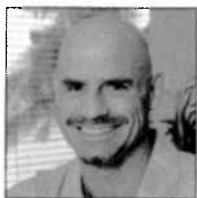


Growth in Clinical Research Productivity and Funding at the University of Hawaii's John A. Burns School of Medicine: The Past 10 Years

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This manuscript was generously supported by awards from the Research Centers in Minority Institutions (P20 RR11091) and the National Center for Research Resources (R25 RR019321), National Institutes of Health.

The authors would like to express their gratitude to Zoë Hammatt for her assistance in the preparation of this manuscript.

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Abstract

Over the last ten years, faculty at the John A. Burns School of Medicine (JABSOM) and the University of Hawaii (UH) have been actively engaged in ongoing efforts to increase the quantity and improve the quality of biomedical research in the State of Hawaii. JABSOM's Clinical Research Center (CRC), funded in 1995 by the National Center for Research Resources (NCRR) and the Research Centers in Minority Institutions (RCMI) of the National Institutes of Health, has provided research infrastructure that has been essential to these efforts. The CRC and other JABSOM departments and affiliated programs have collaborated with public and private entities within the community, particularly in the area of health, related to diverse racial and ethnic populations.

This paper sets forth a number of the significant indicators of research progress, as illustrated primarily through CRC support for various research activities conducted at JABSOM.

Introduction

In 1995, the University of Hawaii's Clinical Research Center (CRC) was funded by the National Center for Research Resources (NCRR) and the Research Centers in Minority Institutions (RCMI) of the National Institutes of Health. The CRC was established collaboratively by JABSOM, the Pacific Biomedical Research Center (PBRC), and the Kapiolani Medical Center for Women and Children (KMCWC). KMCWC hosts the CRC clinical outpatient facility, and CRC investigators also collaborate with other medical facilities and community health centers throughout the state to conduct clinical research studies. The CRC's principal objective is to provide vital infrastructure to foster clinical research relevant to the health needs of Hawaii's multiethnic communities. The CRC has supported research protocols in a broad range of clinical specialties. The majority of research studies conducted by the CRC address health disparities in the areas of infant mortality, cardiovascular disease, HIV/AIDS, perinatology and reproductive biology, neurosciences, diabetes, asthma, autoimmunity, and cancer.

To date, the CRC has provided support for nearly 200 investigators, including faculty, fellows, residents and medical students, as well as post-doctoral, doctoral, and master's degree candidates from JABSOM and other UH research institutes and departments.

Specifically, the CRC offers clinical and laboratory facilities for examining patients and collecting data as well as research nurse coordinators, study coordinators, biostatisticians, epidemiologists, laboratory assistants and other research personnel. These CRC staff members assist in protocol design and development, implementation of clinical research studies, data management, and analysis of results for publication. Upon renewal in Fall 2005, the CRC will further increase support for senior and junior investigators, emphasizing specific thematic research areas, and encouraging innovative, community-based collaborations. Acknowledging the disproportionate burden of disease upon particular racial and ethnic groups in the islands, the CRC ultimately strives to work with JABSOM's leaders to foster clinical research that will reduce disparities between and amongst such groups. Through the combined efforts of a broad range of individuals at UH and throughout the community, clinical research capacity at UH has continued to expand. To be sure, the CRC has been only one of the factors contributing to such expansion. Given the vast contributions of other individuals and factors to augmenting the university's biomedical research capacity, this paper focuses upon those directly related to JABSOM and the CRC.

Expansion of Clinical Research Capacity

Clinical research at JABSOM during the last ten years has evolved from dispersed independent efforts to interdisciplinary, collaborative projects. The first RCMI-funded program at UH (Selective Research Excellence in Biomedicine and Health) began in 1986 as a combined basic and clinical research program and is now in its 4th successful cycle. At least 25

Grant Applications Submitted

(* as of June 2004)

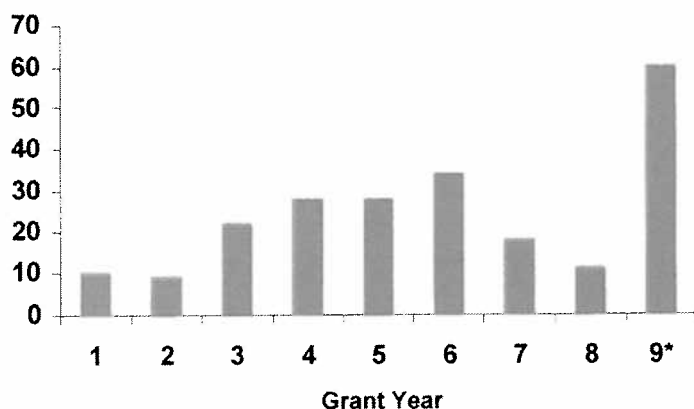


Figure 1.— Grant Applications Submitted by CRC-affiliated Investigators

Papers Published

(* as of June 2004)

