
Six Years and Counting: The NIH-funded Clinical Research Center of Hawaii

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Abstract

The CRC was developed in 1995 to make Hawaii a site of innovative, progressive research. Since then, the numbers of researchers and publications supported by the CRC have increased. In the next several years, the CRC will expand further into Hawaii's research community and apply for GCRC status, a strategy that will attract even more resources and investigators to JABSOM.

Introduction

In October 1995, the Clinical Research Center (CRC) was established to further the goal of making Hawaii a site for innovative, progressive clinical research. The Pacific Biomedical Research Center (PBRC) and the John A. Burns School of Medicine (JABSOM) at the University of Hawaii (UH) and Kapiolani Health (now referred to as Hawaii Pacific Health) collaborated to develop the CRC at Kapiolani Medical Center for Women and Children. Because Hawaii is a state of ethnic minorities, and in conjunction with JABSOM's commitment to expand its clinical research programs, the Research Centers for Minority Institutions (RCMI) program of the National Center for Research Resources (NCRR), National Institutes of Health (NIH), funded the original five-year grant award to the University of Hawaii. Last fall, the CRC achieved a five-year renewal to extend the center through 2005.

The mission of the RCMI program is to foster the development of clinical research through the establishment of an administrative and clinical research infrastructure in predominantly minority institutions. The CRC is the first programmatic opportunity for JABSOM to support junior clinical faculty members (many of whom represent ethnic minority populations) who wish to develop their own research studies, as well as those who have the goal of developing a career in clinical research.

The CRC provides qualified investigators with the resources necessary for developing and conducting clinical research studies, including access to clinical and laboratory facilities, assistance with protocol design, epidemiological and biostatistical analysis, data collection, specimen collection and analysis, and administrative and clerical support, as well as limited funding for study-related expenses. Since its inception in 1995, the CRC has expanded its facilities, resources and staff to 14.8 FTE's. As a measure of success of the CRC, it has been encouraged to apply for status as a General Clinical Research Center (GCRC), which will provide even greater resources and funding to expand clinical research at the University of Hawaii. If successful, this will provide further evidence of JABSOM's ability to pursue competitive research funding at a national level.

Purpose

The main objective of the CRC is to provide resources to investigators who have an interest in pursuing clinical research focusing on health problems affecting Hawaii's populations, including ethnic minorities, women and children. Indeed, in recent years, minority health and ethnic health disparity research has become a priority area of interest to public health, epidemiology, clinical and social science researchers. It has also become a priority area of research funding for the National Institutes of Health. Hawaii is a state with a population consisting mostly of ethnic minorities, and an ideal place to study ethnic disparities in health. The CRC is a part of the overall vision to improve the research milieu in order to further promote the health of Hawaii's people, and to solidify JABSOM's status as a research-intensive school of medicine.

Another purpose for the CRC is to provide a venue for collaboration between the diverse research and healthcare institutions in the state. Indeed, only one third of the research protocols conducted at the CRC are from investigators based at Kapi'olani Medical Center, where the CRC is located. The rest of the studies are generated from research investigators distributed among the community hospitals and research institutes of the University of Hawaii. To be sure, laboratory and clinical facility expansion to locations beyond its main site are part of the CRC's effort to engage Hawaii's health care and research community in participating in clinical research. Moreover, over the last six years, the CRC has cultivated close collaboration not only with investigators at JABSOM, but also with investigators from the University's two organized biomedical research institutes: the Pacific Biomedical Research Center and the Cancer Research Center of Hawaii. The CRC has also fostered research collaboration with investigators at the other local, community hospitals, including St. Francis Medical Center, Kuakini Medical

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Center, the Queen's Medical Center, Tripler Army Medical Center, and Straub Clinic and Hospital. The CRC plans to continue its goal of fostering greater collaboration amongst all of the major research, academic and healthcare institutions in Hawaii.

The CRC's central location, availability of clinical facilities and equipment, access to specialized hospital services, healthcare providers, and diverse patient populations, the expertise of its research staff, and ability to conduct research activities at the CRC's main facility or at other outpatient facilities in the community are some of the strengths that have contributed to the growth of the CRC. It is arguably the most productive and competitive of the six RCMI-funded CRC's in the nation. Further contributing to the CRC's participation in Hawaii's research environment are the summer educational short courses and symposia that the CRC offers each year, which include courses on basic biostatistics and epidemiology. In 2001, this was expanded to include presentations on grant writing, research ethics, and other research issues such as funding opportunities. The CRC also offers a summer research program for students, a Pediatric and Obstetrics and Gynecology residency research program to support the research programs in those respective departments, a faculty development program, and a post-graduate clinical research fellowship.

Current priorities of the CRC are to continue fostering clinical research interests in the investigator community, as well as increasing the number and quality of the clinical research protocols. Concentrating further on minority health issues is also a key emphasis of the CRC. In addition, the CRC will foster its support of research on chronic viral disorders, HIV and emerging pathogens, and addressing native Hawaiian health issues. Neonatal-perinatal health, women's health, cancer, cardiovascular disease, lung disorders, genetics, nutrition, and complementary and alternative medicine are also on the agenda for emphasis in future research.

