

# UNIVERSITY OF HAWAI‘I SYSTEM ANNUAL REPORT



REPORT TO THE 2008 LEGISLATURE

Annual Report on the  
Hawai'i AIDS Research Program for 2008

Act 213  
Session Laws of Hawai'i 2007 (Section 87)

November 2007

November 7, 2007

**Report on Fiscal Year 2007-2008**

**Hawaii State Legislature Appropriation HIGHER EDUCATION –SECTION 87 for the Hawaii AIDS Clinical Research Program**

Reported submitted by Cecilia M. Shikuma M.D.

This Hawaii State legislative appropriation provided general and revolving fund appropriations for the University of Hawaii, Manoa (UOH 100) in the sums of \$800,000 and \$400,000 respectively for fiscal year 2007-2009 and similar amounts for fiscal year 2008-2009 to support the Hawaii AIDS Clinical Research Program and its operational costs. Annual reports were mandated. This report is therefore meant to provide a status report for fiscal year 2007-2008 on the state of the program and on the progress of research, training and care efforts which occurred and/or were initiated as a direct result of these allocated funds.

Fiscal Year 2007-2008 appropriations became available July 1, 2007 and have been used for salaries of programmatic personnel and for operating costs. The funds have enabled HACRP to retain its programmatic personnel and the ability to conduct research, training and medical care activities. Salaries (% FTE) for the following individuals have been supported by these funds: Faculty [C. Shikuma (60%), B. Shiramizu (31%), J. Rudnick (50%), A. McMurtray (35%), L. Marten (25%), L. Eron (1%), M. Gerschenson (12%), D. Chow (20%)]; Unit Coordinator D. Ogata-Arakaki (40%), Nurse Practitioner C. Milne (5%), Research Associate J Taylor (100%), and Clinic Coordinator J Chapman (100%). In addition, funds totaling approximately \$7,000 have been used for operating costs such as copier rental and maintenance, water, pager and physician exchange services.

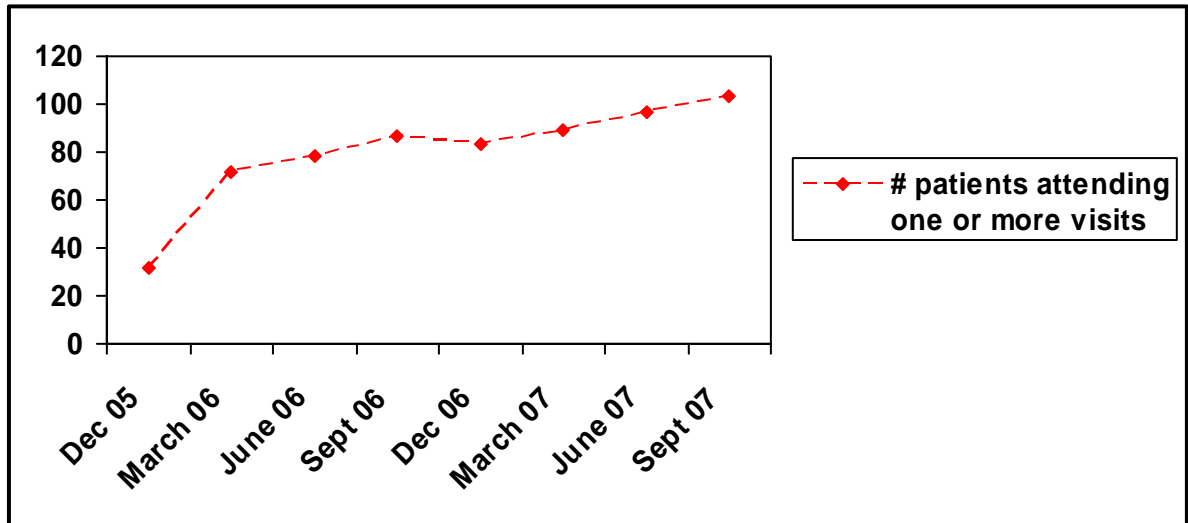
HACRP has used these funds to focus efforts in two crucial areas – providing ready access to and enhancing care for HIV-infected individuals in Hawaii and developing and maintaining a nationally competitive HIV research program for the University of Hawaii:

*Access to HIV Care:*

Our programmatic goals in this area are to provide high quality HIV medical care to disproportionately affected and underserved populations and to act as a HIV consultative resource for the medical community and related health organizations. State funding allowed HACRP to continue the operations of its Clint Spencer Clinic which provides HIV specialty consultative care as well as primary care for HIV-infected individuals. Currently 5 faculty MDs, one Nurse Practitioner, and one RN Clinic Coordinator/Patient Advocate each devote time during the week to provide care to approximately 300 HIV-infected individuals locally on Oahu and an additional 125 patients on the neighbor islands. A social worker from Oahu's AIDS Service Organization (Life Foundation) is available every other Wednesday to assist patients with social service needs. Clinic is held one-half-day/month each in Hilo and in Kona. A clinic was held on the beach in Waianae with assistance from the Life Foundation outreach worker for the first time in October 2007 targeting HIV-infected patients lost to follow up with complicated life situations (homelessness, substance use). This clinic may be continued, or it may be combined with a specialty clinic at the Waianae Coast Comprehensive Health Center. An additional one half-day/month clinic will start at the Maui AIDS Foundation premises this month.

The number of unduplicated patients seen per quarter to September 2007 is shown in the Figure 1 below. The goal of the Clint Spencer Clinic is not necessarily to increase patient volume or compete with private physicians but to ensure that quality health care is available to all HIV-infected individuals in Hawaii. The clinic serves a relatively indigent population. In the most recent quarter (July – Sept 2007) 20% of our clients were uninsured, 27% had Medicaid and 21% had Medicare. About one fourth of our clients are women and about 10% are part Hawaiian with an additional 13% being other Asian/Pacific Islander.