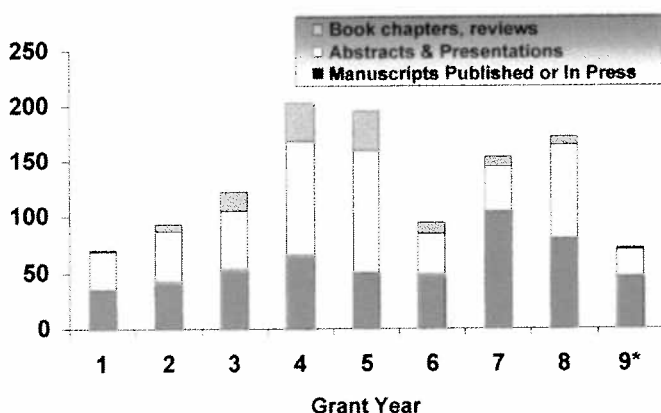


Figure 2.— Papers Published by CRC-affiliated Investigators

Total Value of Grants Awarded

(* as of June 2004)

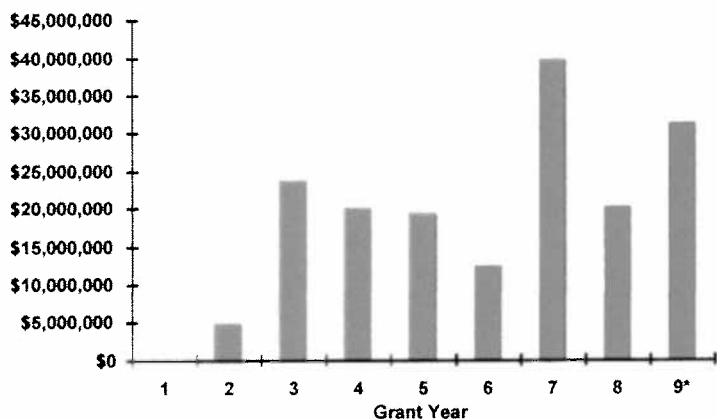


Figure 3.— Total Value of Grants Awarded to CRC-affiliated Investigators

major research programs have been funded in the last twenty years, including the CRC, the Center of Clinical Research Excellence (CCRE), the Masters in Clinical Research, the Interdisciplinary PhD in Clinical Research, as well as thematic research programs related to early human development, HIV/AIDS, retrovirology, molecular pharmacology, immunogenetics, cardiovascular disease, diabetes, emerging infectious pathogens, and neurosciences.

Increased collaboration between basic and clinical scientists is inherent to UH's expanded research capacity. Over the last 9 1/2 years, 69% of research proposals submitted to the CRC originated from MDs and 31% from non-MDs, including those investigators with PhDs. During this same period, out of 184 investigator-initiated studies conducted at the CRC, 43% of the studies resulted in publication, with another 41% resulting in successful grant applications. CRC investigators include faculty from JABSOM, PBRC, the Cancer Research Center of Hawaii (CRCH), the School of Nursing and Dental Hygiene (SONDH), and the College of Tropical Agriculture and Human Resources (CTAHR). There are currently 146 compensated clinical and 80.5 compensated basic science faculty members at JABSOM. Clinicians engaged in clinical research at JABSOM represent faculty from all departments and disciplines, and their affiliations link JABSOM and the CRC to each of the major hospitals as well as several community health centers on Oahu.

Biomedical research designed to benefit diverse ethnic populations is a vital component of JABSOM's research program. Indeed, a recent review of the NIH CRISP database reveals that out of 96 UH-based biomedical research grants, 42 programs involve aspects of minority health, at least 12 of which relate directly to health disparities research.

The number and diversity of investigators utilizing CRC resources, the outcome of protocols, and the success of CRC-affiliated investigators in publishing manuscripts and obtaining extramural support has continued to increase over the last several years.

Figures 1-4 illustrate the continued productivity of CRC investigators in terms of grant applications submitted, papers published, grants awarded, and grant dollars received over the last ten years.

All CRC protocols submitted from September 1995 through December 2004 were recently analyzed. The protocols were categorized as investigator-initiated or industry-sponsored. The investigator-initiated protocols were then identified in terms of approval status by the Scientific Advisory Committee (SAC). As illustrated in Figure 5 below, 238 protocols were submitted to the CRC during the last ten years, the majority of which were investigator-originated (224 or 94%). This demonstrates the CRC's emphasis on supporting hypothesis-driven research initiated by investigators, with limited support to pharmaceutical-

initiated or industry-sponsored studies (14 or 6%).