Research Environment

The Clinical Research Center's primary outpatient clinical facility occupies approximately 4,500 square feet of space on the first floor of the Bingham Building on the Kapiolani Medical Center for Women and Children campus in Honolulu. It consists of four patient exam rooms, a waiting/reception area, a processing laboratory, conference room, and office space for staff. The CRC's molecular research laboratory, established in 2000, occupies approximately 2,390 square feet of space provided by Kapiolani Medical Center in their Young Street facility. Located within walking distance from the CRC's main facility at Kapiolani Medical Center, the molecular research laboratory has been designed with common bench areas, a tissue culture room, tissue processing room, dark room, radioisotope room, and ample storage and office space for investigators and laboratory staff. In addition, the laboratory facility is conveniently located near the UH campus.

Structure/Reality

The Program Director devotes a substantial amount of time to assisting junior investigators in their protocol designs as well as writing and submitting grants to the CRC and for other extramural funding. In addition, personnel support provided by the CRC includes research nurses and study coordinators, as well as biostatistical, epidemiological, computer/database, laboratory, clerical, grants

management, and administrative expertise. Over the last few years, the original staff and facilities has expanded as research protocol submissions have increased. As a key collaborator in the establishment of the CRC, Kapiolani Health Research Institute provides matching seed funds, infrastructure support and clinical staff expertise, all of which have further contributed to the success of the CRC over the last six years.

The CRC is committed to assisting investigators through the research development and application process. In fact, prior to formally writing proposals, they are encouraged to meet with the CRC staff to discuss research ideas, project feasibility, and strategies. This extended planning effort conducted "up front" is an essential step in coaching and developing junior investigators. Once the initial idea is refined through meetings with the CRC staff, the investigator completes the proposal and submits it to the CRC's Scientific Advisory Committee for review. Once funded, the investigator can proceed with implementing the study, analyzing the data, publishing results, and hopefully applying for larger extramural grant awards.

Development over last five years

Since its inception in 1995, the number of new protocols submitted to the CRC has more than tripled, with the vast majority being investigator-originated protocols. The number of publications produced and research grants awarded have also steadily increased. In fact, as a result of CRC support, the amount of dollars awarded to CRC investigators quintupled during the first five years of the center's existence.

Along with its successes, the CRC has also encountered a number of challenges. Although many CRC researchers are skilled and experienced clinicians, few have the expertise needed to design and conduct scientifically valid and competitive research studies. Although a goal of the CRC is to develop junior researchers into independent clinical investigators, the time expended in coaching and guiding investigators through the protocol development process often results in delays in actually implementing the studies. As a consequence of having such a small research community in Hawaii, the CRC has also had its challenges in recruiting qualified personnel experienced in clinical research. Although possessing essential clinical, administrative and interpersonal skills, new personnel recruited for CRC positions often require extensive orientation and training in the clinical research process. Despite these challenges, the CRC has steadily increased its number of researchers (Figure 2), while the number of manuscripts published by CRC affiliated investigators has also increased (Figure 3).

Finally, another challenge has been that protocols supported by the CRC often require approval by two or more institutional review boards (IRB) for protection of human subjects. The University of Hawaii is the primary institution for the CRC, though most studies are conducted on hospital or clinic campuses, requiring both the UH IRB and the participating hospital IRB(s) to approve the protocol. An ongoing effort has been made to establish cooperative agreements between UH and hospital IRB's in order to streamline the review and approval process for clinical research protocols. In fact, the CRC has benefited from one such agreement currently in place between the UH IRB and Kapiolani Medical Center IRB, allowing approval by one IRB with implicit acceptance by the other. It is

hoped that this agreement will be continued for the duration of the CRC grant, and in fact, expanded to include other hospital IRB's as well.

Future goals

Over the next five years, the CRC will strive to accomplish six major goals: to generate community-oriented, collaborative research effort across institutions; to increase the critical mass of clinical researchers in conjunction with the School of Medicine, the School of Nursing and Dental Hygiene and the Cancer Center of Hawaii; to pursue career development awards and other extramural funding opportunities; to facilitate translational research through the increase in UH basic science activity; to increase research protocols focusing on disorders affecting Hawaii's minority populations; and finally, to achieve status as a General Clinical Research Center (GCRC). Attainment of GCRC status will serve as an example both to our community and to the other RCMI-funded CRC's in the nation that growth into a competitive research-intensive institution despite financial and academic challenges is possible with vision and dedication.

Although ambitious, the goal of achieving GCRC status is a priority for UH. There are currently 78 GCRC's located at major medical centers throughout the US, comprising a national network of centers specialized in conducting state-of-the-art, patient-oriented research. GCRC's are generally located at prestigious medical institutions with established research programs, advanced technology, and investigators of national and/or international status with independent, peer-reviewed grant funding. In contrast, RCMI-funded CRC's, like Hawaii's, emphasize fostering research activity, developing promising clinical investigators, building a critical mass of expertise, and strengthening the overall research environment in order for the institutions to become more competitive for extramural funding. Achieving GCRC status will change the role of the CRC from one that primarily fosters clinical researchers to one that produces research of global relevance. The increasing emphasis on state-of-the-art, peer-reviewed research requires a cadre of dedicated and trained clinical investigators. At present, the University of Hawaii lacks this critical mass of investigators, although the efforts of the CRC have contributed measurably to the development of promising investigators with the potential for competitive, independent funding awards.

