Review (Approved RC2, Jul 90)

OBJECTIVES:

A. The purpose of this project is to establish a specimen bank for the preservation of perinatal tissue collected at the time of parturition from pregnant women with HIV infection.

B. To establish routine procedures for the timely collection and processing of placental, fetal membrane and umbilical cord specimens.

C. To enable the assessment of HIV transmission in patients enrolled in the Pediatric/Perinatal HIV Epidemiology Protocol and any subsequent projects which may be developed and approved.

D. To obtain fresh tissue placenta, fetal membranes and umbilical cord specimens for immunohistochemical techniques to phenotype immune cells and detect viral antigens/nucleic acids in tissues derived from pregnancies complicated by HIV infection.

E. To correlate pathologic changes in the placenta and fetal tissues with maternal and neonatal outcome of HIV

infection.

RV53 Neurodevelopmental Outcome in Infants With Perinatal Exposure to HIV.

PI: Dr. Ellen D. Nannis
Status: In Review (Approved RC2, Jul 90)

OBJECTIVES:

A. This study is designed to identify neurodevelopmental deficits which may occur in neonates, infants, and young children with perinatally acquired HIV infection. Further, it will explore the incidence of abnormal neurodevelopment in military dependent infants and children without HIV infection. The neurodevelopment of three groups of infants/children will be followed for 3-4 years. These groups are: infants/children with perinatally acquired HIV infection; perinatally HIV exposed, uninfected infants/children; unexposed infants/children. All infants/children will be military dependents who come from a stable, middle class background.

PROCEDURES FOR THE REVIEW OF HUMAN IMMUNODEFICIENCY VIRUS RESEARCH PROTOCOLS THROUGH THE TRI-SERVICE REVIEW SYSTEM

I. PURPOSE:

1. To provide guidelines for review of human immunodeficiency virus research protocols to insure the scientific merit of the protocol and to fully protect and safeguard the rights and welfare of human subjects enrolled in the protocols, in accordance with the referenced regulatory mandates.

2. To delineate the established uniform procedures and responsibilities to carry out the review of such protocols.

II. REFERENCES:

1. AR 70-25 Use of Volunteers as Subjects of Research.

2. AR 40-38 Clinical Investigation Program.

3. 45 CFR 46 HHS Regulation on Protection of Human Subjects.

4. DoD Directive 3216.2 Protection of Human Subjects in DoD-Supported Research.

5. Guide for Human Use Committees (April 1988, Fourth Edition).

6. AFR 169-3 Use of Human Subjects in Research, Development, Test and Evaluation.

7. AFR 169-6 Clinical Investigation and Human Test Subjects in the Medical Service.

8. SECNAVINST 3900.39B Protection of Human Subjects.

9. Memorandum of Agreement Among the Surgeons General of the Army, Navy and Air Force and the President of the Uniformed Services University of the Health Sciences, 19 July 90.

III. DEFINITION OF A TRI-SERVICE RETROVIRUS RESEARCH PROTOCOL:

For the purpose of this procedural guide, a Tri-Service Retrovirus Research Protocol is a protocol involving as subjects HIV seropositive individuals, or those at risk for becoming HIV seropositive, for which funding is being requested through the Henry M. Jackson Foundation. This protocol may describe a study to be carried out at multiple sites, involving personnel and/or facilities of any or all of the three services, or one which may be begun at a single site but which may be expanded to multiple sites encompassing the three services.

IV. TRI-SERVICE RETROVIRUS RESEARCH PROTOCOL REVIEW PROCEDURES:

Overview

A Tri-Service Retrovirus Research Protocol undergoes several levels of review: within the originating Institution, by the Retrovirus Clinical Review Committee, by an ad hoc scientific review committee drawn from knowledgeable scientists and clinicians with connections to one of the three services, and by The Tri-Service Augmented Surgeon General's Human Subjects Research Review Board.

Submission

1. All Tri-Service Retrovirus Research Protocols are submitted by the PI to the Military Medical Consortium for Applied Retroviral Research (MMCARR). The MMCARR submits the protocol to the Retrovirus Clinical Review Committee, which reviews the concept of the protocol and how well it fits into the overall retrovirus program.

2. Once the protocol is approved in concept, the MMCARR contacts scientists and clinicians from the three services as potential reviewers for scientific merit. The MMCARR submits the protocol and a list of suggested reviewers to the Office of Research Management (ORM) at WRAIR.

Scientific Review

1. Scientific review for all Tri-Service Retrovirus Research Protocols is carried out by the ORM at WRAIR.

2. Upon receipt by the ORM, the protocol is logged into a data base. A Tri-Service Scientific Review Committee, composed of three to five scientists/clinicians from any of the three services with expertise in the scientific topic area of the protocol, is appointed by the ORM to review the protocol for scientific merit.

3. A copy of the protocol is sent by the ORM to each member of the Committee for independent review. For members outside the immediate Washington metropolitan area, the protocol will be sent by means of an express mail service. One member is designated Chairman and is responsible for convening a meeting of or initiating a conference call among the members of the Committee and for writing up a Committee report recommending approval, disapproval, modification, complete revision, etc.

4. The Committee is requested to carry out the review within two weeks of receipt of the protocol.

5. The Committee Chairman's report is sent to the MMCARR and the PI through the ORM, which handles all communication between the Committee, the MMCARR and the PI. The scientific review is complete when the Committee is satisfied that the PI has responded adequately to its comments and questions and the Chairman recommends approval of the protocol. Notification of scientific approval is sent by the ORM to the MMCARR and the PI.

Human Use Review

1. Ethical review of informed consent, confidentiality, risks, benefits, and remuneration aspects of the protocol is carried out by the Tri-Service Augmented Surgeon General's Human Subjects Research Review Board (TS-HSRRB).

2. The complete protocol package, including scientific approval, is sent by the MMCARR to the Human Use Review and Regulatory Affairs Office (HURRAO) at USAMRDC HQ, Ft. Detrick, for inclusion on the agenda of the monthly meeting of the TS-HSRRB. This meeting is held on the second Wednesday of each month. To be included on the agenda, the protocol package must be received by HURRAO at least two weeks prior to the meeting.

3. The minutes of the meeting are sent to the MMCARR, which sends a copy to the PI and the ORM. The PI responds to the comments of the TS-HSRRB through the MMCARR. The protocol may be implemented upon notification by the HURRAO through the MMCARR that the TS-HSRRB comments have been satisfactorily addressed. Notification of approval is sent by the MMCARR to the PI and the ORM.

Local Institutional Review Board Ethical Review

1. At each research site, the Institutional Review Board (IRB) reviews the protocol and informed consent form. This review does not include the scientific design of the protocol, which must remain the same at each research site. Changes in the consent form, which are recommended by the IRB, must be reported to the MMCARR.

2. If an IRB requires a change in experimental design, the PI may decide to drop the research site from the protocol or to comply with the requirement. In the latter event, the change must be submitted as a modification to the protocol, be reviewed as described below and be incorporated into the experimental design at all research sites.

Modifications

1. The PI submits all modifications to the protocol to the MMCARR, which then submits the modification to the ORM for scientific review. Whenever possible, a modification is reviewed for scientific merit by the Chairman of the committee which performed the original scientific review. Notification of approval is sent by the ORM to the MMCARR.

2. Following scientific approval, the modification is sent by the MMCARR to the HURRAO to be reviewed by the TS-HSRRB. Notification of approval is sent by the HURRAO to the MMCARR, which informs the PI and the ORM of the approval.

Continuing Review

1. The TS-HSRRB requires that each human use protocol undergo IRB review at least annually. The MMCARR requests a status report on the protocol (continuing/annual or final report) from the PI during the anniversary month of the date the protocol was approved for implementation.

2. It is the PI's responsibility to prepare a comprehensive status report, encompassing results from all research sites and including local IRB review(s) of the protocol, for submission through the MMCARR to the TS-HSRRB.

3. The annual or final report is submitted by the MMCARR to HURRAO to be put on the agenda of the next TS-HSRRB meeting. The results of the review are sent by the MMCARR to the PI and the ORM.

DEPARTMENT OF THE ARMY
U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND
FORT DETRICK, FREDERICK, MD. 21701-5012

REPLY TO
ATTENTION OF

SGRD-PLA (360)

4 MAY 1990

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: Update of Charter to Reflect Membership Changes on the Management Committee of the Henry M. Jackson Human Immunodeficiency Virus Grant

The enclosed, revised Charter updates committee membership to furnish management oversight of the grant to the Henry M. Jackson Foundation for the study of Acquired Immunodeficiency Syndrome in military populations. The Charter dated 12 February 1988 is rescinded.

Encl

PHILIP R. RUSSELL
Major General, MC
Commanding

DISTRIBUTION:
CHAIRMAN, RESEARCH AREA DIRECTOR, MILITARY INFECTIOUS DISEASE HAZARDS, U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND
COMMAND JUDGE ADVOCATE, U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND
COMPTROLLER, U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND
PRINCIPAL ASSISTANT RESPONSIBLE FOR CONTRACTING, U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND
COMMANDER, U.S. ARMY MEDICAL RESEARCH ACQUISITION ACTIVITY
DIRECTOR AND COMMANDANT, WALTER REED ARMY INSTITUTE OF RESEARCH
DIRECTOR, DIVISION OF RETROVIROLOGY, WALTER REED ARMY INSTITUTE OF RESEARCH
DEPUTY COMMANDER FOR CLINICAL SERVICES, WALTER REED ARMY MEDICAL CENTER
CHIEF, INFECTIOUS DISEASES, WALTER REED ARMY MEDICAL CENTER
GRANT OFFICER'S REPRESENTATIVE(S)
ASSOCIATE FOR ADMINISTRATION, HENRY M. JACKSON FOUNDATION FOR THE ADVANCEMENT OF MILITARY MEDICINE
DEAN, UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES
CHAIRMAN, DEPARTMENT OF MEDICINE, LACKLAND AIR FORCE BASE, TX
CHIEF, MEDICAL RESEARCH & CLINICAL INVESTIGATIONS DIVISIONS, BOLLING AIR FORCE BASE, DC
COMMANDING OFFICER, NAVAL MEDICAL RESEARCH AND DEVELOPMENT COMMAND, NATIONAL NAVAL MEDICAL CENTER, BETHESDA
HIV PROGRAM DIRECTOR, NATIONAL NAVAL MEDICAL CENTER, BETHESDA

MANAGEMENT COMMITTEE CHARTER

I. Designation of Management Committee

This Document formally establishes a U.S. Army Medical Research and Development Command (USAMRDC) Management and Oversight Committee (Committee) for the grant with the Henry M. Jackson Foundation for the Advancement of Military Medicine (Foundation).

II. Mission

The Committee is responsible for oversight of grant activities in accordance with applicable U.S. laws and Federal and DOD directives and regulations. Activities to be reviewed include progress, administrative plans, current financial status, and future financial requirements.

III. Membership

a. The voting membership of the committee shall consist of the following:

Chairman: Research Area Director, Military Infectious Disease Hazards, USAMRDC

Members:

- Commander, U.S. Army Medical Research Acquisition Activity
- Command Judge Advocate, U.S. Army Medical Research and Development Command
- Comptroller, U.S. Army Medical Research and Development Command
- Principal Assistant Responsible for Contracting, U.S. Army Medical Research and Development Command
- Director and Commandant, Walter Reed Army Institute of Research
- Director, Division of Retrovirology, Walter Reed Army Institute of Research
- Deputy Commander for Clinical Services, Walter Reed Army Medical Center
- Chief, Infectious Diseases, Walter Reed Army Medical Center
- Grant Officer's Representative(s)

Chairman, Department of Medicine, Lackland Air Force Base, TX
Chief, Medical Research & Clinical Investigations Divisions, Bolling Air Force Base, DC
Commanding Officer, Naval Medical Research and Development Command, National Naval Medical Center, Bethesda
HIV Program Director, National Naval Medical Center, Bethesda

b. Non-voting membership shall consist of the following:

An official of the Foundation will be expected to attend committee meetings. Other individuals may attend when required.

IV. Authority and Responsibilities

a. Authority:

This Committee has been delegated the authority of the Commander, USAMRDC for the centralized, administrative oversight of the grant with the Foundation.

b. Responsibilities:

The Committee is responsible for:

(1) Reviewing progress on a continuing basis.

(2) Reviewing the administrative management of the grant.

(3) Reviewing the financial management of the grant.

(4) If the Committee determines progress or management is not satisfactory, specific written deficiencies, along with proposed corrective actions will be furnished to the Foundation with an information copy to the Commander, USAMRDC.

c. Resource Management:

The Committee will ensure that the Foundation develops and submits dollar and manpower requirements in a managerially and fiscally responsible manner. The Committee will ensure that these resource requirements are commensurate at all times with the scientific and administrative goals of the grant, as determined by the USAMRDC.

d. Termination:

This Committee will be disbanded within six months after expiration of the grant with the Foundation.

P. K. Russell

PHILIP K. RUSSELL
Major General, MC
Commanding

MEMORANDUM OF UNDERSTANDING
AMONG
WALTER REED ARMY MEDICAL CENTER,
WALTER REED ARMY INSTITUTE OF RESEARCH,
UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES
AND
THE HENRY M. JACKSON FOUNDATION
FOR THE ADVANCEMENT OF MILITARY MEDICINE

SUBJECT: Human Immunodeficiency Virus (HIV) Research

1. Purpose.

A. This agreement is established between the Walter Reed Army Medical Center (WRAMC), the Walter Reed Army Institute of Research (WRAIR, the Uniformed Services University of the Health Sciences (USUHS), and the Henry M. Jackson Foundation for the Advancement of Military Medicine (HMJFAMM), hereinafter collectively referred to as the "parties," for the purpose of coordinating an omnibus clinical and laboratory research program on Human Immunodeficiency Virus (HIV) Research at WRAMC in efforts to develop and test effective chemo/immunotherapy and chemo/immunoprophlaxis for soldiers, to evaluate new treatment modalities, to elucidate the pathogenesis of disease, and to provide for an increase in the quality of life of individuals involved in the study.

B. By this agreement the parties seek to identify their respective responsibilities and authority, to establish the specific services and support to be offered by each in support of the HIV research, and to agree to reporting, dispute resolution and other procedural requirements necessary for the success of the cooperative enterprise into which they have agreed to enter.

2. Background.

A. The United States Congress, recognizing HIV as a health threat to the military population, has appropriated funds to the Army specifically for HIV research. The Army Surgeon General has tasked the Health Services Command to support research efforts conducted by WRAIR in HIV disease. In support of this effort, the WRAMC has been tasked with the additional mission of supporting HIV research in addition to its primary and secondary missions of patient care and the support of education and investigation, respectively. By agreement between Health Services Command and the Medical Research and Development Command (USAMRDC) dated 1 September 1987, the Commander of WRAMC has accepted the HIV research mission and has retained final approval authority over WRAMC in support of the research effort as appropriate. To the extent that the HSC/USAMRDC Memorandum of Understanding

(hereinafter MOU) is consistent with the provisions of the following agreement, its terms are incorporated by reference.

B. The Uniformed Services University of the Health Sciences and the Health Services Command have agreed to establish academic and operational relations between the USUHS and HSC Medical Centers (MEDCENS) in an agreement dated 31 December 1985. Under this authority, and additionally under the 1974 agreement between USUHS and the Surgeons General regarding utilization of the military medical centers in the District of Columbia area, the USUHS has engaged in significant academic and research programs with the WRAMC. USUHS medical personnel have been authorized to apply for staff privileges, and those USUHS personnel who hold hospital privileges have been encouraged to participate with HSC investigators in clinical protocols.

C. The Congress of the United States has directed that "it shall be the purpose of the HMJFAMM (1) to carry out medical research and education projects under cooperative arrangements with the USUHS; (2) to serve as a focus for the interchange between military and civilian medical personnel; and (3) to encourage the participation of the medical, dental, nursing, veterinary, and other biomedical sciences in the work of the Foundation for the mutual benefit of military and civilian medicine;" and that the Foundation is authorized by the Congress to "enter into contracts with the Uniformed Services University of the Health Sciences for the purpose of carrying out cooperative enterprises in medical research, medical consultation, and medical education, including contracts for provision of such personnel and services as may be necessary to carry out such cooperative enterprises.

D. The USUHS has entered into an MOU with the HMJFAMM date October 28, 1987 by which the USUHS has agreed, among other things, to appoint HMJFAMM personnel to any position within the University and to permit the performance of duties of any scientist or other medical personnel as the University may approve. All provisions of the USUHS/MOU are incorporated by reference into the following agreement.

E. The HMJFAMM, as a nonprofit medical research and education corporation, has been awarded a grant from the USAMRDC in response to its grant application entitled "Human Immunodeficiency Virus (HIV) Research," the object of which is to conduct and support clinical trials of therapeutic regimens which show promise of ameliorating and/or preventing the effects of HIV infection, such regimens consisting of drugs or biologicals or combinations thereof in which a Notice of Claimed Investigational Exemption for a New Drug (IND) has been filed with the Food and Drug Administration.

Under the terms of the Grant, the Foundation shall test these regimens in individuals at WRAMC. The provisions of the Grant agreement is incorporated into and made a part of this Grant as though fully set forth herein.

3. Control.

A. The parties recognize the need to minimize the effects of HIV research on WRAMC's primary and secondary missions of patient care and support of education investigation. The parties further recognize that as the Commander, WRAMC is responsible for clinical care for HIV patients both on and off research protocol as well as other patients, he will control the magnitude of the research effort at WRAMC, to include the number and type of patients involved.

B. The Commander, WRAMC, may accept, postpone, or reject new protocols and ongoing research protocols at WRAMC. Notice of these decisions should be forwarded to the Management and Oversight Committee.

C. The parties recognize that the Commander, USAMRDC is responsible for the oversight of the grant and has appointed US Army Medical Research and Development Command Management and Oversight Committee to review the research progress, administrative management and financial management of the grant.

4. Standards of Conduct. The parties recognize that all personnel working under this MOU must place loyalty to country, ethical principles, and law above private gain and other interest to ensure the confidence of the public in the integrity of the government employees and other personnel hired for the research effort. All personnel will comply with the principles enunciated in the Code of Ethics for Government Service and as applicable, other statutes and DOD and DA regulations concerning standards of conduct.

5. The Jackson Foundation agrees to:

A. Furnish necessary personnel, materials, service, facilities and otherwise do all things necessary for or incident to the performance of work statement approved in the grant submission for the HIV research study at WRAMC.

B. Monitor research allocation to ensure that the Foundation is responsive to the needs of the research mission and establish an audit/internal review procedure to ensure funds provided for the research effort are used only to further the objectives of the grant and that extravagant and wasteful methods are not employed.

C. Establish a single organization which shall accomplish applicable non-scientific aspects of the HIV research project by the parties, e.g. hiring, payroll, ordering, receiving, accounting, etc.

(1) All scientific personnel to be hired in support of HIV research will be screened by a committee composed of representatives from the parties. The number of scientific personnel to be hired and their functions will be agreed to by the parties.

(2) Staffing requirements associated with patient care needed to support the research effort at WRAMC will be determined using the model of DA Pamphlet 570-557. Salaries and other benefits will be determined in accordance with competitive rates in the local area.

(3) All personnel hired will be under the operational jurisdiction of the Chief of Infectious Disease Service, Department of Medicine, WRAMC.

D. Hire an Associate Administrator for the HIV project who will administer project funds and contracts, supervise the hiring of personnel, review administrative accountability and procedures, and otherwise serve as the Jackson Foundation's on-site liaison.

(1) Personnel hired by the Jackson Foundation to work at WRAMC will be approved by Commander, WRAMC and will take their instructions on the job through normal WRAMC supervisory channels.

