
The Birth of the RCMI Clinical Research Center is a Joint Venture of the University of Hawaii and Kapiolani Health

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Hawaii established a Clinical Research Center with collaboration from the University of Hawaii Pacific Biomedical Research Center, the John A. Burns School of Medicine and Kapiolani Health via a five year award from the Research Centers in Minority Institutions of the National Institutes of Health. Support offered includes consultative services for protocol design; epidemiological and biostatistical analysis; design of study forms; and data and specimen collection and analysis.

Introduction

For the first time in the history of its medical community, Hawaii has established a Clinical Research Center (CRC). This facility, located at the Kapiolani Medical Center for Women and Children (KMCWC) campus, was a collaborative effort by three community forces. These included the Pacific Biomedical Research Center (PBRC) and the John Burns School of Medicine, both located at the University of Hawaii at Manoa (UHM), and Kapiolani Health.

The Clinical Research Center resulted from a five year grant awarded by the Research Centers in Minority Institutions (RCMI) beginning October 1995. The RCMI, which has a mandate to foster development of clinical research through the establishment of administrative and clinical research infrastructure in designated minority centers, is part of the National Institutes of Health (NIH). These centers are similar to the General Clinical Research Centers (GCRCs) funded in over seventy major mainland academic centers for some 30 years. The difference is that the criteria and funding levels for awards to minority institution Clinical Research Center

grants are tailored to provide a stimulus to clinical research. General Clinical Research Centers are generally housed at institutions already with state of the art technology, and have investigators of national and/or international status. There was much more inpatient research thirty years ago. That fact coupled with concerns over expanding health care costs and the transition to managed care have directed the current trend toward outpatient research. Thus, the Clinical Research Center may be the only way for clinical research to survive the health care cost crunch of the 1990's.

In any case, the Clinical Research Center is the first opportunity for the State of Hawaii to provide a mechanism for our multi-ethnic population to participate in clinical research studies that address its health care concerns. Support offered Hawaii investigators through the Clinical Research Center includes consultative services for protocol design, epidemiological and biostatistical analysis, design of case report forms, assistance with treatment protocols, data collection, specimen collection and analysis, as well as data entry and analysis. The purpose of this report is to inform the Hawaii medical community about this new center as well as to review the activities of the first year.

Purpose

The specific purpose of the Clinical Research Center is to cultivate the development of high quality clinical research in the State of Hawaii, with a major goal being the growth of diverse clinical studies significant to health care issues of minority populations, and to stimulate interest and development of research expertise in junior and, particularly, minority investigators. The vision is to promote clinical research activities in our community and to encourage applications from all health care facilities and providers in Hawaii. The success of the center may lead to future grants from the National Institutes of Health and other agencies, as well as continued core support for the Clinical Research Center, thereby firmly establishing the Clinical Research Center as a community resource.

A centralized facility such as the Clinical Research Center was needed given the scattered nature of existing clinical and basic research activities in the community and the limited number of institutions involved in clinical and basic research. A "Consortium for Biomedical Research" was set up to bring together the institutions involved in biomedical research at the initiative of Dr Sally A. Myers, The Queen's Medical Center, to foster collaboration and sharing of state resources. The University of Hawaii at Manoa is one of these institutions through its John A. Burns School of Medicine and two of its Organized Research Institutes - Pacific Biomedical Research Center and the Cancer Research Center of Hawaii. The other institutions involved with research include the medical centers located in the major private, non-profit, community hospitals affiliated with the Medical School - Kapiolani Medical Centers, St.

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Francis Medical Center, Kuakini Medical Center, The Queen's Medical Center and Tripler Army Medical Center (TAMC). A goal of the Clinical Research Center is to avoid duplication, since the center not only serves the existing limited cadre of clinical researchers but also increases the critical mass by providing linkages between these and the basic researchers located predominantly on the Manoa campus. To bridge this gap, Kapiolani Medical Center for Women and Children has provided a central location with space on the hospital campus as well as matching pilot project seed monies, infrastructure support and clinical staff expertise.