Summary

The success of the Clinical Research Center over the last six years attests to the commitment of Hawaii's research community to collaborate and contribute to clinical research scholarship. Indeed, the CRC has fulfilled a need for such a vital resource in the State of Hawaii. It has provided a locus for collaboration, support, and innovation that encourages both junior and seasoned investigator to pursue areas of interest and opportunities for clinical research. This will invite further funding and attracting even more experienced investigators to join the growing cadre of clinical researchers in the state, ultimately establishing the University of Hawaii and its affiliate institutions as producers of world-class, state-of-the-art clinical research.

Figure 1.— Number of Active Protocols supported by the CRC during the first five years.

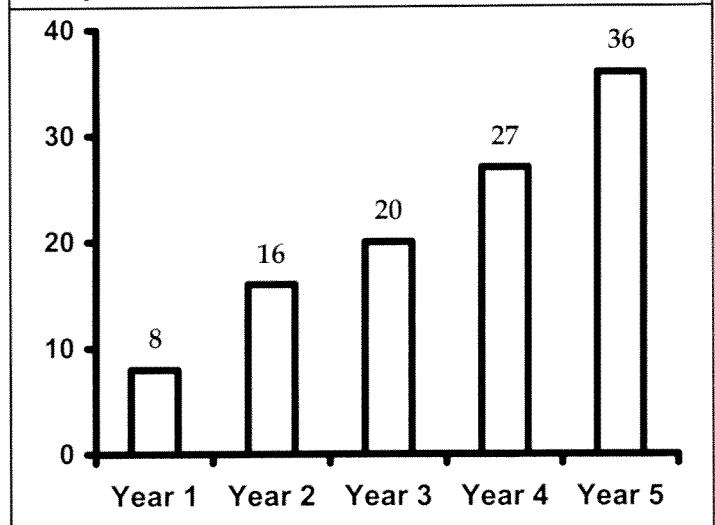


Figure 2.— Number of Investigators supported by the CRC during the first five years (Total = 141).

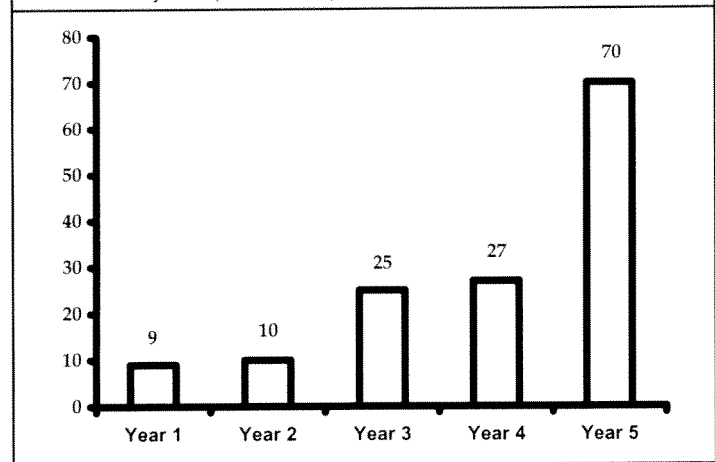
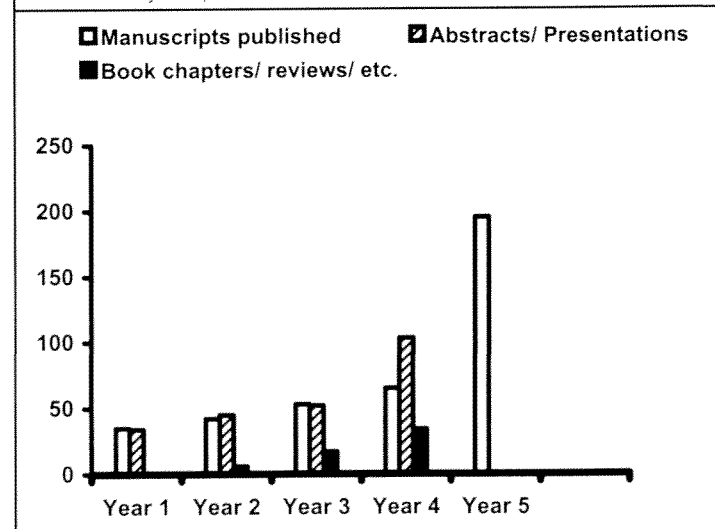


Figure 3.— Number of publications by investigators supported by the CRC. (Book chapters / reviews and abstracts / presentations not available for year 5).



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The Clinical Research Center actively encourages inquiries and applications. If you have an idea for a research study, please call 983-6242 or email crc@kapiolani.org for additional information.


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