(2) Personnel hired by the Jackson Foundation to work at WRAIR will be approved by Director, WRAIR and will take their instructions on the job through normal WRAIR supervisory channels.

(3) Where applicable, personnel hired by the Jackson Foundation are eligible for USUHS departmental faculty appointments upon recommendation by the University's committee on appointments, promotion, and tenure and approved by the USUHS Board of Regents; upon recommendation of the Dean, Hebert School of Medicine they shall participate in the University's teaching program as a condition of their Foundation employment; and such personnel shall be responsible to the Dean Hebert School of Medicine, or his or her designee for instructions regarding required academic participation.

E. Ensure scientific, human use review and other assurances and reviews of research protocols have been accomplished where required by Department of Defense regulations. In the event that protocol review is not accomplished in a timely manner (less than

45 days) or in the event of disagreement between any review committee and an investigator from either WRAMC, WRAIR, or Jackson Foundation, to avoid delay and potential non-compliance with the grant, the Secretary Treasurer of the Jackson Foundation is authorized to bring the matter directly to the attention of the Commander, WRAMC and/or Director, WRAIR.

F. Purchase and maintain any equipment required for HIV research and reimburse WRAMC in accordance with applicable regulations for supplies required for the research in excess of routine patient care requirements.

G. Utilize all funds obtained in grant number DAMD 17-88-Z-8007 in support of collaborative work on HIV research conducted by WRAMC/WRAIR.

7. WRAMC agrees to:

A. Accommodate the added responsibility of HIV research, including integrating new investigative efforts into the existing patient process, procedure, and structure.

B. Provide at WRAMC on a nonreimbursable basis and subject to space availability clinical laboratory and research space required for the HIV project.

C. Establish a subcommittee of the Clinical Investigations Committee which will receive HIV research requests, coordinate all HIV research activities at WRAMC, monitor the adequacies of resources from the Foundation and WRAIR that are transferred to WRAMC for the purpose of supporting the research activities, and assure that all protocols confirm to WRAMC regulations. This committee will report to the Commander WRAMC through the Clinical Investigations Committee structure. Information copies of the reports will be provided to the Director, WRAIR and the Associate Administrator of the HIV project Substantive and administrative issues will be resolved in accordance with this MOU.

D. Provide research investigators appropriate access to HIV seropositive patients as research volunteers to conduct research protocols which address issues relevant to the Army.

E. Provide human use review of all HIV research protocols, including, where necessary, review and/or approval by HSC and OTSG in accordance with existing Army regulations and Memoranda of Understanding between HSC and OTSG.

F. Permit Foundation personnel to apply for privileges and if granted, to participate in clinical protocols.

8. WRAIR agrees to:

A. Establish a committee structure to monitor all efforts at WRAMC related to HIV research. This committee will advise the Director of WRAIR on the inception of new protocols, the continuance of existing protocols and progress and will be charged with assuring that the research is scientifically valid.

B. Assure that the facilities of WRAIR, particularly in Viral and Immunological support, are responsive to the needs of the research protocols and good patient care.

C. Provide scientific review of research protocols.

D. In coordination with US Army Medical Research Development Command, provide physicians to expand the WRAMC Infectious Disease Service.

9. The University agrees to:

A. Permit Foundation employees, if otherwise qualified, to be considered for USUHS faculty status (non-tenured or non-tenure track), provided that such employees shall participate in the University's academic program, as determined by the Dean, Hebert School of Medicine.

B. Provide assurance committee consideration of all protocols submitted through the auspices of the Jackson Foundation.

C. Identify the Associate Dean for Operations as the University's primary point of contact regarding the implementation of all activities in support of HIV research through the Foundation.

10. Release of Information. Any information involving patients, health care providers, or other staff at WRAMC, obtained by studies or surveys by contract individuals or policies and practices at WRAMC, will be fully coordinated with the WRAMC Public Affairs Office prior to release to any news media.

11. Publications. All parties to the MOU recognize the need in the scientific community to promptly publish study results and to provide data to encourage subsequent development work in the private sector. All questions regarding intellectual property rights will be resolved in accordance with the provisions of the Grant.

12. Disputes clause.

A. In the event of disagreement among the parties concerning study progress, administrative management or financial management, guidance will be sought initially from the Research Area Director Military Infectious Disease Hazards, USAMRDC. Additional guidance may be sought from US Army Medical Research and Development Command Management and Oversight Committee.

B. In the event of disagreement among the parties concerning scientific priorities, emphasis, or focus of research, definitive guidance will be sought from the President, Uniformed Services of the Health Sciences who may in his discretion be advised by a scientific committee composed of the following: Chief, Infectious Disease Service, WRAMC; Chief, Clinical Infectious Disease Service, WRAMC; Chief, Virus Department, WRAIR; Director, Division Communicable Diseases and Immunology, WRAIR; and one to three outside reviewers selected by the President, USUHS.

13. Effective Date. This agreement will become effective upon signature of all parties and will remain in effect until cancelled.

14. Modification/Termination of the Agreement. This agreement will be reviewed annually at least 90 days prior to the anniversary date. It may be revised at any time upon mutual consent in writing of the parties concerned.

15. Approval.

KENNETH E. KINNAMON
D.V.M., PhD
Associate Dean for Operations
Uniformed Services University
of the Health Sciences

14 MAR 88
DATE

LEWIS A. MOLOGNE
Major General, MC
Cdr, Walter Reed Army Medical
Center

25 February 1988
DATE

JAY P. SANFORD, M.D.
Secretary-Treasurer
HMJFAMM

3/3/88
DATE

C. FRED TYNER
COL, MC
Dir, Walter Reed Army

2/21/88
DATE

MEMORANDUM OF UNDERSTANDING
AMONG
NATIONAL NAVAL MEDICAL CENTER
US NAVAL HEALTH SCIENCES EDUCATION AND TRAINING COMMAND
US ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND
UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES
AND
HENRY M. JACKSON FOUNDATION
FOR THE ADVANCEMENT OF MILITARY MEDICINE

SUBJECT: Human Immunodeficiency Virus (HIV) Research

1. Purpose.

a. This Memorandum of Understanding (MOU) is established between the National Naval Medical Center, Bethesda (NNMC), the US Naval Health Sciences Education and Training Command (HSETC), the US Army Medical Research and Development Command (USAMRDC), the Uniformed Services University of the Health Sciences (USUHS), and the Henry M. Jackson Foundation for the Advancement of Military Medicine (HMJFAMM), hereinafter collectively referred to as the "parties", for the purpose of coordinating an omnibus clinical research program on Human Immunodeficiency Virus (HIV) Research at NNMC. Efforts to develop and test effective chemo/immunotherapy and chemo/immunoprophylaxis for Armed Forces personnel, to evaluate new treatment modalities, to elucidate the pathogenesis of disease, and to provide for an increase in the quality of life of individuals infected with HIV will make up the thrust of the program.

b. By this agreement the parties identify their respective responsibilities and authority, establish the specific services and resources to be offered by each in support of the program, and agree to methods for problem solving and other procedural requirements necessary for the success of the cooperative enterprise.

2. Background.

a. The United States Congress, recognizing HIV as a health threat to the military population, has appropriated funds to the Department of Defense (DoD) placing monies in the Army Research and Development budget for support of a Tri-Service HIV research program. The U.S. Army has designated the Commander, USAMRDC as the Tri-Service Lead Agent for the execution of the HIV Research Program. The Navy Surgeon General has tasked the Commander, NNMC, to conduct clinical research in HIV disease in support of the Tri-

Service Program, in addition to his primary and secondary missions of patient care and the support of education and clinical investigation. Under the umbrella MOU between NMC and the HMJFAMM dated 2 November 1988, the Commander, NNMC has accepted the HIV research mission and maintains final responsibility for and authority over patients and research subjects under the care of NNMC. To the extent that the NMC/HMJFAMM 1988 MOU is consistent with the provisions of this MOU, its terms are incorporated by reference.

b. The USUHS and the NMC have formally established academic and operational relations between the USUHS and the Naval Medical Centers by agreement dated 31 December 1985. Under this authority, and additionally under the 1974 agreement between the USUHS and the Surgeons General regarding utilization of military medical centers in the District of Columbia area, the USUHS has engaged in significant academic and research programs with the NNMC. USUHS medical personnel have been authorized to apply for staff privileges, and those USUHS personnel who hold hospital privileges have been encouraged to participate with NNMC investigators in clinical protocols.

c. The Congress of the United States has directed that it shall be the purpose of the HMJFAMM (1) to carry out medical research and education projects under cooperative arrangements with the USUHS; (2) to serve as a focus for the interchange between military and civilian medical personnel; and (3) to encourage the participation of the medical, dental, nursing, veterinary, and other biomedical sciences in the work of the HMJFAMM for the mutual benefit of military and civilian medicine.

d. The HMJFAMM, as a nonprofit medical research and education corporation, has been awarded a grant from the USAMRDC in response to its grant application entitled "Human Immunodeficiency Virus (HIV) Research," the object of which is to conduct and support clinical trials of therapeutic regimens which show promise of ameliorating and/or preventing the effects of HIV infection, such regimens consisting of drugs or biologicals or combinations thereof in which a Notice of Claimed Investigational Exemption for a New Drug (IND) has been filed with the Food and Drug Administration.

3. Control.

a. The parties recognize the need to minimize the impact of HIV clinical research on the missions of NNMC which is responsible for patient care and medical education as well as clinical research.

b. The Commander, NNMC may accept, postpone, or reject new protocols and ongoing research protocols at the NNMC. Notice of these decisions should be forwarded to the Management and Oversight

Committee, USAMRDC and service designated medical representatives.

c. The parties recognize that the Commander, USAMRDC is responsible for the oversight of the grant and has appointed a Management and Oversight Committee to review the research progress, administrative management and financial management of the grant.

d. The parties further recognize that the Commander, USAMRDC is also responsible for the scientific direction of the Armed Forces HIV Research Program and has appointed a Retrovirus Scientific Review Committee to review and approve, disapprove or defer all scientific research protocols supported by funds of this program, and to certify program relevance, relative importance and scientific excellence of research protocols of this program.

e. The general guidelines for the scientific direction of the program is provided by the Lead Agent's designated representative, namely, the Deputy Director for HIV Research Program, Walter Reed Army Institute of Research. General guidance for the Navy program will be provided by the Director of Navy Medical HIV Programs, as representative of the Commander, NMC.

4. Standards of Conduct. The parties recognize that all personnel working under this MOU must place loyalty to country, ethical principles, and law above private gain and other interest to ensure the confidence of the public in the integrity of the government employees and other personnel hired for the research effort. All personnel will comply with the principles enunciated in the Code of Ethics for Government Service and as applicable, other statutes and DoD, DON and DA regulations concerning standards of conduct.

5. The HMJFAMM agrees to:

a. Furnish necessary personnel, materials, service, facilities and otherwise do all things necessary for or incident to the performance of work statement approved in the grant for the HIV research study at NNMC.

b. Monitor resource allocation to ensure that the HMJFAMM is responsive to the needs of the research mission and establish an audit/internal review procedure to ensure funds provided for the research effort are used only to further the objectives of the grant and that good management practices and sound economic judgments are applied.

c. Provide an organization which shall accomplish applicable non-scientific aspects of the HIV research project by the parties, e.g. hiring, payroll, ordering, receiving, accounting, facility construction and renovation, etc. The number of scientific

personnel to be hired and their functions will be determined by the HMJFAMM, in coordination with the Director of Naval Medical HIV Programs.

d. Administer project funds, contracts, supervise the hiring of personnel, review administrative accountability and procedures, and provide on-site liaison.

(1) Overall supervisory responsibility for HMJFAMM personnel remains with the HMJFAMM's supervisory structure.

(2) Where applicable, personnel hired by the HMJFAMM are eligible for USUHS departmental faculty appointments upon recommendation by the USUHS Committee on Appointments, Promotion, and Tenure and approved by the USUHS Board of Regents; upon recommendation of the Dean, Hebert School of Medicine they shall participate in the USUHS teaching program as a condition of their HMJFAMM employment; and such personnel shall be responsible to the Dean, Hebert School of Medicine, or his or her designee for instructions regarding required academic participation.

e. Ensure scientific, human use review and other assurances and reviews of research protocols have been accomplished where required by Department of Defense regulations. In the event that protocol review is not accomplished in a timely manner (less than 45 days) or in the event of disagreement between any review committee and an investigator from NNMC or HMJFAMM, to avoid delay and potential non-compliance with the grant, the Secretary/Treasurer of the HMJFAMM is authorized to bring the matter directly to the attention of the Commander, NNMC.

f. Purchase and maintain any equipment required for HIV research and reimburse NNMC in accordance with applicable regulations for supplies required for the research in excess of routine patient care requirements.

6. NNMC agrees to:

a. Accommodate the added responsibility of HIV research, including integrating new investigative efforts into the existing patient care process, procedure, and structure.

b. Provide at NNMC (on a nonreimbursable basis and subject to space availability) space required for the HIV project including facility support services.

c. In his role of approving Internal Review Board recommendations, accept scientific peer review by a Joint Scientific Peer Review Committee administered by the Lead Agent (in lieu of a Scientific Review Board), but to maintain a Committee for the Protection of Human Subjects to ensure protection of patients

and research subjects under its care. Information copies of approved reports will be provided to the HIV Program Coordinator, HSETC, USAMRDC, USUHS and the Associate for HIV Research, HMJFAMM. Issues will be resolved in accordance with this MOU.

d. Provide research investigators appropriate access to HIV seropositive patients as research volunteers for the conduct of research protocols which address issues relevant to the Armed Forces.

e. Ensure that Navy regulations on Clinical Investigation and Protection of Human Subjects are followed; that appropriate administrative, fiscal and legal reviews have been made; and that proper records, reviews and reports are prepared as required by HSETC and NMC.

f. Permit HMJFAMM personnel to apply for privileges and if granted, to participate in clinical protocols.

g. Allow external review of program execution by any organization given this tasking by the management and oversight committee.

h. Operate in compliance with Public Law 95-224 pertaining to relationships with Grantee employees and to avoid relationships with grantee employees which would cause the USAMRDC to be in violation of 31 USC 6304

7. **USAMRDC agrees to:**

a. In the exercise of his Department of Defense responsibility for Armed Forces HIV Research Program, designate as his representative for the execution of this program, the Deputy Director for HIV Research, Walter Reed Army Institute of Research, herein referred to as the Deputy Director for HIV Research Program.

b. Establish a tri-service Joint Retrovirus Scientific Review Committee to review scientific protocols and monitor all efforts at NNMC related to Armed Forces HIV research program. This committee will advise the Deputy Director for HIV Research Program on the inception of new protocols, the continuance of existing protocols and progress and will be charged with assuring that the research is scientifically valid.

c. Assure that the facilities of the HIV Research Laboratory complex are responsive to the needs of the research protocols.

d. Provide for tri-service scientific review of research protocols.

8. USUHS agrees to:

a. Permit HMJFAMM employees, if otherwise qualified, to be considered for USUHS faculty status (non-tenured or non-tenure track), provided that such employees shall participate in the USUHS academic program, as determined by the President, USUHS.

b. Provide assurance committee consideration of all protocols submitted through the auspices of the HMJFAMM.

9. HSETC agrees to:

a. Accept the conditions and provisions of this MOU and to expedite the administration of related protocols under the provisions of the Clinical Investigation Program.

b. Accept review by the Joint Scientific Review Committee in lieu of NNMC-based Scientific Review Board.

c. Ensure under the provisions of the Clinical Investigation Program, that DoD and Navy directives on Clinical Investigation and Protection of Human Subjects have been satisfactorily followed.

10. Release of Information. Any information involving patients, health care providers, or other staff at NNMC, obtained by studies or surveys by contract individuals or policies and practices at NNMC, will be fully coordinated with the NNMC Public Affairs Office; the Public Affairs Officer, USAMRDC; the Navy HIV Research Program Director; the Deputy Director for HIV Research; and HIV Program Director, HMJFAMM prior to release to any news media.

11. Publications. All parties to this MOU recognize the need in the scientific community to promptly publish study results and to provide data to encourage subsequent development work in the private sector. All questions regarding intellectual property rights will be resolved in accordance with the provisions of the Grant to the HMJFAMM. All publications will carry the designation, Armed Forces Retrovirus Research Group, unless otherwise stated by the Deputy Director for HIV Research, WRAIR.

12. Disputes.

a. In the event of disagreement among the parties concerning study progress, administrative management or financial management, guidance will be sought initially from the USAMRDC Management and Oversight Committee.

b. In the event of disagreement among the parties concerning scientific priorities and the emphasis or focus of research, definitive guidance will be sought from the President, USUHS and Commander, NNMC who may in their discretion be advised by a scientific committee composed of the following: Chief, Infectious Disease Service, Bethesda; HIV Program Director, NNMC Bethesda; Deputy Director for HIV Research, WRAIR; and one to three mutually agreed upon outside reviewers.

13. Effective Date. This MOU will become effective upon signature of all parties and will remain in effect until cancelled.

14. Modification/Termination. This MOU will be reviewed annually at least 90 days prior to the anniversary date. It may be revised at any time upon mutual consent in writing of the parties concerned.

15. Approval.

KENNETH E. KINNAMON
D.V.M., Ph.D.
Associate Dean for Operations
Uniformed Services University
of the Health Sciences

14 August 1989

DATE

PHILIP K. RUSSELL, MG, MC
Commander,
U.S. Army Medical Research
and Development Command

28 July 89

DATE

JAY P. SANFORD, M.D.
Secretary-Treasurer
Henry M. Jackson Foundation
for the Advancement of
Military Medicine

15 August 1989

DATE

D. F. HAGEN, RADM, MC, USN
Commander
National Naval Medical
Center

1 Sept 1989

DATE

V. D. SCHINSKI, CAPT, MSC, USN
Commanding Officer
Naval Health Sciences Education
and Training Command

1 Sept 1989

DATE

MEMORANDUM OF UNDERSTANDING
AMONG
US AIR FORCE SURGEON GENERAL'S OFFICE
US ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND
UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES
WILFORD HALL US AIR FORCE MEDICAL CENTER
AND
HENRY M. JACKSON FOUNDATION
FOR THE ADVANCEMENT OF MILITARY MEDICINE

SUBJECT: Human Immunodeficiency Virus (HIV) Research

1. **Purpose.**

A. This Memorandum of Understanding (MOU) is established among the Wilford Hall US Air Force Medical Center (WHMC), the US Air Force Surgeon General (AFSG), the US Army Medical Research and Development Command (USAMRDC), the Uniformed Services University of the Health Sciences (USUHS), and the Henry M. Jackson Foundation for the Advancement of Military Medicine (HMJFAMM), hereinafter collectively referred to as the "parties", for the purpose of coordinating an omnibus clinical research program on Human Immunodeficiency Virus (HIV) Research at WHMC. Efforts to develop and test effective chemo/immunotherapy and chemo/immunoprophylaxis for Armed Forces personnel, to evaluate potential treatment modalities, to elucidate the pathogenesis of disease, and to provide for an increase in the quality of life of individuals infected with HIV will constitute the thrusts of the program.

B. By this agreement the parties identify their respective responsibilities and authority, establish the specific services and resources to be offered by each in support of the program, and agree to methods for problem solving and other procedural requirements necessary for the success of the cooperative enterprise.