Figure 1: Number of unduplicated patients per quarter October 2005 – September 2007



In collaboration with Dr. Peter Whiticar, Director of the Hawaii State Department of Health Sexually Transmitted Disease Branch, Dr. Lisa Marten from our program is currently conducting a needs assessment study to better understand how we can support HIV medical care in locations with insufficient HIV specialists available. The intent is to use the assessment to formulate a sustainable plan for the future. The current problems are most acute on the neighbor islands and in rural Oahu. However, problems are also foreseen in Honolulu as several community physicians who care for significant numbers of HIV patients are approaching retirement age and younger community physicians have not shown an interest in developing expertise in HIV. The needs assessment will investigate the possibilities for providing support on *all* islands through satellite clinics or through technical support to local care providers. Technical support may involve a grant application by the UH School of Nursing to train HIV specialty Nurse Practitioners for the neighbor islands. In an effort to understand the current situation, data is being sought from a variety of sources. These include: health insurance companies, consumers of HIV care, providers of HIV care, potential health care providers such as community clinics, and other key stakeholders.

#### *HIV Research*

The state funds provided needed stability to HACRP faculty to write for and accept grants from NIH and other grant agencies, as well as to have the appropriately trained personnel available to conduct such research. In particular, it has allowed HACRP to retain personnel important to maintaining clinical trials expertise. HACRP continues to see patients already enrolled into the national AIDS Clinical Trials Group (ACTG) trials

and a small amount of phase-out funds will be available to HACRP through November of 2008. Our program has been accepted for participation in the AIDS Malignancy Consortium, a NIH-funded multi-center network of sites participating in trials of HIV-related cancers. HACRP continues its participation in the Vietnam PEPFAR (President's Emergency Plan for AIDS Relief) program. In addition, the following new clinical trials, one sponsored by a pharmaceutical company and one made available through a subcontract from another University, have been opened or are in contract negotiations:

- **Tibotec TMC114-TiDP31** "A randomized, open-label trial to compare the efficacy, safety and tolerability of DRV.rtv (800/100 mg) q.d. versus DRV/rtv (600/100 mg) b.i.d. in early treatment-experienced HIV-1 infected subjects"
- **Univ. of Colorado/NIAID COZI Study** "An Open-Label Randomized Clinical Trial to Evaluate the Efficacy and Safety of Short Course Antiretroviral Therapy for Acute or Recent HIV-1 Infection in Zimbabwe and the United States."

The continued existence of the HACRP program allowed the program to accept the following newly awarded grants which will bring a total of \$5.8 million in direct funding over the next 5 years to the University:

- **Project 3 Clinical Trials Shikuma, C (PI) within NIMH/NIH U19MH081835 UCSF Program Grant - McGrath, M (PI), 08/01/07-07/31/12** "Macrophage Targeted Therapy for HAD and HIV Disease" Major goal is to evaluate the use of polyamine biosynthesis inhibitors as macrophage-targeted therapy for HIV dementia. The goal of the project at the University of Hawaii is to conduct the phase I/early II clinical trials of these compounds; \$1.7 million over 5 years
- **NIAID/NIH R01AI074554 Gerschenson, M (PI) 05/01/08-04/30/13** "Global HIV Drug Therapies and Mitochondrial Complications and Mechanisms" Major goal is to evaluate the mitochondrial toxicity potential of HIV therapies within an antiretroviral clinical trial in a developing country which is directed by our program in collaboration with the Thai Red Cross AIDS Research Centre and the U.S. Armed Forces Research Institute of the Medical Sciences; \$2.5 million over 5 years
- **NIAID/NIH R21AI073250 Yu, Q (PI) 09/15/07-08/31/2009** "Development of Molecular Adjuvants for Therapeutic HIV Vaccines"; Major goal is to explore the role of molecular adjuvants for therapeutic HIV vaccines; \$250,000 direct funds over 2 years
- **NINDS/NIH R01NS053359 Ratto-Kim, S (PI) 08/01/07-07/31/12** "HIV Specific Immune Responses in Thai Individuals with HIV Dementia" The overall goal of the grant will focus on the role of cellular immune responses in patients with or without HIV Dementia in Thailand; \$1.2 million direct funds over 5 years.
- **Gilead Pharmaceutical Shikuma, C (PI) 11/01/07-10/31/08** "Advanced HIV Medical Training for SE Asia" The main goal is to continue advanced training in HIV care for physicians in SE Asia conducted by our SEARCH (South East Asia Research Collaboration with Hawaii) satellite program; \$150,000 direct funds

The following grants have been applied for since July 1, 2007:

- **NINDS/NIH 2U54NS043049 Shikuma C (proposed PI);** 02/01/08-01/31/13; “University of Hawaii NeuroAIDS Specialized Neuroscience Research Program Type II” The main goal will be to assess the role of insulin resistance in the development of dementia in older HIV-infected patients; requested funding \$2.5 million/5 years
- **NIAAA/ NIH R01AA017595 Gerschenson, M and Shikuma, C (proposed Co-PIs);** 02/01/08-01/31/13; “The Impact of Alcohol on HIV Metabolism”, The main goal is to assess the co-morbid or beneficial impact of alcohol on metabolic and mitochondrial changes induced by HIV; requested funding \$2.5 million/5 years
- **HRSA Ryan White Program Chow, D (PI)** “Dental Services for the Clint Spencer Clinic” submitted in response to the ‘Supporting Networks of HIV Care by Enhancing Primary Medical Care’s Intensive Capacity Building’ grant opportunity; The main goal is to obtain logistical support and equipment to initiate dental services for the Clint Spencer Clinic, requested funding \$52,700 direct