From Proposal to Reality

Initially, the Clinical Research Center was to be housed in the Kapiolani Women's Center, a free standing facility several blocks from the hospital campus. However, after considerable administrative discussion, the Clinical Research Center was relocated to the hospital campus as it is much more convenient for investigators and staff and closer to hospital resources as required. With planned renovations successfully completed, the area measures 3500 square feet and consists of four patient exam rooms, a patient waiting area, a reception area, a storage and processing laboratory, a conference room, office space for all staff, and a storage area. However, although the Clinical Research Center was funded by the National Institutes of Health Research Centers in Minority Institutions program as of October 4, 1995, it took several more months before official notification was received, allowing appropriate organizational and administrative structures to be implemented to birth the center. Hiring of research personnel was a time consuming process due to funding concerns and constraints, as well as the limited availability of qualified research personnel in our small community.

Our staff of eleven is comprised of a Program Director, David Easa, MD; Program Coordinator, Susan Pelke, RN; three research nurses; an epidemiologist; a computer specialist; a laboratory assistant; an administrative secretary; a grants specialist; and a biostatistician. The current staff of experienced nurses and other research personnel resulted from not only an evaluation of qualifications and experience, but also an appreciation of personality traits that would foster the teamwork and collegiality necessary in creating an appropriate research infrastructure environment. It was also clear the research personnel hired for the Clinical Research Center were appropriately committed to the Research Centers in Minorities Institutions' goal of fostering quality clinical investigation into the health problems of minorities. In that regard, the research staff currently consists of an ethnic mixture of two Asian females, one Filipino female, one Filipino/Portuguese female, one Japanese/Caucasian male, three Caucasians females and three Caucasian males.

The extraordinary amount of time needed to assist potential investigators with protocol development was unanticipated. While many are experienced clinicians and/or specialists, few are adept at the research process. Because coaching of inexperienced investigators is a major goal of the program, many hours have been spent by the Program Director, Program Coordinator and staff in guiding potential investigators and revising protocols, thereby delaying actual protocol implementation.

Another unexpected, time-consuming and cumbersome situation is the current requirement for each protocol supported by our Clinical Research Center to be approved by at least two Institutional Review Boards (IRB). These bodies approve all studies to insure human subjects protection. Because University of Hawaii at Manoa is administratively responsible for Clinical Research Center activities yet research subjects are seen on the Kapiolani Medical Center for Women and Children campus, both the Kapiolani Medical

Center Institutional Review Committee and the University of Hawaii Committee on Human Studies must approve Clinical Research Center protocols. In an effort to ease this situation, Clinical Research Center stimulated discussions are progressing toward acceptance by the University's Committee on Human Studies to accept, without a second review, the recommendations of the Kapiolani Institutional Review Committee.

The Clinical Research Center's Scientific Advisory Committee (SAC) was established as the official source of review for scientific merit for potential Clinical Research Center protocols. Patricia L. Blanchette, MD, MPH, Director of the Division of Geriatric Medicine, University of Hawaii at Manoa School of Medicine, currently chairs the committee. In addition, representatives from each of the major hospitals of the community sit on the committee. Several institutions, including Kapiolani Medical Center for Women and Children, Pacific Biomedical Research Center, the Cancer Research Center, and the University of Hawaii at Manoa School of Medicine, have provided more than one member. The organization and construction of such a committee of clinical and basic science scholars committed to the Clinical Research Center was a long and laborious process, but one that forged a formidable group, displaying enthusiasm, expertise, and comprising some of the best clinical researchers in the community. To date, 16 projects have been approved and funded. These projects represent researchers affiliated with various institutions including Kapiolani Medical Center for Women and Children, Leahi Hospital, Pacific Biomedical Research Center, Queen's Medical Center, the Cancer Research Center, Tripler Army Medical Center, University of Hawaii at Manoa, and private physicians.