2. **Background.**

A. The United States Congress, recognizing HIV as a health threat to the military population, has appropriated funds to the Department of Defense (DoD) placing monies in the Army Research and Development budget for support of a Tri-Service HIV research program. The U.S. Army has designated the Commander, USAMRDC as the Tri-Service Lead Agent for the execution of the HIV Research Program. The Air Force Surgeon General has tasked the Commander, WHMC, to conduct clinical research in HIV disease in support of the Tri-Service Program, in addition to his primary and secondary

missions of patient care and the support of education and clinical investigation. Under the umbrella MOU between the US Air Force Surgeon General's Office and the HMJFAMM dated 30 April 1989, the Commander, WHMC has accepted the HIV research mission and maintains full responsibility for and authority over patients and research subjects under the care of WHMC. To the extent that the AFSG/HMJFAMM 1989 MOU is consistent with the provisions of this MOU, its terms are incorporated by reference.

B. The USUHS and AFSG have formally established academic and operational relations between the USUHS and the Wilford Hall Air Force Medical Center (WHMC) by agreement dated 31 December 1985. Under this authority, and additionally under the 1974 agreement between the USUHS and the Surgeon General regarding utilization of medical centers, the USUHS has engaged in significant academic and research programs with the WHMC. USUHS medical personnel have been authorized to apply for staff privileges at DoD hospitals, and those USUHS personnel who hold hospital privileges have been encouraged to participate with WHMC investigators in clinical protocols. If this includes seeing patients at WHMC they must be credentialed through the WHMC credentialing process.

C. The Congress of the United States has directed that it shall be the purpose of the HMJFAMM (1) to carry out medical research and education projects under cooperative arrangements with the USUHS; (2) to serve as a focus for the interchange between military and civilian medical personnel; and (3) to encourage the participation of the medical, dental, nursing, veterinary, and other biomedical sciences in the work of the HMJFAMM for the mutual benefit of military and civilian medicine.

D. The HMJFAMM, as a nonprofit medical research and education corporation, has been awarded a grant from the USAMRDC in response to its grant application entitled "Human Immunodeficiency Virus (HIV) Research," the object of which is to conduct and support clinical trials of therapeutic regimens which show promise of ameliorating and/or preventing the effects of HIV infection, such regimens consisting of drugs or biologicals, or combinations thereof, for which a Notice of Claimed Investigational Exemption for a New Drug (IND) has been filed with the Food and Drug Administration.

E. The parties recognize the need to minimize the impact of HIV clinical research on the missions of WHMC which are patient care and support of medical education and clinical research.

3. Control.

A. The Commander, WHMC may accept, postpone, or reject new protocols and ongoing research protocols at the WHMC. Notice of these decisions should be forwarded to the Management and Oversight Committee, USAMRDC and service designated medical representatives.

B. The parties recognize that the Commander, USAMRDC is responsible for the oversight of the grant and has appointed a Management and Oversight Committee to review the research progress, administrative management and financial management of the grant.

C. The parties further recognize that the Commander, USAMRDC is also responsible for the scientific direction of the Armed Forces HIV Research Program and has appointed a Joint Services Scientific Review Committee to review and approve, disapprove or defer all scientific research protocols supported by funds of this program. Additionally, this committee will certify program relevance and judge relative importance and scientific excellence of research protocols.

D. The general guidelines for the scientific direction of the program are provided by the Lead Agent's designated representative, namely, the Deputy Director for HIV Research Program, Walter Reed Army Institute of Research. General guidance for the Air Force program will be provided by the Chairman, Department of Medicine, WHMC as representative of the Commander, WHMC/AFSG.

4. **Standards of Conduct.** The parties recognize that all personnel working under this MOU must place loyalty to country, ethical principles, and law above private gain and other interest to ensure the confidence of the public in the integrity of the government employees and other personnel hired for the research effort. All personnel will comply with the principles enunciated in the Code of Ethics for Government Service and as applicable, other statutes and all service regulations concerning standards of conduct.

5. **The HMJFAMM agrees to:**

A. Furnish necessary personnel, materials, service, facilities and otherwise do all things necessary for or incident to the performance of the Work Statement approved in the grant for the HIV research study at WHMC.

B. Monitor resource allocation to ensure the HMJFAMM is responsive to the needs of the research mission and establish procedures to ensure funds provided for the research effort are used only to further the objectives of the grant and that good management practices and sound economic judgments are applied.

C. Provide an organization which shall accomplish applicable non-scientific aspects of the HIV research project including, but not limited to hiring, payroll, purchasing, contracting, ordering, receiving, accounting, facilities

construction and facilities renovation. The number of scientific personnel to be hired and their functions will be the responsibility of the HMJFAMM, in coordination with the Director of Air Force Medical HIV Programs.

D. Administer project fund and contracts, supervise the hiring of personnel, review administrative accountability and procedures, and provide on-site liaison.

(1) Supervisory responsibility for HMJFAMM personnel remains with the HMJFAMM's supervisory structure.

(2) Where applicable, personnel hired by the HMJFAMM are eligible for USUHS departmental faculty appointments upon recommendation by the USUHS's Committee on Appointments, Promotion, and Tenure and approved by the USUHS Board of Regents. Upon recommendation of the Dean, Hebert School of Medicine they shall participate in the USUHS's teaching program as a condition of their HMJFAMM employment; and such personnel shall be responsible to the Dean, Herbert School of Medicine, or his or her designee for instructions regarding required academic participation.

E. Ensure scientific, human use review and other assurances and reviews of research protocols have been accomplished where required by government laws or regulations. In the event that protocol review is not accomplished in a timely manner (less than 45 days) or in the event of disagreement between any review committee and an investigator from WHMC or HMJFAMM, to avoid delay and potential non-compliance with the grant, the Secretary-Treasurer of the HMJFAMM is authorized to bring the matter directly to the attention of the Commander, WHMC.

F. Purchase and maintain any equipment required for HIV research and reimburse WHMC in accordance with applicable regulations for supplies required for the research in excess of routine patient care requirements.

6. **WHMC agrees to:**

A. Accommodate the added responsibility of HIV research, including integrating new investigative efforts into existing processes, procedures, and structures.

B. Provide at WHMC (on a nonreimbursable basis and subject to space availability) space required for the HIV project including facility support services.

C. In his role of approving IRB recommendations, accept scientific peer review of HIV Research protocols by a Joint Services Scientific Review Committee administered by the Lead Agent

(in lieu of a Scientific Review Board), but to maintain a Committee for the Protection of Human Subjects to ensure protection of patients and research subjects under his care. Issues will be resolved in accordance with this MOU.

D. Provide research investigators appropriate access to HIV seropositive patients for recruitment as research volunteers to conduct research protocols which address issues relevant to the Armed Forces.

E. Ensure that Air Force regulations on Clinical Investigation and Protection of Human Subjects are followed; that appropriate administrative, fiscal and legal reviews have been made; and that proper records, reviews and reports are prepared as required by AF.

F. Permit HMJFAMM personnel to apply for privileges and if granted, to participate in clinical protocols.

G. Allow external review of the execution of the program by any organization given this tasking by the Management and Oversight Committee.

H. Interface with the Grantee in a manner consistent with 31 USC 6301-6308 and FAR Part 37.104; i.e. Government direction and control of the research effort will be limited to that which is necessary to ensure effective execution of approved protocols.

7. **USAMRDC agrees to:**

A. In the exercise of his Department of Defense responsibility for Armed Forces HIV Research Program, designate as his representative for the execution of this program, the Deputy Director for HIV Research, Walter Reed Army Institute of Research, herein referred to as the Deputy Director for HIV Research Program.

B. Establish a tri-service, Joint Services Retrovirus Scientific Review Committee to review scientific protocols and monitor all scientific efforts at WHMC related to Armed Forces HIV research program. This committee will advise the Deputy Director for HIV Research Program on the inception of new protocols, the continuance of existing protocols and progress and will be charged with assuring that the research is scientifically valid.

C. Assure that the facilities of the HIV Research Laboratory complex are responsive to the needs of the research protocols.

D. Provide for tri-service scientific review of research protocols.

8. USUHS agrees to:

A. Permit HMJFAMM employees, if otherwise qualified, to be considered for USUHS faculty status (non-tenured) provided that such employees shall participate in the USUHS's academic program, as determined by the President, USUHS.

B. Provide Assurance Committee consideration of all protocols submitted through the auspices of the HMJFAMM.

9. AFSG agrees to:

A. Accept the conditions and provisions of this MOU and to expedite the administration of related protocols under the provisions of the USAF Human Use Program.

B. Accept review by the Joint Services Scientific Review Committee in lieu of WHMC-based Scientific Review Board.

C. Assign two billets for doctoral level research scientists to the Division of Retrovirology, Walter Reed Army Institute of Research in infectious disease, immunology or related fields to participate on a full time basis in the laboratory research component of the HIV Research Program. These billets will be filled with MC or BSC investigators. The first billet will be filed on or before 30 Sep 1990, with the second, on or before 30 Sep 1991. Assignments will be minimum 2 year controlled tours.

D. Ensure under the provisions of the USAF Human Use Program, that all applicable government DoD and Air Force directives on Clinical Investigation and Protection of Human Subjects have been satisfactorily followed.

10. Release of Information. Any information involving patients, health care providers, or other staff at WHMC, obtained by studies or surveys by contract individuals, or policies and practices at WHMC will be fully coordinated with the WHMC Public Affairs Office; the Public Affairs Officer, USAMRDC; the Air Force HIV Research Program Director; the Deputy Director for HIV Research; and HIV Program Director, HMJFAMM prior to release to any news media.

11. Publications. All parties to this MOU recognize the need in the scientific community to promptly publish study results and to provide data to encourage subsequent development work in the private sector. All questions regarding intellectual property rights will be resolved in accordance with the provisions of the Grant to the HMJFAMM. All publications will carry the designation, Armed Forces Retrovirus Research Group, unless otherwise directed

by the Deputy Director for HIV Research, WRAIR.

12. **Disputes.**

A. In the event of disagreement among the parties concerning study progress, administrative management or financial management, guidance will be sought initially from the USAMRDC Management and Oversight Committee.

B. In the event of disagreement among the parties concerning scientific priorities and the emphasis or focus of research, definitive guidance will be sought from the President, USUHS and Commander, WHMC who may in their discretion be advised by a scientific committee composed of the following: Chief, Department of Medicine, WHMC; HIV Program Director, WHMC; Deputy Director for HIV Research, WRAIR; and one to three mutually agreed upon outside reviewers.

13. **Effective Date.** This MOU will become effective upon signature of all parties and will remain in effect until cancelled.

14. **Modification/Termination.** This MOU will be reviewed annually at least 90 days prior to the anniversary date. It may be revised at any time upon mutual consent in writing of the parties concerned.

15. Approval.

KENNETH E. KINNAMON
D.V.M., Ph.D.
Associate Dean for Operations
Uniformed Services University
of the Health Sciences

26 Dec 89
DATE

PHILLIP K. RUSSELL, MG, MC, USA
Commander,
U. S. Army Medical Research
and Development Command

5 Jan 90
DATE

JAY P. SANFORD, M.D.
Secretary-Treasurer
Henry M. Jackson Foundation
for the Advancement of
Military Medicine

4 Jan 90
DATE

MONTE B. MILLER
Lieutenant General, USAF, MC
Surgeon General

1 December 1989
DATE

VERNON CHONG, MG, MC, USAF
Commander
Wilford Hall
USAF Medical Center

5 December 1989
DATE

MEMORANDUM OF UNDERSTANDING
AMONG
NAVAL HOSPITAL, SAN DIEGO,
NAVAL HEALTH SCIENCES EDUCATION AND TRAINING COMMAND,
ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND,
UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES,
AND
HENRY M. JACKSON FOUNDATION
FOR THE ADVANCEMENT OF MILITARY MEDICINE

SUBJECT: Human Immunodeficiency Virus (HIV) Research

1. Purpose.

a. This Memorandum of Understanding (MOU) is established among the Naval Hospital, San Diego (NHSD); the Naval Health Sciences Education and Training Command (HSETC); the Army Medical Research and Development Command (AMRDC); the Uniformed Services University of the Health Sciences (USUHS); and the Henry M. Jackson Foundation for the Advancement of Military Medicine (HMJFAMM), hereinafter collectively referred to as the "parties", for the purpose of coordinating an omnibus clinical research program on Human Immunodeficiency Virus (HIV) Research at NHSD. Efforts to develop and test effective chemo/immunotherapy and chemo/immunoprophylaxis for Armed Forces personnel, to evaluate new treatment modalities, to elucidate the pathogenesis of disease, and to provide for an increase in the quality of life of individuals infected with HIV will make up the thrust of the program.

b. By this agreement the parties identify their respective responsibilities and authority, establish the specific services and resources to be offered by each in support of the program, and agree to methods for problem solving and other procedural requirements necessary for the success of the cooperative enterprise.

2. Background.

a. The United States Congress, recognizing HIV as a health threat to the military population, has appropriated funds to the Department of Defense (DoD) placing monies in the Army Research and Development budget for support of a Tri-Service HIV research program. The Army has designated the Commander, AMRDC as the Tri-Service Lead Agent for the execution of the HIV Research Program. The Navy Surgeon General has tasked the Commanding Officer, NHSD, to conduct clinical research in HIV disease in support of the Tri-Service Program, in addition to his primary and secondary missions of patient care and the support of education and clinical investigation. Under the umbrella MOU between BUMED (the Naval Medical Command) and HMJFAMM dated 2 November 1988, the Commanding Officer, NHSD has accepted the HIV

research mission and maintains final responsibility for and authority over patients and research subjects under the care of NHSD. To the extent that the BUMED/HMJFAMM 1988 MOU is consistent with the provisions of this MOU, its terms are incorporated by reference.

b. The USUHS and the BUMED have formally established academic and operational relations between the USUHS and the Naval Medical Centers by agreement dated 31 December 1985.

c. The Congress of the United States has directed that it shall be the purpose of the HMJFAMM (1) to carry out medical research and education projects under cooperative arrangements with the USUHS; (2) to serve as a focus for the interchange between military and civilian medical personnel; and (3) to encourage the participation of the medical, dental, nursing, veterinary, and other biomedical sciences in the work of the HMJFAMM for the mutual benefit of military and civilian medicine.

d. The HMJFAMM, as a nonprofit medical research and education corporation, has been awarded a grant from the AMRDC in response to its grant application entitled "Human Immunodeficiency Virus (HIV) Research," the object of which is to conduct and support clinical trials of therapeutic regimens which show promise of ameliorating and/or preventing the effects of HIV infection, such regimens consisting of drugs or biologicals or combinations thereof in which a Notice of Claimed Investigational Exemption for a New Drug (IND) has been filed with the Food and Drug Administration.

3. Control.

a. The parties recognize the need to minimize the impact of HIV clinical research on the missions of NHSD which is responsible for patient care and medical education as well as clinical research.

b. The Commanding Officer, NHSD may accept, postpone, or reject new protocols and ongoing research protocols at the NHSD. Notice of these decisions should be forwarded to the Management and Oversight Committee, AMRDC and service designated medical representatives.

c. The parties recognize that the Commander, AMRDC is responsible for the oversight of the grant and has appointed a Management and Oversight Committee to review the research progress, administrative management and financial management of the grant.

d. The parties further recognize that the Commander, AMRDC is also responsible for the scientific direction of the Armed Forces HIV Research Program and has appointed a Retrovirus

Scientific Review Committee to review and approve, disapprove or defer all scientific research protocols supported by funds of this program, and to certify program relevance, relative importance and scientific excellence of research protocols of this program.

e. The general guidelines for the scientific direction of the program is provided by the Lead Agent's designated representative, namely, the Deputy Director for HIV Research Program, Walter Reed Army Institute of Research (WRAIR). General guidance for the Navy program will be provided by the Director of Navy Medical HIV Programs, as representative of the Chief, BUMED.

4. Standards of Conduct. The parties recognize that all personnel working under this MOU must place loyalty to country, ethical principles, and law above private gain and other interest to ensure the confidence of the public in the integrity of the government employees and other personnel hired for the research effort. All personnel will comply with the principles enunciated in the Code of Ethics for Government Service and as applicable, other statutes and DoD, DON and DA regulations concerning standards of conduct.

5. The HMJFAMM agrees to:

a. Furnish necessary personnel, materials, service, facilities and otherwise do all things necessary for or incident to the performance of work statement approved in the grant for the HIV research study at NHSD.

b. Monitor resource allocation to ensure that the HMJFAMM is responsive to the needs of the research mission and establish an audit/internal review procedure to ensure funds provided for the research effort are used only to further the objectives of the grant and that good management practices and sound economic judgements are applied.

c. Provide an organization which shall accomplish applicable non-scientific aspects of the HIV research project by the parties, e.g. hiring, payroll, ordering, receiving, accounting. The number of scientific personnel to be hired and their functions will be determined by the HMJFAMM, in coordination with the Director of Naval Medical HIV Programs.

d. Administer project funds, contracts, supervise the hiring of personnel, review administrative accountability and procedures, and provide on-site liaison.

(1) Overall supervisory responsibility for HMJFAMM personnel remains with the HMJFAMM's supervisory structure.

(2) Where applicable, personnel hired by the HMJFAMM are eligible for USUHS departmental faculty appointments upon recommendation by the USUHS Committee on Appointments, Promotion, and Tenure and approved by the USUHS Board of Regents; upon recommendation of the Dean, Hebert School of Medicine they shall participate in the USUHS teaching program as a condition of their HMJFAMM employment; and such personnel shall be responsible to the Dean, Hebert School of Medicine, or his or her designee for instructions regarding required academic participation.

e. Ensure scientific, human use review and other assurances and reviews of research protocols have been accomplished where required by Department of Defense regulations. In the event that protocol review is not accomplished in a timely manner (less than 45 days) or in the event of disagreement between any review committee and an investigator from NHSD or HMJFAMM, to avoid delay and potential non-compliance with the grant, the Secretary/Treasurer of the HMJFAMM is authorized to bring the matter directly to the attention of the Commander, NHSD.

f. Purchase and maintain any equipment required for HIV research and reimburse NHSD in accordance with applicable regulations for supplies required for the research in excess of routine patient care requirements.

6. NHSD agrees to:

a. Accommodate the added responsibility of HIV research, including integrating new investigative efforts into the existing patient care process, procedure, and structure.

b. Provide at NHSD (on a nonreimbursable basis and subject to space availability) space required for the HIV project including facility support services.

c. The Commanding Officer in his role of approving Internal Review Board recommendations, accept scientific peer review by a Joint Scientific Peer Review Committee administered by the Lead Agent (in lieu of a Scientific Review Board), but to maintain a Committee for the Protection of Human Subjects to ensure protection of patients and research subjects under its care. Information copies of approved reports will be provided to the HIV Program Coordinator, HSETC, AMRDC, USUHS and the Associate for HIV Research, HMJFAMM. Issues will be resolved in accordance with this MOU.

d. Provide research investigators appropriate access to HIV seropositive patients as research volunteers for the conduct of research protocols which address issues relevant to the Armed Forces.

e. Ensure that Navy regulations on Clinical Investigation and Protection of Human Subjects are followed; that appropriate administrative, fiscal and legal reviews have been made; and that proper records, reviews and reports are prepared as required by HSETC and BUMED.

f. Permit HMJFAMM personnel to apply for privileges and if granted, to participate in clinical protocols.

g. Allow external review of program execution by any organization given this tasking by the management and oversight committee.

h. Operate in compliance with Public Law 95-224 pertaining to relationships with Grantee employees and to avoid relationships with grantee employees which would cause the AMRDC to be in violation of 31 USC 6304.

7. AMRDC agrees to:

a. In the exercise of his Department of Defense responsibility for Armed Forces HIV Research Program, designate as his representative for the execution of this program, the Deputy Director for HIV Research, Walter Reed Army Institute of Research, herein referred to as the Deputy Director for HIV Research Program.

b. Establish a tri-service Joint Retrovirus Scientific Review Committee to review scientific protocols and monitor all efforts at NHSD related to Armed Forces HIV research program. This committee will advise the Deputy Director for HIV Research Program on the inception of new protocols, the continuance of existing protocols and progress and will be charged with assuring that the research is scientifically valid.

c. Assure that the facilities of the HIV Research Laboratory complex are responsive to the needs of the research protocols.

d. Provide for tri-service scientific review of research protocols.