In keeping with the mission of the CRC, investigators are encouraged to develop protocols that address health disparities or adverse outcomes observed in the clinical or laboratory setting. Given the emphasis on investigator-originated protocols, substantial support is provided by the CRC's Protocol Development Team (PDT) to ensure sound scientific design. The high rate of SAC approval demonstrates the effectiveness of the PDT process. For example, of the 224 investigator-originated protocols submitted to the CRC, the SAC approved 184 (82%), while only 40 (18%) were deferred, disapproved, or withdrawn by the investigator due to relocation, new appointment, or loss of funding. Of the 184 protocols approved by the SAC, 112 (61%) were successfully completed, 12 (7%) were not completed, 43 (23%) are currently active, and 17 (9%) required only limited support for biostatistical consultation or scientific poster design and printing. Figure 6 illustrates the status of the CRC's 182 SAC-approved protocols as of December 2004.

CRC investigators who completed protocols demonstrated an 84% success rate in generating publications or grant awards. Of the 112 protocols completed, nine (8%) have led to the investigator obtaining an R-level award, 37 (33%) have led to the investigator obtaining salary support through a career development award, three (3%) resulted in grant submissions with notification of an award still pending, 48 (43%) have resulted in a publication, and only 15 (13%) were completed without publications or grant submissions.

Number and Qualifications of JABSOM Faculty

As of 2004, JABSOM has a full-time compensated clinical faculty of 146 FTE, with an additional 208 part-time members. There are also 80.5 FTE basic science faculty positions in the departments of Anatomy, Biochemistry, Physiology, Tropical Medicine and Microbiology, Pharmacology, Cell and Molecular Biology, and Pathology. These positions are partitioned to 101 individuals. Clinical faculty as categorized by academic rank is illustrated in Table 1.

Faculty and Research Development

Without a university hospital or dedicated institutional support for clinical or basic research development, JABSOM has relied upon extramural funding for new research programs. In this environment, the CRC has played a pivotal role in promoting the development of clinical research in the community. Indeed, over the last two years, the CRC Program Director has met with over 60 junior faculty to offer mentoring and career guidance; junior faculty are encouraged to develop pilot projects, participate in the Masters in Clinical Research and PhD in Clinical Research

Grant Dollars Received Per Year

(* as of June 2004)