Research Environment

To support professional growth and development, our biostatistician has already conducted two consecutive six hour courses in biostatistics for our staff, current and potential investigators throughout the community as well as medical center and University of Hawaii at Manoa personnel. The course was co-sponsored by the Clinical Research Center and Kapiolani Health Resource Institute (KHRI) and is in keeping with our educational goals to foster research expertise for inexperienced investigators. Another Kapiolani-sponsored conference entitled "Protecting the Rights of Human Subjects in Research," was presented this summer and added to the expertise of community investigators involved or planning research with human subjects. Additional courses in epidemiology and other basic research topics are currently being planned.

Invitation to the Community

To advertise and encourage applications from community centers, the Program Director and Program Coordinator attended regularly scheduled Institutional Review Board meetings of each community hospital, presenting an overview of the Clinical Research Center and explaining the type and extent of support that may be possible for each institution or individual investigator. Originally, applications from hospitals other than Kapiolani Medical Center for Women and Children were limited, but there was a great desire to support clinical research studies proposed by investigators from other hospitals. This may expand the number and type of clinical research studies performed in the Clinical Research Center.

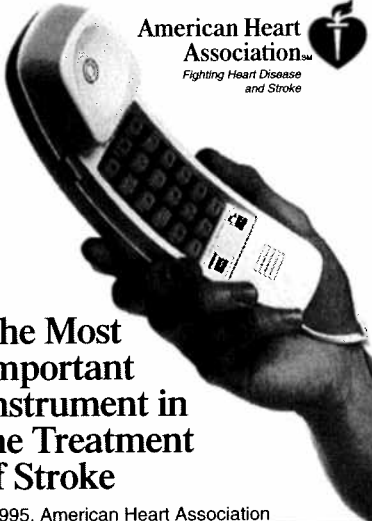
Since the Clinical Research Center has been funded for sixteen months, it is early yet to measure its impact on institutional development. As Clinical Research Center activities intensify over the next several years, a greater number of collaborations will be possible between institutions in the community, between the University and community hospitals, and between basic scientists and

clinicians. Investigator initiated research projects or RO1 awards are the primary research award from the National Institutes of Health for clinical and basic researchers. As these RO1 awards become more difficult to obtain, it becomes all the more important to combine the expertise and ability of basic scientists with clinical scientists to expand the focus and depth of any clinical research study with potential for meaningful data so a reasonable chance of being funded is possible in the future. We believe the central location for this collaboration should and will be in the Clinical Research Center.

Summary

For the first time, the State of Hawaii has a clinical research center to meet the health needs of its multi-ethnic population who are distanced from clinical research centers on the mainland. Major benefits of utilizing Clinical Research Center services are sharing expertise of the Clinical Research Center staff with potential investigators and expediting implementation of clinical studies. In short, the Clinical Research Center has brought about an opportunity for unlimited collaboration and cooperation between community resources to maximize the clinical research potential for the State of Hawaii and its people.

The Clinical Research Center is actively encouraging the submission of new protocols. Interested investigators are encouraged to call the Clinical Research Center at 973-5242 for additional information. Assistance is available with protocol design, as well as application submission, dates for Scientific Advisory Committee and Institutional Review Boards meetings. Help with other aspects of clinical research protocols development such as input by an epidemiologist and biostatistician, design of data collection forms, data collection, specimen collection and analysis, and data entry and analysis are also available.



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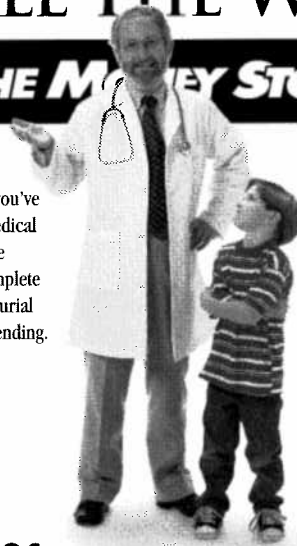
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