8. USUHS agrees to:

a. Permit HMJFAMM employees, if otherwise qualified, to be considered for USUHS faculty status (non-tenured or non-tenure track), provided that such employees shall participate in the USUHS academic program, as determined by the President, USUHS.

b. Provide assurance of committee consideration of all protocols submitted through the auspices of the HMJFAMM.

9. HSETC agrees to:

a. Accept the conditions and provisions of this MOU and to expedite the administration of related protocols under the provisions of the Clinical Investigation Program.

b. Accept review by the Joint Scientific Review Committee in lieu of NHSD based Scientific Review Board.

c. Ensure under the provisions of the Clinical Investigation Program, that DoD and Navy directives on Clinical Investigation and Protection of Human Subjects have been satisfactorily followed.

10. Release of Information. Any information involving patients, health care providers, or other staff at NHSD, obtained by studies or surveys by contract individuals or policies and practices at NHSD, will be fully coordinated with the Public Affairs Office; the Public Affairs Officer, AMRDC; the Navy HIV Research Program Director; the Deputy Director for HIV Research; and HIV Program Director, HMJFAMM prior to release to any news media.

11. Publications. All parties to this MOU recognize the need in the scientific community to promptly publish study results and to provide data to encourage subsequent development work in the private sector. All questions regarding intellectual property rights will be resolved in accordance with the provisions of the Grant to the HMJFAMM. All publications will carry the designation, Armed Forces Retrovirus Research Group, unless otherwise stated by the Deputy Director for HIV Research, WRAIR.

12. Disputes.

a. In the event of disagreement among the parties concerning study progress, administrative management or financial management, guidance will be sought initially from the AMRDC Management and Oversight Committee.

b. In the event of disagreement among the parties concerning scientific priorities and the emphasis or focus of research, definitive guidance will be sought from the President, USUHS and Commanding Officer, NHSD who may in their discretion be advised by a scientific committee composed of the following: Head, Infectious Disease Division, NHSD; HIV Program Director,

NHSD; Deputy Director for HIV Research, WRAIR; and one to three mutually agreed upon outside reviewers.

13. Effective Date. This MOU will become effective upon signature of all parties and will remain in effect until cancelled.

14. Modification/Termination. This MOU will be reviewed annually at least 90 days prior to the anniversary date. It may be revised at any time upon mutual consent in writing of the parties concerned.

15. Approval.

KENNETH E. KINNAMON
D.V.M., Ph. D.
Associate Dean for Operations
Uniformed Services University
of the Health Sciences

16 May 1990
DATE

PHILIP K. RUSSELL, MG, MC
Commander,
U.S. Army Medical Research
and Development Command

26 JUL 1990
DATE

JAY P. SANFORD, M.D.
Secretary-Treasurer
Henry M. Jackson Foundation
for the Advancement of
Military Medicine

16 May 1990
DATE

R. B. HALDER
RADM, MC, USN
Commanding Officer
Naval Hospital, San Diego

3/15/90
DATE

V. D. SCHINSKI, CAPT, MSC, USN
Commanding Officer
Naval Health Sciences Education
and Training Command

23 Mar 90
DATE

GRANT AGREEMENT

GRANT NO.	EFFECTIVE DATE	GRANT AMOUNT	PAGE 1 OF 2
DAMD17-88-Z-8007 Modification No P80002	1 July 1988	$38,000,000.00	

PROJECT NO. AND TITLE:

Human Immunodeficiency Virus (HIV) Research

PERFORMANCE PERIOD	PRINCIPAL INVESTIGATOR
25 February 1988 through 24 February 1993	Bryce C. Redington, Ph.D.

AWARDED BY:	ADMINISTERED BY AWARDING COMMAND
US Army Medical Research Acquisition Activity **ATTN: SGRD-RMA-RC** **Fort Detrick** **Frederick, Maryland 21701-5014**	**PAYMENT WILL BE MADE BY:** **FINANCE AND ACCOUNTING OFFICE** **Fort Detrick, Frederick, MD 21701-5000**
AWARDED TO: The Henry M. Jackson Foundation for the Advancement of Military Medicine 4301 Jones Bridge Road, RM A1019 Bethesda, Maryland 20814-4799	**MAIL PAYMENTS TO:** The Henry M. Jackson Foundation for the Advancement of Military Medicine 4301 Jones Bridge Road, RM A1019 Bethesda, Maryland 20914-4799
SCHEDULE OF PAYMENTS N/C	**ACCOUNTING AND APPROPRIATION DATA** SEE Page 2

SCOPE OF WORK:

SEE PAGE 2

RECIPIENT	GRANT OFFICER
ACCEPTED BY:	**UNITED STATES OF AMERICA**
SIGNATURE	**BY**
NAME AND TITLE **DATE**	**NAME OF GRANT OFFICER** **DATE**
	John R. Derr, Maj, MS 1 JUL 88

Upon the effective date of this modification the subject grant is modified as follows:

1. ARTICLE II entitled, "Funds Currently Available" is hereby deleted in its entirety and the following is substituted in lieu thereof:

"ARTICLE II - Funds Currently Available

Pursuant to ARTICLE III, entitled, "Limitation of Funds," funds currently available and allotted to this grant amount to $8,683,190.00. It is estimated that the amount currently allotted will cover performance of the first sixteen (16) months of the grant. The above-stated allotment may be amended from time-to-time by the Granting Officer without concurrence of the Recipient."

2. Accounting and Appropriation Data is amended to add the following:

"2182040 875-8119 623105.H29AD 4150 S18064 AZ8D DCRNC0415 $3,000,000.00 Increase"

3. As a result of this modification the total amount of funds currently available and allotted to this grant is hereby increased by $3,000,000.00 from $5,683,190.00 to $8,683,190.00.

4. All other terms and conditions of this grant remain unchanged as a result of this modification.

GRANT AGREEMENT

GRANT NO.	EFFECTIVE DATE	GRANT AMOUNT	PAGE 1 OF 5
DAMD17-88-Z-8007 Modification P80003	See Grant Officer's Signature Date	$44,365,047.00	

PROJECT NO AND TITLE

Human Immunodeficiency Virus (HIV) Research

PERFORMANCE PERIOD	PRINCIPAL INVESTIGATOR
25 February 1988 through 24 February 1993	Bryce C. Redington, Ph.D.
AWARDED BY: U.S. Army Medical Research Acquisition Activity,/ATTN: SGRD-RMA-RCM Fort Detrick Frederick, Maryland 21701-5014	**ADMINIS. BY AWARDING COMMAND PAYMENT WILL BE MADE BY:** FINANCE AND ACCOUNTING OFFICE Fort Detrick, Frederick, MD 21701-5000
AWARDED TO: The Henry M. Jackson Foundation for the Advancement of Military Medicine 4301 Jones Bridge Road, RM A1019 Bethesda, Maryland 20814-4799	**MAIL PAYMENTS TO:** The Henry M. Jackson Foundation for the Advancement of Military Medicine 4301 Jones Bridge Road, RM A1019 Bethesda, Maryland 20814-4799
SCHEDULE OF PAYMENTS See Page 2 Item No. 2	**ACCOUNTING & APPROPRIATION DATA** See Page 2 Item No. 1

SCOPE OF WORK:

SEE PAGES 2 THROUGH 5

RECIPIENT	GRANT OFFICER
ACCEPTED BY: SIGNATURE	**UNITED STATES OF AMERICA** BY:
NAME AND TITLE Jay P. Sanford,M.D. Director - Secretary/Treasurer	**NAME OF GRANT OFFICER DATE** JOHN R. DERR, MAJ, MS

USAMRAA FORM 25-R. 1 JUN 88

Upon the effective date of this modification the subject grant is modified as follows:

1. Accounting and Appropriation Data is hereby amended to add the following:

2182040 875-8119 623105.H29 S18064 TY73 DCRNCO415 $102,059.00

2182040 875-8119 623105.H29 S18064 TY74 DCRNCO415 $200,000.00

2172040 775-8119 623105.H29AD 4150 S18064 AZ8D DCRNC0415 $57,000.00

2. ARTICLE I entitled, "Schedule of Payment" is hereby deleted in its entirety and the following is substituted in lieu thereof:

"a. The estimated cost of performing the work under this grant is forty-four million three hundred sixty five thousand and forty-seven dollars ($44,365,047.00). The total grant amount is subject to the provisions of ARTICLE III of this grant entitled, "Limitation of Funds." The Recipient will receive funding as follows:

(1) Human Immunodeficiency Virus (HIV) Research (Basic)

(a) For Year 1 the Recipient will be paid in four (4) quarterly installments. The approximate amounts for the individual installments are as follows: First Quarter - $2,000,000.00, Second Quarter - $1,289,117.00, Third Quarter - $1,088,293.00, and Fourth Quarter - $1,305,780.00. The total funding during the first year is $5,683,190.00.

(b) For Years 2 - 5 the Recipient will be paid in sixteen (16) quarterly installments. The approximate amounts for the individual installments are $2,019,425.62. The total funding for years 2 - 5 is $32,310,810.00.

(2) Natural History of Oral Manifestations of HIV Infection in a U.S. Military Population

The Recipient will be paid as follows:

Upon execution of this modification	$102,059.00
On or about 25 February 1989	$284,425.00
On or about 25 February 1990	$294,275.00
On or about 25 February 1991	$310,313.00
On or about 25 February 1992	$327,634.00
On or about 1 October 1992	$346,341.00
Total Funding is	$1,665,047.00

(3) Epidemiology of HIV in Pediatric and Perinatal Patients

The Recipient will be paid as follows:

Upon execution of this modification	$200,000.00
On or about 25 February 1989	$500,000.00
On or about 25 February 1990	$1,000,000.00
On or about 25 February 1991	$1,500,000.00
On or about 25 February 1992	$1,500,000.00
Total Funding is	$4,700,000.00

b. Invoices will be prepared by U.S. Army Medical Research Acquisition Activity and forwarded to the appropriate Finance and Accounting Office for payment to the Recipient."

3. ARTICLE II entitled, "Funds Currently Available" is hereby deleted in its entirety and the following is substituted in lieu thereof:

"ARTICLE II - Funds Currently Available

Pursuant to ARTICLE III, entitled "Limitation of Funds," funds currently available and allotted to this grant amount to $8,985,249.00. It is estimated that the amount currently allotted will cover performance of the first sixteen (16) months of the grant. The above-stated allotment may be amended from time-to-time by the Granting Officer without concurrence of the Recipient."

4. ARTICLE IV subsection b. entitled, "Work Statement" is hereby amended to add the following:

"(1) Department of Health and Human Services, Public Health Service, Interagency Agreement No. 1Y01-DE-80005-00 between the National Institute of Dental Research, National Institutes of Health and U.S. Army Medical Research and Development Command entitled, "Natural History of Oral Manifestations of HIV Infection in a U.S. Military Population" and Associated Protocols (Attachment 8) is hereby incorporated into and made a part of this grant as though fully set forth herein; except however, in the event of a conflict between said agreement and any other terms and conditions of this grant, then all other terms and conditions of this grant shall take precedence over the agreement.

(2) Department of Health and Human Services, Public Health Service, Interagency Agreement No. 1Y02-HD-8-1244-00 between the National Institute of Child Health and Human Development, National Institutes of Health and the U.S. Army Medical Research and Development Command entitled, "Epidemiology of HIV in Pediatric and Perinatal Patients: A Natural History Study" and the Grant application submitted by the Henry M. Jackson Foundation for the Advancement of Military Medicine entitled "Epidemiology of HIV in Pediatric and Perinatal Patients: A Research History Study" (Attachment 9) are hereby incorporated into and made a part of this grant as though fully set forth herein; except however, in the event of a conflict between said agreement/grant application and any other terms and conditions of this grant, then all other terms and conditions of this grant shall take precedence over the agreement/grant application.

(3) The personnel listed in the grant application from the Henry M. Jackson Foundation (HMJF) to the Public Health Service, i.e., Dr. Gerald Fischer, Dr. Philip G. Petlett, Dr. John Brundage, Dr. Don Burke, Dr. Val Hemming and Dr. Robert Scott are personnel representing the Department of the Army (DA) in fulfilling the terms of the Interagency Agreement between the DA and the Public Health Service. These personnel are not employees of HMJF and will not be remunerated by the HMJF."

5. ARTICLE VII entitled, "Reporting Requirements" is hereby amended to add the following:

GRANT AGREEMENT

GRANT NO.	EFFECTIVE DATE	GRANT AMOUNT	PAGE 1 OF 2
DAMD17-88-Z-8007 Modification P90004	23 November 1988	$44,365,047.00	

PROJECT NO AND TITLE
Human Immunodeficiency Virus (HIV) Research

PERFORMANCE PERIOD	PRINCIPAL INVESTIGATOR
25 February 1988 - 24 February 1993	Bryce C. Redington, Ph.D.

AWARDED BY:	ADMINIS. BY AWARDING COMMAND PAYMENT WILL BE MADE BY:
U.S. Army Medical Research Acquisition Activity/ATTN: SGRD-RMA-RCM Fort Detrick Frederick, Maryland 21701-5014	FINANCE AND ACCOUNTING OFFICE Fort Detrick, Frederick, MD 21701-5000
AWARDED TO: The Henry M. Jackson Foundation for the Advancement of Military Medicine 4301 Jones Bridge Road, RM A1019 Bethesda, Maryland 20814-4799.	**MAIL PAYMENTS TO:** The Henry M. Jackson Foundation for the Advancement of Military Medicine 4301 Jones Bridge Road, RM A1019 Bethesda, Maryland 20914-4799
SCHEDULE OF PAYMENTS N/C	**ACCOUNTING & APPROPRIATION DATA** See Page 2

SCOPE OF WORK:

SEE PAGE 2

RECIPIENT	GRANT OFFICER
ACCEPTED BY:	**UNITED STATES OF AMERICA** **BY:**
SIGNATURE	
NAME AND TITLE DATE	NAME OF GRANT OFFICER DATE John R. Derr, Maj, MS 11/28/88

USAMRAA FORM 25-R. 1 JUN 88

Upon the effective date of this modification the subject grant is modified as follows:

1. ARTICLE II entitled, "Funds Currently Available" is hereby modified as follows: "Pursuant to ARTICLE III, entitled, "Limitation of Funds," funds currently available and allotted to this grant amount to $10,353,187.00. It is estimated that the amount currently allotted will cover performance of the first sixteen (16) months of the grant. The above-stated allotment may be amended from time-to-time by the Granting Officer without concurrence of the Recipient."

2. Accounting and Appropriation Data is amended as follows:

"2182040 875-8119 623105.H29 4150 S18064 TY73 DCRNCO415 $102,059.00 (NO CHANGE)

2182040 875-8119 623105.H29 4150 S18064 TY74 DCRNC0415 $200,000.00 (NO CHANGE)

2192040 975-8119 623105.H29AD 4150 S18064 AZ8D DCRNCO415 $1,310,940.00 (INCREASE)"

3. As a result of this modification the total amount of funds currently available and allotted to this grant is hereby increased by $1,310,940.00 from $9,042,247.00 to $10,353,187.00.

All other terms and conditions of this grant remain unchanged as a result of this modification.

POC: Joyce Richardson (301) 695-2807

GRANT AGREEMENT

GRANT NO.	EFFECTIVE DATE	GRANT AMOUNT	PAGE 1 OF 2
DAMD17-88-Z-8007 Modification P90005	7 December 1988	$44,365,047.00	

PROJECT NO AND TITLE

Human Immunodeficiency Virus (HIV) Research

PERFORMANCE PERIOD	PRINCIPAL INVESTIGATOR
25 February 1988- 24 February 1993	Bryce C. Redington, Ph.D

AWARDED BY:	ADMINIS. BY AWARDING COMMAND PAYMENT WILL BE MADE BY:
U.S. Army Medical Research Acquisition Activity,/ATTN: SGRD-RMA-RCM Fort Detrick Frederick, Maryland 21701-5014	FINANCE AND ACCOUNTING OFFICE Fort Detrick, Frederick, MD 21701-5000
AWARDED TO: The Henry M. Jackson Foundation for the Advancement of Military Medicine 4301 Jones Bridge Road, RM A1019 Bethesda, Maryland 20814-4799	**MAIL PAYMENTS TO:** The Henry M. Jackson Foundation for the Advancement of Military Medicine 4301 Jones Bridge Road, RM A1019 Bethesda, Maryland 20914-4799
SCHEDULE OF PAYMENTS N/C	**ACCOUNTING & APPROPRIATION DATA** 2192040 975.8119 623105.H29AD 4150 S18064 AZ8D DCRNC0415 $3,709,762.48 88Z8007

SCOPE OF WORK:

SEE PAGE 2

RECIPIENT	GRANT OFFICER
ACCEPTED BY:	UNITED STATES OF AMERICA
_____ SIGNATURE	BY: _____
NAME AND TITLE DATE	NAME OF GRANT OFFICER DATE
	John R. Derr, ~~Maj~~, MS 19 DEC 88

USAMRAA FORM 25-R. 1 JUN 88

Subject grant is modified as follows:

1. ARTICLE II entitled, "Funds Currently Available" is hereby modified as follows: "Pursuant to ARTICLE III, entitled, "Limitation of Funds," funds currently available and allotted to this grant amount to $14,062,951.48. It is estimated that the amount currently allotted will cover performance of the first sixteen (16) months of the grant. The above-stated allotment may be amended from time-to time by the Granting Officer without concurrence of the Recipient."

2. As a result of this modification the total amount of funds currently available and allotted to this grant is increased by $3,709,762.48 from $10,353,187.00 to $14,062,951.48.

3. All other terms and conditions of this grant remain unchanged.

POC: Joyce Richardson (301) 695-2807

GRANT AGREEMENT

GRANT NO.	EFFECTIVE DATE	GRANT AMOUNT	PAGE 1 OF 1
DAMD17-88-Z-8007 Modification P90006	3 Jan 89	$44,365,047.00	

PROJECT NO AND TITLE
Human Immunodeficiency Virus (HIV) Research

PERFORMANCE PERIOD	PRINCIPAL INVESTIGATOR
25 February 1988 - 24 February 1993	Bryce C. Redington, Ph.D

AWARDED BY:	ADMINIS. BY AWARDING COMMAND PAYMENT WILL BE MADE BY:
U.S. Army Medical Research Acquisition Activity,/ATTN: SGRD-RMA-RCM Fort Detrick Frederick, Maryland 21701-5014	FINANCE AND ACCOUNTING OFFICE Fort Detrick, Frederick, MD 21701-5000
AWARDED TO: The Henry M. Jackson Foundation for the Advancement of Military Medicine 4301 Jones Bridge Road, RM A1019 Bethesda, Maryland 20814-4799	**MAIL PAYMENTS TO:** The Henry M. Jackson Foundation for the Advancement of Military Medicine 4301 Jones Bridge Road, RM A1019 Bethesda, Maryland 20814-4799
SCHEDULE OF PAYMENTS N/C	**ACCOUNTING & APPROPRIATION DATA** See Below

SCOPE OF WORK:

1. The purpose of this modification is to correct accounting and appropriation data in modification P90004.

FROM:

2192040 975-8119 623105.H29AD 4150 S18064 AZ8D DCRNC0415 $1,310,940.00 (INCREASE)

TO:

2182040 875-8119 623105.H29AD 4150 S18064 AZ8D DCRNC0415 $1,310,940.00 (INCREASE)

2. All other terms and conditions of this grant remain unchanged.

3. The total amount of funds currently available under this grant is unchanged and remains $14,062,951.48.

RECIPIENT	GRANT OFFICER
ACCEPTED BY:	UNITED STATES OF AMERICA
_____ SIGNATURE	BY: _____
NAME AND TITLE DATE	NAME OF GRANT OFFICER DATE
	John R. Derr, Major, MS 5 JAN 89

USAMRAA FORM 25-R. 1 JUN 88

POC: Joyce R[illegible]hardson (301) 695-2807

GRANT AGREEMENT

GRANT NO.	EFFECTIVE DATE	GRANT AMOUNT	PAGE 1 OF 1
DAMD17-88-Z-8007 Modification P90007	20 March 1989	$44,365,047.00	

PROJECT NO AND TITLE

Human Immunodeficiency Virus (HIV) Research

PERFORMANCE PERIOD	PRINCIPAL INVESTIGATOR
25 February 1988 - 24 February 1993	Bryce C. Redington, Ph.D

AWARDED BY:	ADMINIS. BY AWARDING COMMAND PAYMENT WILL BE MADE BY:
U.S. Army Medical Research Acquisition Activity,/ATTN: SGRD-RMA-RCM Fort Detrick Frederick, Maryland 21701-5014	FINANCE AND ACCOUNTING OFFICE Fort Detrick, Frederick, MD 21701-5000
AWARDED TO:	**MAIL PAYMENTS TO:**
The Henry M. Jackson Foundation for the Advancement of Military Medicine 4301 Jones Bridge Road, RM A1019 Bethesda, Maryland 20814-4799	The Henry M. Jackson Foundation for the Advancement of Military Medicine 4301 Jones Bridge Road, RM A1019 Bethesda, Maryland 20814-4799
SCHEDULE OF PAYMENTS	**ACCOUNTING & APPROPRIATION DATA**
N/C	See Below

SCOPE OF WORK:

Subject grant is modified as follows:

1. ARTICLE II entitled, "Funds Currently Available" is hereby modified as follows: "Pursuant to ARTICLE III, entitled, "Limitation of Funds," funds currently available and allotted to this grant amount to $22,925,078.96. The above-stated allotment may be amended from time-to-time by the Granting Officer without concurrence of the Recipient."

2. As a result of this modification the total amount of funds currently available and allotted to this grant is increased by $8,862,127.48 from $14,062,951.48 to $22,925,078.96.

3. Accounting and Appropriation Data is hereby amended to add the following:

2192040 975-8119 623105.H29AD 4150 S18064 AZ8D DCRNC0415 88Z8007 $8,077,702.48 (INCREASE)
2192040 975-8119 623105.H29 4150 S18064 TY81 DCRNC0415 88Z8007 $500,000.00 (INCREASE)
2192040 975-8119 623105.H29 4150 S18064 TY80 DCRNC0415 88Z8007 $284,425.00 (INCREASE)

4. All other terms and conditions of this grant remain unchanged.

RECIPIENT	GRANT OFFICER
ACCEPTED BY:	UNITED STATES OF AMERICA BY: John R. Dern
SIGNATURE	
NAME AND TITLE DATE	NAME OF GRANT OFFICER DATE John R. Dern, Major, MS 27 MAR 89

USAMRAA FORM 25-R. 1 JUN 88

DEPARTMENT OF THE ARMY
U.S. ARMY MEDICAL RESEARCH ACQUISITION ACTIVITY
FORT DETRICK, FREDERICK, MD. 21701-5014

August 18, 1989

REPLY TO
ATTENTION OF:

Major Support Contracts Branch

SUBJECT: DAMD17-88-Z-8007
Modification No. P90008

Dr. Jay P. Sanford
Director - Secretary/Treasurer
The Henry M. Jackson Foundation for
the Advancement of Military Medicine
4301 Jones Bridge Road
Room A1019
Bethesda, Maryland 20814-4799

Dear Dr. Sanford:

Enclosed for your records is a fully executed copy of Modification No. P90008 to Grant No. DAMD17-88-Z-8007.

If you have any questions concerning this matter, please contact the undersigned at (301) 695-2807.

Sincerely,

Joyce R. Richardson

Joyce R. Richardson
Grant Specialist

Enclosure

P.O.C.: JOYCE R. RICHARDSON (301) 695-2807

GRANT AGREEMENT

GRANT NO.	EFFECTIVE DATE	GRANT AMOUNT	PAGE 1 OF 5
DAMD17-88-Z-8007 Modification P90008	1 May 1989	$45,122,967.00	

PROJECT NO AND TITLE

HUMAN IMMUNODEFICIENCY VIRUS (HIV) RESEARCH

PERFORMANCE PERIOD	PRINCIPAL INVESTIGATOR
25 February 1988 - 24 February 1993	Bryce C. Redington, Ph.D.

AWARDED BY:	ADMINIS. BY AWARDING COMMAND PAYMENT WILL BE MADE BY:
U.S. Army Medical Research Acquisition Activity,/ATTN: SGRD-RMA-RCM Fort Detrick Frederick, Maryland 21701-5014	FINANCE AND ACCOUNTING OFFICE Fort Detrick, Frederick, MD 21701-5000
AWARDED TO: The Henry M. Jackson Foundation for the Advancement of Military Medicine 4301 Jones Bridge Road, Rm. A1019 Bethesda, Maryland 20814-4799	**MAIL PAYMENTS TO:** The Henry M. Jackson Foundation for the Advancement of Military Medicine 4301 Jones Bridge Road, Rm. A1019 Bethesda, Maryland 20814-4799
SCHEDULE OF PAYMENTS NO CHANGE	**ACCOUNTING & APPROPRIATION DATA** 2192040 975-8119 623105.H29 4150 S18064 TY82 DCRNC0415 88Z8007 $232,920.00

SCOPE OF WORK:

SEE PAGE 2

RECIPIENT	GRANT OFFICER
ACCEPTED BY:	UNITED STATES OF AMERICA
SIGNATURE	BY:
NAME AND TITLE Jay P. Sanford, M.D. Director - Secretary/Treasurer HMJFAMM	NAME OF GRANT OFFICER DATE CRAIG D. LEBO CONTRACTING OFFICER

USAMRAA FORM 25-R. 1 JUN 88

1. The purpose of this modification is to incorporate the terms and conditions of Department of Health and Human Services, Public Health Service, National Institutes of Health Inter-Agency Agreement No. 1-Y01-AR-90008-00 between The National Institute of Arthritis and Musculoskeletal and Skin (NIAMS) Diseases and U.S. Army Medical Research and Development Command. Agreement is entitled, "Clinical and Epidemiological Studies of Cutaneous Manifestations Associated With HIV Infection in U.S. Army Personnel. This agreement is for three years and increases the total grant amount by $757,920.00 from $44,365,047.00 to $45,122,967.00.

2. Modification P80003 paragraph 2, concerning ARTICLE I entitled, "Schedule of Payment" is hereby deleted in its entirety and the following is substituted in lieu thereof:

"a. The estimated cost of performing the work under this grant is forty-five million one hundred twenty-two thousand nine hundred sixty-seven dollars ($45,122,967.00). The total grant is subject to the provisions of ARTICLE III of this grant entitled, "Limitation of Funds." The recipient will receive funding for each area of study as follows:

(1) Human Immunodeficiency Virus (HIV) Research (Basic)

(a) For Year1 the Recipient will be paid four (4) quarterly payments. The approximate amount for each individual payment is as follows: First Quarter- $2,000,000.00, Second Quarter- $1,289,117.00, Third Quarter- $1,088,293.00, and Fourth Quarter- $1,305,780.00. The total funding for Year 1 is $5,683,190.00.

(b) For Years 2-5 the Recipient will be paid sixteen (16) quarterly payments. The approximate amount for each individual payment is $2,019,425.62. The total funding for years 2-5 is $32,310,810.00.

(c) Payments shall be made at the beginning of each quarter. First quarter begins 25 February, second quarter begins 25 May, third quarter begins 25 August and fourth quarter begins 25 November.

(2) Natural History of Oral Manifestations of HIV Infection in a U.S. Military Population

(a) Total funding for the study is one million six hundred sixty-five thousand forty-seven dollars ($1,665,047.00).

(b) Payment amounts and schedules follow:

Upon execution of modification P80003	$102,059.00
25 February 1989	$284,425.00
25 February 1990	$294,275.00
25 February 1991	$310,313.00
25 February 1992	$327,634.00
01 October 1992	$346,341.00
Total	$1,665,047.00

(3) Epidemiology of HIV in Pediatric and Perinatal Patients

(a) Total funding for this study is four million seven hundred thousand dollars ($4,700,000.00).

(b) Payment amounts and schedules follow:

Upon execution of modification P80003	$200,000.00
25 February 1989	$500,000.00
25 February 1990	$1,000,000.00
25 February 1991	$1,500,000.00
25 February 1992	$1,500,000.00
Total	$4,700,000.00

(4) Chemical and Epidemiological Studies of Cutaneous Manifestations Associated with HIV Infection in U.S. Army Personnel

(a) Total funding for this study is seven hundred fifty-seven thousand nine hundred twenty dollars ($757,920.00).

(b) Payment amounts and schedules follow:

Upon execution of modification of P90008	$232,920.00
25 May 1990	$250,000.00
25 May 1991	$275,000.00
Total	$757,920.00

b. Vouchers will be prepared by U.S. Army Medical Research Acquisition Activity and forwarded to the appropriate Finance and Accounting Office for payment to the Recipient."

3. ARTICLE II entitled, "Funds Currently Available" is hereby deleted in its entirety and the following is substituted in lieu thereof:

"ARTICLE II- Funds Currently Available
Pursuant to ARTICLE III, entitled "Limitation of Funds," funds currently available and allotted to this grant amount to $23,157,998.96.

4. ARTICLE IV subsection b entitled, "Work Statement" is hereby amended to add the following:

(4) Department of Health and Human Services, Public Health Service, National Institutes of Health Inter-Agency Agreement No. 1-Y01-AR-90008-00 between The National Institute of Arthritis and Musculoskeletal and Skin (NAIMS) Diseases and U. S. Army Medical Research and Development Command entitled "Clinical and Epidemiological Studies of Cutaneous Manifestations Associated With HIV Infection in U. S. Army Personnel" (Attachment 10) is incorporated into this grant. Principal Investigators are LTC William D. James and LTC Kathleen Smith. Project Officers are Stephen P. Heyse, M. D. and Reva Lawrence, M.P.H.

5. ARTICLE VII entitled, Reporting Requirements is amended to add the following:

n. Three (3) copies of a quarterly technical progress report shall be submitted to the NIAMS Project Officers. The report shall include all laboratory findings and a description of the technical effort and progress made during the reporting period. (See Attachment 10)

6. As a result of this modification the total amount of funds currently available and allotted to this grant is increased by $232,920.00 from $22,925,078.96 to $23,157,998.96.

Department of Health and Human Services
Public Health Service
National Institutes of Health

Inter-Agency Agreement Between
The National Institute of Arthritis
and Musculoskeletal and Skin Diseases

and

U.S. Army Medical Research and Development Command

Pursuant to the authority contained in Section 601 of the Economy Act of 1932, as amended (31 USC 1535), and NIH Delegation of Authority 1130, Grants and Awards, No. 4, the Department of Health and Human Services, Public Health Service, National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), agrees to reimburse the U.S. Army Medical Research and Development Command (USAMRDC), Fort Detrick, Maryland, for the performance of the services described below.

I. Purpose:

To reimburse the USAMRDC for services provided to conduct clinical and epidemiological studies of cutaneous manifestations associated with HIV infection in U.S. Army personnel. This study will be conducted under the auspices of Grant No. DAMD17-88-Z-8007 between USAMRDC and the Henry M. Jackson Foundation for the Advancement of Military Medicine (HMJFAMM).

II. Period of Agreement:

This agreement will be in effect upon execution by both parties and will continue until September 30, 1991. The agreement may be modified or extended if necessary upon consent of the parties or terminated by either party upon a 30-day written advance notice.

III. Project Description:

Investigators from multiple institutions have reported on the concurrence of AIDS or HIV infection and severe skin manifestations. It is unknown whether a biological connection exists between certain skin diseases or conditions and HIV infection or whether the concurrence of these entities is merely the result of coincidence. The skin, in particular, appears to be intimately involved in HIV diseases.

The USAMRDC and the Walter Reed Army Medical Center under the provisions of an MOU, dated September 1, 1987, entitled "Human Immunodeficiency Virus (HIV) Research," will collaborate with NIAMS staff to carry out clinical and epidemiologic studies of the cutaneous findings associated with HIV infection in U.S. Army personnel. It is estimated that there will be 400 new cases per year. This study is an addendum to the Walter Reed Medical Research Center Natural History Protocol. It is anticipated that this will be a longitudinal study with a 10 year duration.

The specific aims of the study are: (1) to estimate the incidence, prevalence and natural history of skin diseases of all types in each Walter Reed stage of HIV patients; (2) to investigate the association between the use of specific drugs with rashes or eruptions in patients with anergy and T helper cell depletion; (3) to determine the frequency, prognostic and diagnostic value of tubuloreticular inclusion bodies for each Walter Reed stage of HIV infection; and, (4) to determine the role of the skin in the diagnosis of subclinical systemic infections.

IV. Estimated Cost and Future Year Estimates:

1. The costs of services for FY 1989 shall not exceed $232,920.

   Appropriation: 0888
   CAN: 9-8425036

2. Estimates for future years are:

   FY 1990 - $250,000
   FY 1991 - $275,000

V. Method of Payment:

The USAMRDC shall utilize SF 1080/1081 for billing purposes. The SF 1080/1081 shall be submitted to:

Division of Financial Management
Building 31, Room B1B04
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Administrative billing requirements shall be in accordance with the GAO Policy and Procedure, Title 7, Sections 8.4 and 13.2 (1).

VI. Full-Time Equivalency (FTE) Responsibility:

No transfer of FTEs is required.

VII. Designation of Responsible Officials:

NIAMS Project Officers:

Stephen P. Heyse, M.D., M.P.H.
Associate Director,
Prevention, Epidemiology and Clinical Applications

Reva Lawrence, M.P.H.
Epidemiology/Data Systems Program Officer Office of
Prevention, Epidemiology and Clinical Applications

USAMRDC Grant Officer:

Major John R. Derr
U.S. Army Medical Research Acquisition Activity
Fort Detrick
Frederick, Maryland 21701-5012

Principal Investigators:

William D. James, M.D., LTC, MC, USA
Chief, Dermatology, WRAMC

Kathleen Smith, M.D., LTC, MC, USA
Staff, AFIP, Dermatology

VIII. Reporting Requirements:

Three (3) copies of a quarterly technical progress report shall be submitted to the NIAMS Project Officers. These reports shall include a description of the technical effort and progress made during the reporting period. In addition, these reports shall include all laboratory findings.

IX. Approvals:

Approved and accepted for the National Institute of Arthritis and Musculoskeletal and Skin Diseases:

By: Dr. Robert L. Bruun, Sc.D.
Title: Executive Officer, NIAMS

Date: 16 MAR 89

Approved and accepted for the U.S. Army Medical Research and Development Command:

By: Maj John R. Derr
Title: USAMRDC Grant Officer

Date: 13 MAR 89

P.O.C.: JOYCE RICHARDSON (301) 695-2807

GRANT AGREEMENT

GRANT NO.	EFFECTIVE DATE	GRANT AMOUNT	PAGE 1 OF 1
DAMD17-88-Z-8007 Modification P90009	See Grant Officer's Signature Block	$45,122,967.00	

PROJECT NO AND TITLE

HUMAN IMMUNODEFICIENCY VIRUS (HIV) RESEARCH

PERFORMANCE PERIOD	PRINCIPAL INVESTIGATOR
25 February 1988 - 24 February 1993	Bryce C. Redington, Ph.D.
AWARDED BY: U.S. Army Medical Research Acquisition Activity,/ATTN: SGRD-RMA-RCM Fort Detrick Frederick, Maryland 21701-5014	**ADMINIS. BY AWARDING COMMAND PAYMENT WILL BE MADE BY:** FINANCE AND ACCOUNTING OFFICE Fort Detrick, Frederick, MD 21701-5000
AWARDED TO: The Henry M. Jackson Foundation for the Advancement of Military Medicine 4301 Jones Bridge Road, Rm. A1019 Bethesda, Maryland 20814-4799	**MAIL PAYMENTS TO:** The Henry M. Jackson Foundation for the Advancement of Military Medicine 4301 Jones Bridge Road, Rm. A1019 Bethesda, Maryland 20814-4799
SCHEDULE OF PAYMENTS NO CHANGE	**ACCOUNTING & APPROPRIATION DATA** NO CHANGE

SCOPE OF WORK:

This modification expands the HIV Research base to the U.S. Air Force and the U.S. Navy. Protocols shall be conducted in other military medical centers, such as the National Naval Medical Center, Bethesda, Maryland and Wilford Hall Air Force Medical Center, San Antonio, Texas, under the aegis of the U.S. Army, as the Department of Defense lead agency for HIV research.

RECIPIENT	GRANT OFFICER
ACCEPTED BY: Jay P. Sanford SIGNATURE	**UNITED STATES OF AMERICA** BY:
NAME AND TITLE Jay P. Sanford, M.D. Director - Secretary/Treasurer HMJFAMM DATE 9/11/89	**NAME OF GRANT OFFICER** REGINALD D. LEBO CONTRACTING OFFICER DATE 9/12/89

USAMRAA FORM 25-R. 1 JUN 88

P.O.C.: JOYCE RICHARDSON (301) 695-2807

GRANT AGREEMENT

GRANT NO.	EFFECTIVE DATE	GRANT AMOUNT	PAGE 1 OF 2
DAMD17-88-Z-8007 Modification P90010	See Grant Officer's Signature Block	$45,122,967.00	

PROJECT NO AND TITLE

HUMAN IMMUNODEFICIENCY VIRUS (HIV) RESEARCH

PERFORMANCE PERIOD	PRINCIPAL INVESTIGATOR
5 February 1988 - 24 February 1993	Bryce C. Redington, Ph. D.
AWARDED BY: U.S. Army Medical Research Acquisition Activity,/ATTN: SGRD-RMA-RCM Fort Detrick Frederick, Maryland 21701-5014	**ADMINIS. BY AWARDING COMMAND** **PAYMENT WILL BE MADE BY:** FINANCE AND ACCOUNTING OFFICE Fort Detrick, Frederick, MD 21701-5000
AWARDED TO: The Henry M. Jackson Foundation for the Advancement of Military Medicine 4301 Jones Bridge Road, Rm. A1019 Bethesda, Maryland 20814-4799	**MAIL PAYMENTS TO:** The Henry M. Jackson Foundation for the Advancement of Military Medicine 4301 Jones Bridge Road, Rm. A1019 Bethesda, Maryland 20814-4799
SCHEDULE OF PAYMENTS CHANGE	**ACCOUNTING & APPROPRIATION DATA** REIMBURSEABLE (NIH) Appro. No. 75-9-0844, CAN: 9-8421107 9-8421009

SCOPE OF WORK:

A. This modification releases funds in the amount of $250,000.00 in the above cited accounting and appropriation data. It is understood that these funds will be used to support a study entitled: "Comprehensive System of Service Delivery to HIV-Infected Infants,Toddlers, and Preschoolers and Their Families." This study has not yet been formally accepted into this protocol but it is understood that the parties will progress toward formalizing the incorporation of this project

B. As a result of this modification, the total amount of funding available for this grant is increased $250,000.00

RECIPIENT	GRANT OFFICER
ACCEPTED BY: SIGNATURE NOT REQUIRED SIGNATURE	UNITED STATES OF AMERICA BY:
NAME AND TITLE DATE	NAME OF GRANT OFFICER DATE CRAIG D. [illegible] CONTRACTING OFFICER 9/29/89

USAMRAA FORM 25-R. 1 JUN 88

C. Article II entitled, "Funds Currently Available" is hereby deleted in its entirey and the following is substituted in lieu thereof:

"ARTICLE II--Funds Currently Available

Pursuant to ARTICLE III, entitled "Limitation of Funds," funds currently available and allotted to this grant amount to $23,407,998.96.

D. This effort relates to Inter-Agency Agreement between National Institute of Child Health and Human Development, National Institutes of Health, and the Department of Defense, represented by U.S. Army Medical Research Acquisition Activity.

P.O.C.: JOYCE RICHARDSON/mh/(301) 695-2

GRANT AGREEMENT

GRANT NO.	EFFECTIVE DATE	GRANT AMOUNT	PAGE 1 OF 2
DAMD17-88-Z-8007 Modification P00011	See Grant Officer's Signature Block	$45,122,967.00	

PROJECT NO. AND TITLE

HUMAN IMMUNODEFICIENCY VIRUS (HIV) RESEARCH

PERFORMANCE PERIOD	PRINCIPAL INVESTIGATOR
22 February 1988 - 24 February 1993	Bryce C. Redington, Ph.D.

AWARDED AND ADMINISTERED BY:	PAYMENT WILL BE MADE BY:
U.S. Army Medical Research Acquisition Activity/ATTN: SGRD-RMA-RCM Fort Detrick Frederick, Maryland 21701-5014	FINANCE AND ACCOUNTING OFFICE BLDG. 810, Fort Detrick Frederick, Maryland 21701-5000

AWARDED TO:	MAIL PAYMENTS TO:
The Henry M. Jackson Foundation for the Advancement of Military Medicine 4301 Jones Bridge Road, Rm. A1019 Bethesda, Maryland 20814-4799	The Henry M. Jackson Foundation for the Advancement of Military Medicine 4301 Jones Bridge Road, Rm. A1019 Bethesda, Maryland 20814-4799

SCHEDULE OF PAYMENTS	ACCOUNTING & APPROPRIATION DATA
NO CHANGE	SEE PAGE 2

GRANT SCHEDULE:

SEE PAGE 2

RECIPIENT		GRANT OFFICER	
ACCEPTED BY: _____ SIGNATURE		UNITED STATES OF AMERICA BY:	
NAME AND TITLE	DATE	NAME OF GRANT OFFICER CRAIG D. LEBO Grants Officer	DATE 11 JAN

USAMRAA FORM 25-R 1 OCT 89

1. The purpose of this modification is to deobligate $3,000,000.00 in incremental funding. Therefore, accounting and appropriation data is amended as follows:

2192040 975-8119 623105.H29AD 4150 S18064 AZ8D DCRN0415 88Z8007 ($3,000,000.00) DECREASE

2. "ARTICLE II- Funds Currently Available

Pursuant to ARTICLE III, entitled "Limitation of Funds", Funds currently available and allotted to this grant amount to $20,407,998.96.

3. As a result of this modification the total amount of funds currently available and allotted to this grant is decreased by $3,000,000.00 from $23,407,998.96 to $20,407,998.96.

DEPARTMENT OF THE ARMY
U.S. ARMY MEDICAL RESEARCH ACQUISITION ACTIVITY
FORT DETRICK, FREDERICK, MD 21701-5014

January 24, 1990

REPLY TO
ATTENTION OF

Major Support Contracts Branch

SUBJECT: DAMD17-88-Z-8007
Modification No. P00012

Mr. John W. Lowe
The Henry M. Jackson Foundation for
the Advancement of Military Medicine
11426 Rockville Pike
Suite 400
Rockville, Maryland 20852-3007

Dear Mr. Lowe:

Enclosed for your records is a fully executed copy of Modification No. P00012 to Contract No. DAMD17-88-Z-8007.

If you have any questions concerning this matter, please contact the undersigned at (301) 695-2807.

Sincerely,

Joyce R. Richardson
Contract Specialist

Enclosure

P.O.C.: JOYCE RICHARDSON/mh/301-695-2807

GRANT AGREEMENT

GRANT NO.	EFFECTIVE DATE	GRANT AMOUNT	PAGE 1 OF 1
DAMD17-88-Z-8007 Modification P00012	See Grant Officer's Signature Block	$45,122,967.00	

PROJECT NO. AND TITLE

HUMAN IMMUNODEFICIENCY VIRUS (HIV) RESEARCH

PERFORMANCE PERIOD	PRINCIPAL INVESTIGATOR
22 February 1988 - 24 February 1993	Bryce C. Redington, Ph.D.

AWARDED AND ADMINISTERED BY:	PAYMENT WILL BE MADE BY:
U.S. Army Medical Research Acquisition Activity/ATTN: SGRD-RMA-RCM Fort Detrick Frederick, Maryland 21701-5014	FINANCE AND ACCOUNTING OFFICE BLDG. 810, Fort Detrick Frederick, Maryland 21701-5000

AWARDED TO:	MAIL PAYMENTS TO:
The Henry M. Jackson Foundation for the Advancement of Military Medicine 4301 Jones Bridge Road, Rm. A1019 Bethesda, Maryland 20814-4799	The Henry M. Jackson Foundation for the Advancement of Military Medicine 4301 Jones Bridge Road, Rm. A1019 Bethesda, Maryland 20814-4799

SCHEDULE OF PAYMENTS	ACCOUNTING & APPROPRIATION DATA
NO CHANGE	SEE BELOW

GRANT SCHEDULE:

1. The purpose of this modification is to correct modification P00011, paragraph 1., accounting and appropriation data. It is changed

FROM:
2192040 975-8119 623105.H29AD 4150 S18064 AZ8D DCRN0415 88Z8007 ($3,000,000.00) DECREASE

TO:
2192040 975-8119 623105.H29AD 4150 S18064 AZ8D DCRNC0415 88Z8007 ($3,000,000.00) DECREASE

2. All other terms and conditions of this grant remain unchanged. Total amount of funds currently available and allotted to this grant is $20,407,998.96.

RECIPIENT		GRANT OFFICER	
ACCEPTED BY: _____ SIGNATURE		UNITED STATES OF AMERICA BY:	
NAME AND TITLE	DATE	NAME OF GRANT OFFICER CRAIG D. LEBO Grants Officer	DATE 1/23/90

USAMRAA FORM 25-R 1 OCT 89

DEPARTMENT OF THE ARMY
U.S. ARMY MEDICAL RESEARCH ACQUISITION ACTIVITY
FORT DETRICK, FREDERICK, MD. 21701-5014

REPLY TO
ATTENTION OF

April 10, 1990

Major Support Contracts Branch

SUBJECT: Grant No. DAMD17-88-Z-8007
Modification No. P00013

Mr. John W. Lowe
Associate for HIV Research
The Henry M. Jackson Foundation for
the Advancement of Military Medicine
11426 Rockville Pike
Suite 400
Rockville, Maryland 20852-3007

Dear Mr. Lowe:

Enclosed for your records is a fully executed copy of Modification No. P00013 to Grant No. DAMD17-88-Z-8007.

If you have any questions concerning this matter, please contact the undersigned at (301) 695-2807.

Sincerely,

Joyce R. Richardson
Grant Specialist

Enclosure

GRANT AGREEMENT

GRANT NO.	EFFECTIVE DATE	GRANT AMOUNT	PAGE 1 OF 1
DAMD17-88-Z-8007 Modification P00013	See Grant Officer's Signature Block	$45,122,967.00	

PROJECT NO AND TITLE

HUMAN IMMUNODEFICIENCY VIRUS (HIV) RESEARCH

PERFORMANCE PERIOD	PRINCIPAL INVESTIGATOR
22 February 1988 - 24 February 1993	Bryce C. Redington, Ph.D.
AWARDED BY: **U.S. Army Medical Research Acquisition Activity,/ATTN: SGRD-RMA-** **Fort Detrick** **Frederick, Maryland 21701-5014**	**ADMINIS. BY AWARDING COMMAND PAYMENT WILL BE MADE BY:** **FINANCE AND ACCOUNTING OFFICE** **Fort Detrick, Frederick, MD 21701-5000**
AWARDED TO: The Henry M. Jackson Foundation for the Advancement of Military Medicine 4301 Jones Bridge Road, Rm. A1019 Bethesda, Maryland 20814-4799	**MAIL PAYMENTS TO:** The Henry M. Jackson Foundation for the Advancement of Military Medicine 4301 Jones Bridge Road, Rm. A1019 Bethesda, Maryland 20814-4799
SCHEDULE OF PAYMENTS	**ACCOUNTING & APPROPRIATION DATA** 2102040 075-8119 611102.S13 4150 S18064 TY97 DCRNC0415 NIH Agreement No. 1Y01-DE-80005-02 88Z8007 $294,275.00

SCOPE OF WORK:

The purpose of this modification is to add $294,275.00.

"Article II - Funds Currently Available

Pursuant to ARTICLE III, entitled "Limiation of Funds", Funds currently available and allotted to this grant amount to $20,702,273.96.

As a result of this modification the total amount of funds currently available and allotted to this grant is increased by $294,275.00 from $20,407,998.96 to $20,702,273.96.

RECIPIENT	GRANT OFFICER
ACCEPTED BY: _____ **SIGNATURE**	**UNITED STATES OF AMERICA** **BY:** _____
NAME AND TITLE **DATE**	**NAME OF GRANT OFFICER** **DATE** CRAIG D. LEBO Grants Officer

DEPARTMENT OF THE ARMY
U.S. ARMY MEDICAL RESEARCH ACQUISITION ACTIVITY
FORT DETRICK, FREDERICK, MD. 21701-5014

May 22, 1990

REPLY TO
ATTENTION OF

Major Support Contracts Branch

SUBJECT: Grant No. DAMD17-88-Z-8007
Modification No. P00014

Mr. John W. Lowe
Associate for HIV Research
The Henry M. Jackson Foundation for
the Advancement of Military Medicine
11426 Rockville Pike
Suite 400
Rockville, Maryland 20852-3007

Dear Mr. Lowe:

Enclosed for your records is a fully executed copy of Modification No. P00014 to Grant No. DAMD17-88-Z-8007.

If you have any questions concerning this matter, please contact the undersigned at (301) 695-2807.

Sincerely,

Joyce R. Richardson

Joyce R. Richardson
Grant Specialist

Enclosure

P.O.C.: J. RICHARDSON/mh/301-695-2807

GRANT AGREEMENT

GRANT NO.	EFFECTIVE DATE	GRANT AMOUNT	PAGE 1 OF 2
DAMD17-88-Z-8007 Modification P00014	SEE GRANT OFFICER'S SIGNATURE BLOCK	$45,372,967.00	

PROJECT NO. AND TITLE

Human Immunodeficiency Virus (HIV) Research

PERFORMANCE PERIOD	PRINCIPAL INVESTIGATOR
22 February 1988 - 24 February 1993	Bryce C. Redington, Ph.D.

AWARDED AND ADMINISTERED BY:	PAYMENT WILL BE MADE BY:
U.S. Army Medical Research Acquisition Activity/ATTN: SGRD-RMA-RCM Fort Detrick Frederick, Maryland 21701-5014	FINANCE AND ACCOUNTING OFFICE BLDG. 810, Fort Detrick Frederick, Maryland 21701-5000

AWARDED TO:	MAIL PAYMENTS TO:
The Henry M. Jackson Foundation for the Advancement of Military Medicine 11426 Rockville Pike, Suite 400 Rockville, Maryland 20852	The Henry M. Jackson Foundation for the Advancement of Military Medicine 11426 Rockville Pike, Suite 400 Rockville, Maryland 20852

SCHEDULE OF PAYMENTS	ACCOUNTING & APPROPRIATION DATA
NO CHANGE	SEE PAGE 2

GRANT SCHEDULE:

SEE PAGE 2

RECIPIENT		GRANT OFFICER	
ACCEPTED BY: John W. Lowe SIGNATURE		UNITED STATES OF AMERICA BY:	
NAME AND TITLE John W. Lowe Acting Deputy Executive Director	DATE 5/15/90	NAME OF GRANT OFFICER CRAIG D. LEBO, GRANT OFFICER	DATE 5/21/90

USAMRAA FORM 25-R 1 OCT 89

The purposes of this modification are:

1. To change the accounting and appropriation data on Modification P90010 as follows:

FROM: REIMBURSEABLE (NIH) Appro. No.75-9-0844, CAN: 9-8421107 9-8421009 $250,000.00

TO: 2102040 075-8119 623105.H29AC 4150 S18064 TY94 DCRNC0415 88Z8007 $250,000.00.

2. To add the following to Modification P90010:

"The total amount of this grant is hereby increased by $250,000.00 from $45,122,967.00 to $45,372,967.00."

3. To change the accounting and appropriation data on Modification P00013 as follows:

FROM: 2102040 075-8119 611102.S13 4150 S18064 TY97 DCRNC0415 88Z8007 NIH Agreement No. 1Y01-DE-80005-02 $294,275.00

TO: 2102040 075-8119 623105.H29 4150 S18064 TY97 DCRNC0415 88Z8007 NIH Agreement No. 1Y01-DE-80005-02 $294,275.00.

4. To change the Grantee's mailing address to the address printed on Page 1 of this modification.

5. To add $2,200,000.00 to the funds currently available on this grant. Therefore, ARTICLE II entitled, "Funds Currently Available" is hereby modified as follows: "Pursuant to ARTICLE III, entitled, "Limitation of Funds," funds currently available and allotted to this grant amount to $22,607,998.96. The above-stated allotment may be amended from time-to-time by the Granting Officer without concurrence of the Recepient."

This money is added under the following accounting and appropriation data:

2102040 075-8119 623105.H29AD 4150 S18064 AZ8D DCRNC0415 88Z8007 $2,200,000.00

6. All other terms and conditions of this grant remain unchanged. Total amount of funds currently available and allotted to this grant is $22,607,998.96.

POC: Joyce Richardson/wac/301-663-2034

GRANT AGREEMENT

GRANT NO.	EFFECTIVE DATE	GRANT AMOUNT	PAGE 1 OF 3
DAMD17-88-Z-8007 Mod. No. P00015	See Grant Officer's Signature Block	$45,372,967.00	

PROJECT NO. AND TITLE

Human Immunodeficiency Virus (HIV) Research

PERFORMANCE PERIOD	PRINCIPAL INVESTIGATOR
22 February 1988 - 24 February 1993	Bryce C. Redington, Ph.D.

AWARDED AND ADMINISTERED BY:	PAYMENT WILL BE MADE BY:
U.S. Army Medical Research Acquisition Activity/ATTN: SGRD-RMA-RCM Fort Detrick Frederick, Maryland 21702-5014	FINANCE AND ACCOUNTING OFFICE BLDG. 810, Fort Detrick Frederick, Maryland 21702-5000

AWARDED TO:	MAIL PAYMENTS TO:
The Henry M. Jackson Foundation for the Advancement of Military Medicine 11426 Rockville Pike Suite 400 Rockville, Maryland 20852	The Henry M. Jackson Foundation for the Advancement of Military Medicine 11426 Rockville Pike Suite 400 Rockville, Maryland 20852

SCHEDULE OF PAYMENTS	ACCOUNTING & APPROPRIATION DATA
No Change	See Page 2

GRANT SCHEDULE:

See Page 2

RECIPIENT		GRANT OFFICER	
ACCEPTED BY: John W. Howe SIGNATURE		UNITED STATES OF AMERICA BY:	
NAME AND TITLE John W. Howe Deputy Executive Director	DATE Jul 27, 90	NAME OF GRANT OFFICER CRAIG D. LEBO	DATE 7/31/90

USAMRAA FORM 25-R 1 OCT 89

The purposes of this modification are:

1. To correct Modification P00014, paragraph 5, to read: "To add $2,200,000.00 to the funds currently available on this grant. Therefore ARTICLE II entitled, 'Funds Currently Available' is hereby modified as follows: 'Pursuant to ARTICLE III, entitled, 'Limitation of Funds,' funds currently available and allotted to this grant amount to $22,902,273.96. The above-stated allotment may be amended from time-to-time by the Granting Officer without concurrence of the Recipient."

2. To correct Modification P00014, paragraph 6, to read: "All other terms and conditions of this grant remain unchanged. Total amount of funds currently available and allotted to this grant is $22,902,273.96."

3. To change the quarterly report due date to within 30 days after the end of each quarter in lieu of within 15 days after the end of each quarter. Therefore, ARTICLE VII,c.3. is changed to read: "Copies of the report shall be submitted to the addresses shown below within 30 days after the end of each quarter. Internal Government distribution will be made by those offices."

4. To add $17,211,405.04 to the funds currently available on this grant. Therefore ARTICLE II entitled, "Funds Currently Available" is hereby modified as follows: "Pursuant to ARTICLE III, entitled, "Limitation of Funds," funds currently available and allotted to this grant amount to $40,113,679.00. The above-stated allotment may be amended from time-to-time by the Granting Officer without concurrence of the Recipient."

This money is added under the following accounting and appropriation data:

2102040 075-8119 623105.H29AD 4150 S18064 AZ8D DCRN C0415 88Z8007 $12,335,567.29

2102040 075-8119 623105.H29AD 4150 S18064 AZ8D DCRN C0415 88Z8007 $4,625,837.75

2102040 075-8119 623105.H29AC 4150 S18064 TY99 DCRN C0415 NIH Agreement No. 2-Y01-AR-90008-01 88Z8007 $250,000.00

DERm.

5. All other terms and conditions of this grant remain unchanged. Total amount of funds currently available and allotted to this grant is $40,113,679.00.

SELECTIONS FOR THIS REPORT:
FUND: 0997, AREA: 201, ORG: 0701

		CURRENT MONTH			GRANT BUDGET YEAR - TO - DATE				
CODE	OBJECT DESCRIPTION	ENCUMBRANCES	EXPENDITURES	TOTAL OBLIGATIONS	OUTSTANDING ENCUMBRANCES	EXPENDITURES	TOTAL OBLIGATIONS	GRANT BUDGET (NOFA)	UNOBLIGATED BUDGET BALANCE
0601	SALARIES	0.00	0.00	0.00	0.00	1,036,851.41	1,036,851.41	1,036,851	0.00
0602	BENEFITS	0.00	0.00	0.00	0.00	173,279.06	173,279.06	181,898	8,619.30
0603	CONTRACT SER	0.00	0.00	0.00	0.00	172,830.76	172,830.76	0	172,830.76-
0604	ACTG/LEGAL	0.00	0.00	0.00	0.00	520.00	520.00	0	520.00-
0605	ADVERTISING	0.00	0.00	0.00	0.00	24,167.15	24,167.15	0	24,167.15-
0607	DUES,PUB,SUB	0.00	0.00	0.00	0.00	5,469.76	5,469.76	0	5,469.76-
0608	EQUIP RENT	0.00	0.00	0.00	0.00	6,245.51	6,245.51	0	6,245.51-
0609	EQUIP PURCH.	0.00	0.00	0.00	0.00	1,546,299.46	1,546,299.46	1,545,044	1,255.93-
0612	INSURANCE	0.00	0.00	0.00	0.00	2,923.00	2,923.00	0	2,923.00-
0613	MAINT/REPAIR	0.00	0.00	0.00	0.00	1,127.22	1,127.22	0	1,127.22-
0614	MEETING EXP.	0.00	0.00	0.00	0.00	645.20	645.20	0	645.20-
0616	POSTAGE/SHIP	0.00	0.00	0.00	0.00	4,362.45	4,362.45	0	4,362.45-
0617	PRINT/REPRO	0.00	0.00	0.00	0.00	729.64	729.64	0	729.64-
0618	RENT OTHER	0.00	0.00	0.00	0.00	55,162.71	55,162.71	55,163	0.00
0619	SERVICE CHRG	0.00	0.00	0.00	0.00	12.54	12.54	0	12.54-
0620	SUPPLIES	0.00	0.00	0.00	0.00	229,205.57	229,205.57	477,744	248,538.79
0621	TELEPHONE	0.00	0.00	0.00	0.00	8,042.92	8,042.92	0	8,042.92-
0622	TRAV/DOMEST.	0.00	0.00	0.00	0.00	39,506.98	39,506.98	42,007	2,500.45
0623	TRAV/FOREIGN	0.00	0.00	0.00	0.00	2,500.45	2,500.45	0	2,500.45-
0626	COMPUTER TME	0.00	0.00	0.00	0.00	625.00	625.00	0	625.00-
0630	TRAIN/EDUC.	0.00	0.00	0.00	0.00	12,790.42	12,790.42	0	12,790.42-
0654	OCC HLTH	0.00	0.00	0.00	0.00	8,619.30	8,619.30	0	8,619.30-
0655	PATIENT COST	0.00	0.00	0.00	0.00	48.30	48.30	0	48.30-
0665	RENOVATION	0.00	0.00	0.00	0.00	1,172,079.31	1,172,079.31	1,184,801	12,721.85
0667	SVC CONTRACT	0.00	0.00	0.00	0.00	9,782.15	9,782.15	0	9,782.15-
0690	INDIRECT EXP	0.00	0.00	0.00	0.00	362,648.62	362,648.62	361,483	1,165.62-
1620	ADP SUPPLIES	0.00	0.00	0.00	0.00	3,875.00	3,875.00	0	3,875.00-
2000	USU BUDGET	0.00	0.00	0.00	0.00	0.00	0.00	6,801	6,801.00
2691	USU-CD-AV	0.00	0.00	0.00	0.00	2,220.50	2,220.50	0	2,220.50-
2692	USU-STORE	0.00	0.00	0.00	0.00	2,478.44	2,478.44	0	2,478.44-
2693	USU-CD-DUPL	0.00	0.00	0.00	0.00	197.50	197.50	0	197.50-

HENRY M. JACKSO'[redacted]NDATION FOR THE
ADVANCEMENT OF [redacted]ITARY MEDICINE
DETAIL LISTING OF OBLIGATIONS VS. BUDGET
FOR MONTH ENDING 31-AUG-90

SELECTIONS FOR THIS REPORT:
FUND: 0997, AREA: 201, ORG: 0701

		CURRENT MONTH			GRANT BUDGET YEAR - TO - DATE				
CODE	OBJECT DESCRIPTION	ENCUMBRANCES	EXPENDITURES	TOTAL OBLIGATIONS	OUTSTANDING ENCUMBRANCES	EXPENDITURES	TOTAL OBLIGATIONS	GRANT BUDGET (NOFA)	UNOBLIGATED BUDGET BALANCE
	GRAND-TOTAL	0.00	0.00	0.00	0.00	4,885,246.33	4,885,246.33	4,891,793	6,546.63

SELECTIONS FOR THIS REPORT:
FUND: 0997, AREA: **2, ORG: ALL

		CURRENT MONTH			GRANT BUDGET YEAR - TO - DATE				
CODE	OBJECT DESCRIPTION	ENCUMBRANCES	EXPENDITURES	TOTAL OBLIGATIONS	OUTSTANDING ENCUMBRANCES	EXPENDITURES	TOTAL OBLIGATIONS	GRANT BUDGET (NOFA)	UNOBLIGATED BUDGET BALANCE
0601	SALARIES	0.00	0.00	0.00	0.00	3,433,510.51	3,433,510.51	3,418,543	14,967.56-
0602	BENEFITS	0.00	0.00	0.00	0.00	517,400.01	517,400.01	541,384	23,984.22
0603	CONTRACT SER	0.00	0.00	0.00	16,698.78	247,935.29	264,634.07	252,810	11,824.07-
0605	ADVERTISING	0.00	0.00	0.00	0.00	54,877.99	54,877.99	37,800	17,077.99-
0607	DUES,PUB,SUB	0.00	0.00	0.00	26.75	33,083.25	33,110.00	20,600	12,510.00-
0608	EQUIP RENT	0.00	0.00	0.00	0.00	5,971.74	5,971.74	7,200	1,228.26
0609	EQUIP PURCH.	0.00	0.00	0.00	10,901.84	1,543,824.96	1,554,726.80	1,520,939	33,787.33-
0611	HONORARIUM	0.00	0.00	0.00	0.00	2,000.00	2,000.00	4,000	2,000.00
0612	INSURANCE	0.00	0.00	0.00	3,159.48	22,325.86	25,485.34	33,200	7,714.66
0613	MAINT/REPAIR	0.00	0.00	0.00	10,237.52	20,294.21	30,531.73	62,125	31,593.27
0614	MEETING EXP.	0.00	0.00	0.00	1,520.74	1,079.71	2,600.45	4,000	1,399.55
0615	MISC. EXP.	0.00	0.00	0.00	0.00	174.59	174.59	6,500	6,325.41
0616	POSTAGE/SHIP	0.00	0.00	0.00	0.00	25,876.30	25,876.30	15,510	10,366.30-
0617	PRINT/REPRO	0.00	0.00	0.00	0.00	5,292.66	5,292.66	13,000	7,707.34
0618	RENT OTHER	0.00	0.00	0.00	0.00	214,129.74	214,129.74	211,595	2,534.74-
0619	SERVICE CHRG	0.00	0.00	0.00	0.00	52.00	52.00	2,050	1,998.00
0620	SUPPLIES	0.00	0.00	0.00	39,723.21	1,168,002.17	1,207,725.38	1,434,968	227,242.48
0621	TELEPHONE	0.00	0.00	0.00	280.00	28,827.05	29,107.05	35,600	6,492.95
0622	TRAV/DOMEST.	0.00	0.00	0.00	3,135.85	224,836.28	227,972.13	199,493	28,479.37-
0623	TRAV/FOREIGN	0.00	0.00	0.00	0.00	10,137.12	10,137.12	2,000	8,137.12-
0630	TRAIN/EDUC.	0.00	0.00	0.00	2,235.00	44,590.05	46,825.05	43,969	2,855.61-
0650	AUDIO VISUAL	0.00	0.00	0.00	0.00	590.00	590.00	6,500	5,910.00
0651	COMM SERVICE	0.00	0.00	0.00	39.90	34,473.77	34,513.67	11,560	22,953.67-
0653	LAB/DIAG TES	0.00	0.00	0.00	3,600.00	74,288.15	77,888.15	174,386	96,497.81
0654	OCC HLTH	0.00	0.00	0.00	0.00	18,573.05	18,573.05	15,667	2,905.85-
0660	PUB/PAGE FEE	0.00	0.00	0.00	0.00	800.00	800.00	1,000	200.00
0661	PROP MAINT	0.00	0.00	0.00	0.00	0.00	0.00	2,000	2,000.00
0665	RENOVATION	0.00	0.00	0.00	2,463.80	192,064.71	194,528.51	137,941	56,587.51-
0667	SVC CONTRACT	0.00	0.00	0.00	310.80	8,202.61	8,513.41	3,000	5,513.41-
0668	WASTE DISP	0.00	0.00	0.00	0.00	7,467.00	7,467.00	10,500	3,033.00
0670	MECH/ADP SER	0.00	0.00	0.00	0.00	480.00	480.00	0	480.00-
0671	UTILITIES	0.00	0.00	0.00	0.00	5,009.28	5,009.28	0	5,009.28-
0680	FINE/PENALTY	0.00	0.00	0.00	0.00	349.96	349.96	0	349.96-
0690	INDIRECT EXP	0.00	0.00	0.00	0.00	920,733.71	920,733.71	944,982	24,248.67
1609	ADP EQUIP	0.00	0.00	0.00	4,700.00	676,072.73	680,772.73	585,300	95,472.73-
1620	ADP SUPPLIES	0.00	0.00	0.00	2,824.00	181,844.76	184,668.76	225,020	40,351.24
2000	USU BUDGET	0.00	0.00	0.00	0.00	0.00	0.00	4,000	4,000.00
2515	USU-CONTRACT	0.00	0.00	0.00	0.00	0.00	0.00	1,000	1,000.00
2619	USU-GENERAL	0.00	0.00	0.00	0.00	665.61	665.61	0	665.61-
2691	USU-CD-AV	0.00	0.00	0.00	0.00	2,307.90	2,307.90	0	2,307.90-
2692	USU-STORE	0.00	0.00	0.00	0.00	19,539.70	19,539.70	11,100	8,439.70-
2693	USU-CD-DUPL	0.00	0.00	0.00	0.00	200.00	200.00	0	200.00-
3111	USU-EQUIP	0.00	0.00	0.00	0.00	25,241.00	25,241.00	0	25,241.00-

HENRY M. JACKSO[redacted]NDATION FOR THE
ADVANCEMENT OF [redacted]ITARY MEDICINE
DETAIL LISTING OF OBLIGATIONS VS. BUDGET
FOR MONTH ENDING 31-AUG-90

SELECTIONS FOR THIS REPORT:
FUND: 0997, AREA: **2, ORG: ALL

		CURRENT MONTH			GRANT BUDGET YEAR - TO - DATE				
CODE	OBJECT DESCRIPTION	ENCUMBRANCES	EXPENDITURES	TOTAL OBLIGATIONS	OUTSTANDING ENCUMBRANCES	EXPENDITURES	TOTAL OBLIGATIONS	GRANT BUDGET (NOFA)	UNOBLIGATED BUDGET BALANCE
	GRAND-TOTAL	0.00	0.00	0.00	101,857.67	9,773,125.43	9,874,983.10	10,001,243	126,260.15

HENRY M. JACKSO[redacted]UNDATION FOR THE
ADVANCEMENT OF [redacted]ITARY MEDICINE
DETAIL LISTING OF OBLIGATIONS VS. BUDGET
FOR MONTH ENDING 31-AUG-90

SELECTIONS FOR THIS REPORT:
FUND: 0997, AREA: **3, ORG: ALL

		CURRENT MONTH			GRANT BUDGET YEAR - TO - DATE				
CODE	OBJECT DESCRIPTION	ENCUMBRANCES	EXPENDITURES	TOTAL OBLIGATIONS	OUTSTANDING ENCUMBRANCES	EXPENDITURES	TOTAL OBLIGATIONS	GRANT BUDGET (NOFA)	UNOBLIGATED BUDGET BALANCE
0601	SALARIES	0.00	0.00	0.00	0.00	3,443,833.94	3,443,833.94	6,928,410	3,484,576.16
0602	BENEFITS	0.00	0.00	0.00	0.00	739,144.90	739,144.90	1,513,508	774,363.52
0603	CONTRACT SER	0.00	0.00	0.00	382,485.85	245,624.76	628,110.61	1,229,585	601,474.39
0605	ADVERTISING	0.00	0.00	0.00	6,775.70	65,688.44	72,464.14	78,170	5,705.86
0607	DUES,PUB,SUB	0.00	0.00	0.00	2,574.56	18,537.05	21,111.61	30,475	9,363.39
0608	EQUIP RENT	0.00	0.00	0.00	1,143.36	2,288.64	3,432.00	2,085	1,347.00-
0609	EQUIP PURCH.	0.00	0.00	0.00	340,159.07	338,415.69	678,574.76	9,330,441	8,651,866.46
0611	HONORARIUM	0.00	0.00	0.00	0.00	6,400.00	6,400.00	6,975	575.00
0612	INSURANCE	0.00	0.00	0.00	0.00	25,538.91	25,538.91	43,770	18,231.09
0613	MAINT/REPAIR	0.00	0.00	0.00	11,943.89	24,373.79	36,317.68	52,575	16,257.32
0614	MEETING EXP.	0.00	0.00	0.00	0.00	446.00	446.00	510	64.00
0616	POSTAGE/SHIP	0.00	0.00	0.00	1,594.42	14,286.71	15,881.13	52,617	36,735.87
0617	PRINT/REPRO	0.00	0.00	0.00	1,208.50	4,499.07	5,707.57	15,790	10,082.43
0618	RENT OTHER	0.00	0.00	0.00	74,490.68	174,827.30	249,317.98	289,158	39,840.02
0619	SERVICE CHRG	0.00	0.00	0.00	77.00	962.00	1,039.00	2,700	1,661.00
0620	SUPPLIES	0.00	0.00	0.00	421,600.87	766,587.33	1,188,188.20	2,231,958	1,043,769.53
0621	TELEPHONE	0.00	0.00	0.00	0.00	29,697.41	29,697.41	39,600	9,902.59
0622	TRAV/DOMEST.	0.00	0.00	0.00	12,657.75	221,217.58	233,875.33	477,405	243,529.37
0623	TRAV/FOREIGN	0.00	0.00	0.00	375.00	2,308.00	2,683.00	12,500	9,817.00
0624	SUBCONTRACT	0.00	0.00	0.00	156,128.22	109,571.78	265,700.00	266,000	300.00
0626	COMPUTER TME	0.00	0.00	0.00	322.14	6,520.42	6,842.56	0	6,842.56-
0630	TRAIN/EDUC.	0.00	0.00	0.00	980.00	24,733.19	25,713.19	27,325	1,611.81
0650	AUDIO VISUAL	0.00	0.00	0.00	0.00	0.00	0.00	9,790	9,790.00
0651	COMM SERVICE	0.00	0.00	0.00	6,885.51	34,846.98	41,732.49	46,250	4,517.51
0653	LAB/DIAG TES	0.00	0.00	0.00	28,944.77	99,288.28	128,233.05	187,803	59,569.95
0654	OCC HLTH	0.00	0.00	0.00	0.00	22,835.20	22,835.20	29,298	6,462.80
0660	PUB/PAGE FEE	0.00	0.00	0.00	0.00	0.00	0.00	3,150	3,150.00
0665	RENOVATION	0.00	0.00	0.00	27,622.14	486,455.70	514,077.84	866,673	352,595.16
0667	SVC CONTRACT	0.00	0.00	0.00	8,958.12	12,683.58	21,641.70	67,075	45,433.30
0668	WASTE DISP	0.00	0.00	0.00	271.82	4,218.44	4,490.26	8,626	4,135.74
0671	UTILITIES	0.00	0.00	0.00	0.00	16,660.89	16,660.89	16,200	460.89-
0680	FINE/PENALTY	0.00	0.00	0.00	0.00	148.69	148.69	0	148.69-
0690	INDIRECT EXP	0.00	0.00	0.00	0.00	957,010.41	957,010.41	2,286,419	1,329,408.21
1609	ADP EQUIP	0.00	0.00	0.00	177,779.19	147,990.97	325,770.16	345,760	19,989.84
1620	ADP SUPPLIES	0.00	0.00	0.00	13,820.33	50,746.15	64,566.48	107,500	42,933.52
2000	USU BUDGET	0.00	0.00	0.00	0.00	0.00	0.00	4,950	4,950.00
2691	USU-CD-AV	0.00	0.00	0.00	0.00	2,877.00	2,877.00	0	2,877.00-
2692	USU-STORE	0.00	0.00	0.00	0.00	16,271.67	16,271.67	0	16,271.67-
2693	USU-CD-DUPL	0.00	0.00	0.00	0.00	678.17	678.17	0	678.17-
2695	USU-CD-LAM	0.00	0.00	0.00	0.00	1,744.71	1,744.71	0	1,744.71-

HENRY M. JACKSO[redacted]UNDATION FOR THE
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FOR MONTH ENDING 31-AUG-90

SELECTIONS FOR THIS REPORT:
FUND: 0997, AREA: **3, ORG: ALL

		CURRENT MONTH			GRANT BUDGET YEAR - TO - DATE				
CODE	OBJECT DESCRIPTION	ENCUMBRANCES	EXPENDITURES	TOTAL OBLIGATIONS	OUTSTANDING ENCUMBRANCES	EXPENDITURES	TOTAL OBLIGATIONS	GRANT BUDGET (NOFA)	UNOBLIGATED BUDGET BALANCE
	GRAND-TOTAL	0.00	0.00	0.00	1,678,798.89	8,119,959.75	9,798,758.64	26,611,051	16,812,292.15

27-Sep-90

	YEALOCATION HIRE DATE	NAME 09/18/90	JOB TITLE
1	02/16/88 CENTRAL	LOWE, JOHN	HIV RESEARCH PROGRAM DIRECTOR
2	04/11/88 CENTRAL	SHAW, MARTHA	HEALTH CARE PLANNER
3	04/18/88 WARD 11	HALL, MARY K.	CLINICAL PROGRAM COORDINATOR
4	05/16/88 CENTRAL	PETERSON, LAWRENCE T.	CHIEF, FINANCIAL AND RESOURCES MANAGEMENT FOR HIV RESEARCH
5	06/06/88 GUDE DR	EDDY, GERALD, DVM PhD	LABORATORY DIRECTOR
6	06/13/88 WARD 76	STEVENS, LYNN	HIV CASE COORDINATOR
7	06/27/88 CENTRAL	SLINKARD, REVA	PROGRAM MANAGEMENT COORDINATOR
8	07/01/88 NAVY	JOHNSON, KEITH	HIV RESEARCH PROGRAM ASSOCIATE
9	07/11/88 WARD 11	NAU, NICKI	ASSISTANT COORDINATOR FOR PEDIATRIC HIV RESEARCH
10	07/11/88 WARD 52	OLIGNY, CHRISTOPHER	PHYSICIAN ASSISTANT
11	07/15/88 MED CTR DR	GENDLEMAN, HOWARD, MD	RESEARCH PHYSICIAN
12	08/01/88 MED CTR DR	KALTER, CHESTER, MD	RESEARCH PHYSICIAN
13	08/22/88 BLDG 7	ROLLER, TINA	RESEARCH PSYCHOLOGIST
14	09/01/88 CENTRAL	FITZGERALD, KATHY	INFORMATION SYSTEM MANAGER
15	09/12/88 BLDG 7	LAW, WENDY, PhD	RESEARCH PSYCHOLOGIST
16	09/19/88 WARD 52	LASHLEY, JESSIE	CLINICAL NURSE
17	09/26/88 BLDG 7	CARMACK, DESIREE	DATA ENTRY CLERK/TYPIST
18	09/26/88 WARD 51	MORGAN, CHARLENE	PHYSICIAN ASSISTANT-PEDIATRICS
19	09/26/88 WARD 52	DENT, HOWARD	NURSING ASSISTANT
20	10/01/88 WARD 11	KONZELMAN, JOSEPH, DDS	CLINICAL DIRECTOR-ORAL HEALTH RESEARCH ACTIVITY
21	10/01/88 NAVY	WAGNER, KENNETH, DO	SENIOR RESEARCH PHYSICIAN
22	10/03/88 BLDG 2 2B73	ESCOBAR, MATILDE	MEDICAL TECHNOLOGIST
23	10/31/88 GUDE DR	DANIELS, CHERYL	LABORATORY SUPPLY MANAGER
24	11/14/88 GUDE DR	McCUTCHAN, FRANCINE, PhD	PRINCIPAL INVESTIGATOR
25	11/14/88 WARD 11	PERRY, PAULA	ADMINISTRATIVE ASSISTANT/PERSONNEL TECHNICIAN
26	11/21/88 BLDG 1 1H00	SCHOPPERT, MONICA	DIAGNOSTIC RADIOLOGIC TECHNICIAN
27	12/01/88 GUDE DR	MOSCA, JOSEPH, PhD	PRINCIPAL INVESTIGATOR
28	12/12/88 BLDG 40	SHARP, ERICA S.	EPIDEMIOLOGIST/INTERVIEWER
29	12/12/88 WARD 52	HOFFMAN, BUENAVENTURA	LICENSED PRACTICAL NURSE
30	01/20/89 GUDE DR	ROSENBERG, YVONNE, PhD	PRINCIPAL INVESTIGATOR
31	01/30/89 GUDE DR	RITCHEY, DAVID	RESEARCH ASSISTANT
32	02/06/89 GUDE DR	RIVERA, LYNNE	ADMINISTRATIVE ASSISTANT
33	02/14/89 GUDE DR	D'ARCY, LISA	RESEARCH ASSISTANT
34	02/16/89 NAVY	KERNOZEK, PAUL	SENIOR PROTOCOL COORDINATOR
35	02/16/89 WARD 52	HATCHER, FRAN	NURSING ASSISTANT
36	02/21/89 WARD 52	CLAIBORNE, ELSIE	CLINICAL NURSE(NIGHT)
37	02/27/89 WARD 11	KIRKLAND-DEMPSEY, VONJA	RESEARCH MANAGER - ORAL HEALTH COMPONENT
38	02/27/89 CENTRAL	HUGHES, EDNA	SUPPLY OPERATIONS MANAGER
39	03/06/89 GUDE DR	O'HARA, KAREN	LABORATORY ADMINISTRATOR
40	03/13/89 WARD 52	YOUNG, LORETHA	CLINICAL NURSE
41	04/10/89 GUDE DR	SANDERS-BUELL, ERIC	RESEARCH ASSISTANT
42	04/10/89 AIR FORCE	BEAN, LINDA	SENIOR PROTOCOL COORDINATOR
43	04/12/89 CENTRAL	HUNTER, VICTORIA	GRAPHICS AND PUBLICATIONS PRODUCTION MANAGER
44	04/17/89 TAFT CT	NICKLAS, MARTIN	RESEARCH ASSISTANT II
45	05/12/89 AFIP	RIBAS, JORGE L, DVM	ANIMAL MODEL RESEARCH COORDINATOR-HIV RESEARCH
46	05/15/89 TAFT CT	WHITE, SHERRY D.	ADMINISTRATOR FOR LABORATORY RESEARCH MANAGEMENT/PROGRAM SAFETY M
47	05/15/89 WARD 52	WILLIAMS, KENNETH W.	LICENSED PRACTICAL NURSE
48	05/16/89 CENTRAL	McGUADE, ANNE MARIE	SECRETARY/TRAVEL COORDINATOR
49	05/22/89 WARD 52	STASKO, ROBERT S., MD	RESEARCH PHYSICIAN
50	06/01/89 BLDG T20	LEWIS, CHARLENE, PhD	HIV PSYCHOSOCIAL RESEARCH PROGRAM COORDINATOR

	YEALOCATION HIRE DATE	NAME 09/18/90	JOB TITLE
51	06/12/89 GUDE DR	BRENNAN, TERRANCE	RESEARCH ASSISTANT
52	06/13/89 GUDE DR	WHITE, BRIAN	RESEARCH ASSISTANT
53	06/19/89 WARD 11	SAN NICOLAS, KARMEN B	ADMINISTRATIVE SUPPORT ASSISTANT
54	06/26/89 CENTRAL	JOYNES, DEBORAH A.	GRAPHICS & PUBLICATIONS PRODUCTION ASSISTANT
55	07/05/89 GUDE DR	LAI, CHUN-YEN, PhD	PRINCIPAL SCIENTIST
56	07/10/89 CENTRAL	PEARSON, L. DENISE	RESEARCH SUPPORT ASSISTANT
57	07/17/89 CENTRAL	NEMAZIE, ANN	SYSTEM ADMINISTRATOR
58	07/17/89 TAFT CT	KERSEY, KATHRYN S.	RESEARCH ASSOCIATE
59	07/21/89 WARD 11	KONCHAN, CAROL L.	PERINATAL HIV RESEARCH COORDINATOR
60	07/24/89 TAFT CT	KUCHERA, MARY J.	RESEARCH ASSISTANT
61	07/24/89 WARD 11	GLASGOW, P. BETH	PEDIATRIC HIV CLINICAL DATABASE COORDINATOR
62	08/07/89 GUDE DR	HEGERICH, PATRICIA A.	RESEARCH ASSISTANT
63	08/11/89 BLDG 2 2B73	KALLOO, MARGRETE C.	MEDICAL TECHNOLOGIST
64	08/21/89 GUDE DR	TUCKER, WILLIAM C.	LABORATORY ASSISTANT
65	08/28/89 TAFT CT	SMITH, MICHAEL A.	RESEARCH ASSISTANT
66	09/01/89 CENTRAL	DRUMMOND, CYNTHIA	COST ANALYSST
67	09/01/89 WARD 11	TEMOSHOK, LYDIA, PhD	PRINCIPAL SCIENTIST/PROGRAM MANAGER FOR HIV STRESS MANAGEMENT
68	09/05/89 NAVY	DEAN, JANE A.	PEDIATRIC CLINICAL PROGRAM COORDINATOR - STUDY NURSE
69	09/11/89 WARD 11	ERICKSON, JOHN C.	DATA COORDINATOR
70	09/11/89 WARD 76	DE SOTO, ANN ROSE	WARD RECEPTIONIST
71	09/11/89 WARD 11	NANNIS, ELLEN DEBRA, PhD	CLINICAL/RESEARCH PSYCHOLOGIST FOR NEURODEVELOPMENTAL ASSESSMENT
72	09/11/89 WARD 76	VIRANI, NZEERA A., MD	HIV RESEARCH PHYSICIAN
73	09/18/89 WARD 11	McCARDLE, PEGGY D., PhD	CLINICAL/RESERCH LANGUAGE SPECIALIST FOR NEURODEVELOPMENTAL ASSES
74	09/18/89 CENTRAL	MORRIS, BILL	CONTRACTS MANAGER
75	09/25/89 WARD 76	SHELLIE, ELAYNE	PROTOCOL COORDINATOR
76	10/04/89 GUDE DR	KAUFMANN, VIKTORAS P.	RESEARCH ASSISTANT
77	10/06/89 AIR FORCE	DEPONTE, JOE	HIV RESEARCH PROGRAM ASSOCIATE
78	10/16/89 BLDG T20	KECK, LOIS T., PhD	SOCIAL SCIENCE ANALYST
79	10/30/89 CENTRAL	LORTON, LEWIS	SENIOR CLINICAL RESEARCH ASSOCIATE
80	11/01/89 WARD 11	SWINGLER, SCOTT	HIV RESEARCH PROGRAM ASSOCIATE
81	12/04/89 WARD 11	SMITH, MICKEY W	RESEARCH ASSISTANT
82	12/16/89 CENTRAL	NGUYEN, GEORGE	PROGRAMMER ANANLYST
83	12/18/89 BLDG 2 2B53	TEEL, LOUISE	MICROBIOLOGY TECHNOLOGIST
84	12/18/89 WARD 11	FEELY, BRIAN R.	LICENSED PRACTICAL NURSE
85	12/18/89 AIR FORCE	TATEISHI, DEIRDRE C.	PROTOCOL COORDINATOR
86	12/19/89 BLDG T2	GUTHRIE, VICKI	HISTOTECHNOLOGIST
87	12/20/89 WARD 11	WOODFORK, SHARLES L.	RECEPTIONIST
88	12/20/89 WARD 11	McNEIL, WILLIAM S.	PROGRAM SUPPORT ASSISTANT/MAIL HANDLER
89	12/22/89 CENTRAL	OLDROYD, MICHELLE	ASSISTANT HEALTH CARE PLANNER
90	01/01/90 USUHS	UNGAR, BETH L. M.D.	INTERNATIONAL HEALTH PROJECT OFFICER
91	01/02/90 CENTRAL	BEAVERS, TINA L.	SECRETARY
92	01/02/90 WARD 76	JONES, VIOLA L.	RESEARCH ASSISTANT/ADMIN
93	01/02/90 WARD 11	GOODWIN, DANA M.	PROGRAM SECRETARY
94	01/08/90 USUHS	MARTIN, LAURA JOAN	RESEARCH ASSISTANT
95	01/15/90 AIR FORCE	BALTES, SUZETTE MARIE	MEDICAL TECHNICIAN (MICROBIOLOGIST)
96	01/22/90 AIR FORCE	HANNIBAL, SANDRA L	MEDICAL TECHNOLOGIST (DIAGNOSTIC IMMUNOLOGY)
97	01/22/90 TAFT CT	WOOD, MARIA A.	RESEARCH ASSISTANT
98	01/22/90 WARD 11	CAREY, MARTHA ANN, PhD	LOCAL PROJECT MANAGER, BEHAVIORAL RESEARCH STUDIES
99	01/22/90 WARD 76	BURNS-GOMEZ, JACQUELYN	PROGRAM RESOURCE PLANNER/ASSISTANT ADMINISTRATOR
100	01/25/90 WARD 52	REMPSON, YOLANDA	NURSE ASSISTANT

	YEALOCATION HIRE DATE	NAME 09/18/90	JOB TITLE
101	01/25/90 WARD 76	BROOKS, SHEILA	MEDICAL RECORDS TECHNICIAN
102	01/29/90 AIR FORCE	BARNES, DIANA	NURSE PRACTITIONER
103	01/29/90 WARD 52	HEREFORD, JUANITA	MEDICAL RECORDS TECHNICIAN
104	01/31/90 WARD 76	POPE, DENISE	PROTOCOL COORDINATOR
105	02/01 90 S G OFFICE	COOK, DAVID R. Ph.D.	ASSOCIATE FOR COMPREHENSIVE SERVICES TO HIV INFECTED CHILDREN AND
106	02/05/90 AIR FORCE	MUNLEY, MARSHA KAY	RESEARCH CLINICIAN
107	02/07/90 WARD 76	HENDERSON, MICHELLE	MEDICAL RECORDS TECHNICIAN
108	02/16/90 AIR FORCE	POPLINSKI, LEE A.	RESEARCH ASSISTANT
109	02/16/90 GUDE DR	SURMAN, SONJA R.	RESEARCH ASSISTANT
110	02/16/90 AIR FORCE	URDIALES, CATHERINE	FLOW CYTOMETRY TECHNOLOGIST
111	02/16/90 AIR FORCE	GIBBONEY, AUDREY L.	TECHNICAL SUPPORT SPECIALIST
112	02/19/90 AIR FORCE	RODRIGUEZ, GILBERTO	PROGRAMMER/ANALYST
113	02/20/90 CENTRAL	HILL, DUANE O.	SUPPLY CLERK
114	02/26/90 WARD 76	SWATSON, MERCY	PROTOCOL COORDINATOR
115	02/26/90 GUDE DR	PAPERMASTER, SUSAN	RESEARCH ASSISTANT
116	02/26/90 WARD 52	JACKSON, BARBARA	CLINICAL NURSE
117	03/12/90 NAVY	SCHOUTEN, ANGELA T.	ADMINISTRATIVE ASSISTANT
118	03/12/90 CENTRAL	RAY, RONALD H.	PROGRAM SUPPORT ASSISTANT/COURIER
119	03/12/90 WARD 52	EAVES, VICTOR	CLINICAL NURSE
120	03/19/90 AIR FORCE	ROGERS, SHIRLEY R.	RESEARCH TECHNICIAN (CLERICAL)
121	03/19/90 CENTRAL	QUINN, KEVIN	COMPUTER SPECIALIST
122	03/19/90 AIR FORCE	MEDINA, LEAH C.	UNIT SECRETATY
123	03/26/90 WARD 76	OVADIA, REBECCA M.	PROTOCOL COORDINATOR
124	04/02/90 AIR FORCE	KOOPMAN, TAMMY	FLOW CYTOMETRY TECHNOLOGIST
125	04/02/90 AIR FORCE	KOZJAK, JOHN A.	RESEARCH ASSISTANT
126	04/02/90 WARD 11	JENKINS, WINSTON	DATA ENTRY CLERK
127	04/02/90 WARD 11	ROBERTS, ROSA	PROJECT ADMINISTRATIVE ASSISTANT (RV-26)
128	04/02/90 WARD 11	THOMPSON, ERLENE F.	PROGRAM SECRETARY
129	04/09/90 AIR FORCE	YOUNG-HUMPHREY, MELINDA	STAFF LICENSED VOCATIONAL NURSE
130	04/09/90 WARD 52	IRISH, DALIS	CLINICAL NURSE
131	04/15/90 AIR FORCE	AAKHUS, ROBERT A.	FLOW CYTOMETRY TECHNOLOGIST
132	04/16/90 WARD 51	SMITH, RENEE	CLINICAL/RESEARCH ASSESSOR
133	04/19/90 WARD 76	FOSTER, JANET S.	PHARMACY TECHNICIAN
134	04/30/90 MED CTR DR	WIER, JERRY P., Ph D	MOLECULAR VIROLOGIST
135	04/30/90 BLDG T2	COATES, JERRY	IMMUNOHISTOCHEMIST
136	04/30/90 TAFT CT	BIBLE, NANETTE	ADMINISTRATIVE ASSISTANT
137	05/01/90 NAVY	KOCH, JANE	PROTOCOL COORDINATOR
138	05/03/90 WARD 11	EVANS, LILLIE M.	DATA ENTRY CLERK
139	05/03/90 WARD 76	NIELSEN, ROBIN	CLINICAL NURSE
140	05/07/90 WARD 11	CURRY, ELLEN	CLINICAL RESEARCH ASSISTANT/NEURODEVELOPMENTAL ASSESSMENT
141	05/14/90 WARD 76	SKLAREK, IRENE	PROTOCOL COORDINATOR
142	05/14/90 WARD 11	BRADLEY, DOROTHEA	DATA ENTRY CLERK
143	05/15/90 GUDE DR	WAGNER, TARA J.	OFFICE ASSISTANT
144	05/21/90 TAFT CT	COHEN, HENNA	RECEPTIONIST
145	05/21/90 TAFT CT	LOPEZ, FELIX	PROTEIN BIOCHEMISTRY TECHNICIAN
146	05/25/90 AIR FORCE	BARBER, FAYE A.	REGISTERED NURSE
147	05/29/90 AIR FORCE	CORPREW, MARY-MARGRET	CLISNCAL STAFF LVN
148	05/31/90 WARD 11	BLAKE, SUSAN M.	SENIOR SCIENTISTS/PROJECT DIRECTOR PSYCHOLOGY NATURAL HISTORY
149	06/01/90 WARD 52	YOUNG, PAULINE	CLINICAL NURSE
150	06/01/90 ELLICOT CTY	MANDELSON, CHRISTINA	EARLY CHILDHOOD DEVELOPMENTAL SPECIALIST

	YEALOCATION HIRE DATE	NAME 09/18/90	JOB TITLE
151	06/01/90 CENTRAL	WIERZBA, THOMAS F.	EPIDEMIOLOGIST
152	06/02/90 WARD 11	JOHNSON, CECILLA T.	RESEARCH ASSOCIATES/LEBS INTERVIEWER
153	06/04/90 WARD 11	GOLDSCHMIDT, MICHELE H.	RESEARCH ASSOCIATE
154	06/04/90 WARD 76	PASCAL, LOUISE M.	PROTOCOL COORDINATOR
155	06/12/90 SAN DIEGO	REICH, SHELLENE D.	PEDIATRIC CLINICAL PROGRAM COORDINATOR
156	06/14/90 GUDE DR	PERERA, LIYANAGE PARAKRAMA	POSTDOCTORAL FELLOW
157	06/15/90 NAVY	BALFOUR, TERI F.	RESEARCH PHARMACY TECHNICIAN
158	06/15/90 BLDG 7	MAPOU, ROBERT L. Ph.D.	RESEARCH NEUROPSYCHOLOGIST
159	06/18/90 BLDG 40	GUBENIA, STEPHEN R.	EPIDEMIOLOGY/NATURAL HISTORY MISSION AREA PROTOCOL MANAGER
160	06/18/90 AIR FORCE	CROSS, CONNIE B.	EXECUTIVE SECRETARY
161	06/18/90 AIR FORCE	MOORE, GEORGE H.	CLINICAL STAFF NURSE
162	06/25/90 AIR FORCE	HUGHES, HUBERT M., III	SENIOR PROGRAMMER/ANALYST
163	06/25/90 AIR FORCE	PENNYPACKER, SUSAN	NURSE PROTOCOL COORDINATOR
164	06/25/90 WARD 11	HARTFORD, LAURA	SENIOR RESEARCH ASSISTANT
165	06/25/90 WARD 51	HOWARD, MELINDA L.	HIV EPIDEMIOLOGY PROTOCOL COORDINATOR FOR FAMILY SUPPORT
166	07/02/90 AIR FORCE	KENDALL, SARAH NESSELHOF	RESEARCH PSYCHOLOGIST
167	07/02/90 GUDE DR	ST. LOUIS, DANIEL C.	STAFF SCIENTIST, BIOCHEMIST
168	07/16/90 WARD 11	JENKINS, RICHARD A., Ph.D.	RESEARCH PSYCHOLOGIST
169	07/16/90 NAVY	RUIZ, NANCY M.	HIV RESEARCH PHYSICIAN
170	07/16/90 WARD 76	PLEASANT, JAMES D.	PATIENT SERVICES COORDINATOR/PATIENT EDUCATOR
171	07/16/90 TAFT CT	PERFETTO, STEPHEN	MEDICAL RESEARCH TECHNOLOGIST
172	07/23/90 GUDE DR	MARKS, CHRISTOPHER A.	RESEARCH ASSISTANT
173	07/30/90 NAVY	MARSH, SHARON J.	PROTOCOL COORDINATOR
174	07/30/90 WARD 11	KOLESSER, CAROL	PEDIATRIC PROGRAM SECRETARY
175	07/30/90 NAVY	FUJIMURA-JUSTICE, MARIE	PROTOCOL COORDINATOR
176	08/01/90 CENTRAL	ORGANIC, MIRIAM	COMPUTER PROGRAMMER
177	08/01/90 NAVY	FRANKEL, JANA L.	RESEARCH ASSISTANT
178	08/01/90 CENTRAL	MANSFIELD, JAY L.	CLINICAL RESEARCH ASSOCIATE
179	08/01/90 AFIP	HADICK, SUSAN P.	LABORATORY IMMUNOHISTOTECHNICIAN
180	08/01/90 CENTRAL	ESCOBAR, LAURA	COMPUTER OPERATOR
181	08/01/90 WARD 11	BURNETT, GLORIA	DATA ENTRY SUPERVISOR
182	08/06/90 CENTRAL	MAKINODAN, ROBERT H.	DATA ANALYST
183	08/06/90 NAVY	BOWEN, PHILLIP JAMES	RESEARCH ASSISTANT/ADMIN
184	08/06/90 WARD 51	WASER, JULIE	PEDIATRIC STUDY NURSE
185	08/06/90 NAVY	JEWETT, KATHRYN J.	PROTOCOL COORDINATOR
186	08/07/90 NAVY	BUTLER, DONNA L.	PROTOCOL COORDINATOR
187	08/10/90 NAVY	DEVINE, FRANK E.	PATIENT RECRUITER
188	08/20/90 TAFT CT	LOVELAND, JOAN E.	RESEARCH PROTOCOL COORDINATOR
189	08/20/90 TAFT CT	CHANG, GEORGE SU TAI	RESEARCH ASSISTANT I
190	08/20/90 TAFT CT	GOLD, LYN G.	RESEARCH ASSISTANT III
191	08/27/90 TAFT CT	WESTERLUND, L. ERIC	RESEARCH ASSISTANY I