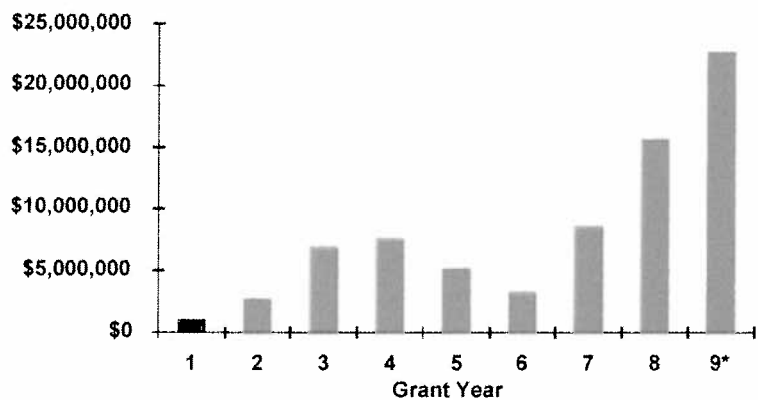


Figure 4.— Grant Dollars Received Per Year by CRC-affiliated Investigators

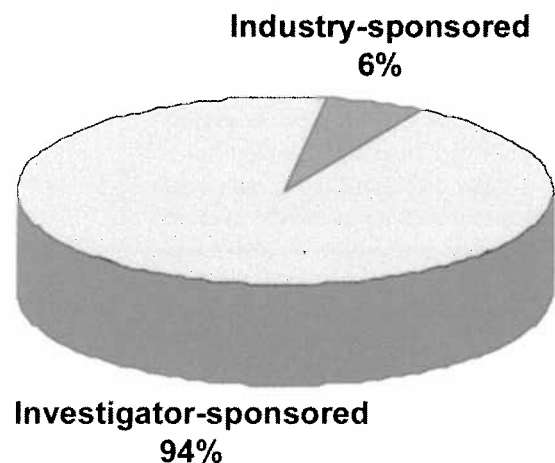


Figure 5.— Overall Distribution of CRC Protocols by Type of Protocol

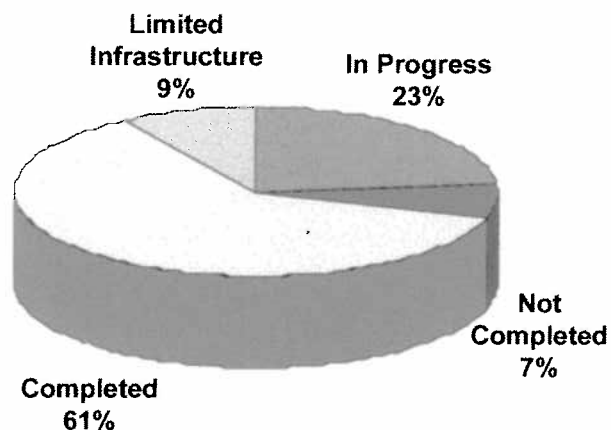


Figure 6.— Current Status of CRC Protocols (as of December 2004)

programs, establish collaborative links with other scientists and programs, and submit applications for career development awards.

Other JABSOM-affiliated Faculty

Several distinguished faculty members are affiliated with other research institutes. For example, the Pacific Health Research Institute (PHRI), lead by Dr. David Curb, conducts a number of renowned population-based epidemiological studies, such as the Honolulu Heart Program. Although PHRI is not fiscally linked to the University of Hawaii, it shares resources and faculty with JABSOM. PHRI collaborates with JABSOM and the CRC on several important research projects. Dr. Curb has been a member of the CRC's SAC, contributing valuable expertise to CRC-related studies and program governance.

Faculty from other UH research programs, including those at the CRCH, the SONDH, the CTAHR, and other departments such as the Department of Psychology, also participate in CRC activities.

Recent Grant Awards with Career Development Components

When the CRC was funded in 1995, there were no clinical faculty members with career development funds. As of 2004, the number of junior faculty supported by NIH grants with a significant component of salary support has progressively increased to 47, 26 of whom are JABSOM faculty. During the last year, the CRC Program Director and Grants Development Office have been involved in eleven major successful research and training grant applications that include aspects related to faculty training and career development. In addition, the CRC provides continued support for the programs as they evolve, including infrastructure, personnel, protocol and research application development, and continued mentoring and training of investigators and research staff. The applications listed in Tables 2 and 3, correspond to programs with significant emphasis upon training and career development. The amounts listed in Table 2 represent funding from July 2004 to October 2005 and not the full funding provided by each grant award.

Funded NIH Research Programs

Research funding has increased dramatically over the last five years. JABSOM has received more than \$60 million over the last two years (not all grants are listed below). Funding of the CRC renewal cycle (for years 2006-2011) will increase the amount to over \$70 million. The UH RCMI Steering Committee's commitment to promoting collaborations and resource sharing between NCCR- and RCMI-funded programs is reflected in JABSOM's continued efforts to link educational and research programs. Recent program grants and links to the CRC are illustrated in Table 4.

Clinical Faculty	Full Time Assistant	Full Time Associate	Full Time Prof
Allied Medical Sciences	4	4	1
Family Medicine	10	5	2
Geriatrics	8	2	2
Internal Medicine	7	5	7
Native Hawaiian Health	4	1	1
Ob-Gyn	6	1	3
Pediatrics	6	6	6
Psychiatry	11	5	6
Public Health	12	3	8
Surgery	1	3	3
Dean's Office & Others	2	1	0

Principal Investigator	Title	Source of Support	Award Number	Amount
Harrigan, Rosanne	Master of Science in Clinical Research (9 scholars)	NCCR	5 R25 RR019321-02	\$536,999
Boyd, Charles	A COBRE Center for Cardiovascular Research	NCCR	5 P20 RR016453-04	\$1,852,641
Cadman, Edwin	RCMI Clinical Research Infrastructure Initiative	NCCR	RR011091-10	\$1,706,492
Cadman, Edwin	Selective Research Excellence in Biomedicine and Health	NCCR	RR003061-19	\$2,778,974
Smith, Dean	Cellular Basis of Immunological and Neurological Diseases	NCCR	RR016467-04	\$2,431,230
Smith, Dean	Cellular Basis of Immunological and Neurological Diseases	NCCR	2 P20 RR016467-04 (Revised)	\$77,336
Spiess, Joachim	Emotion and Cognition on Gene, Cell, and Systems Levels	NINDS	2 U54 NS039406-06	\$1,966,926
Ward, Kenneth	Pacific Research Center for Early Human Development (5 scholars)	NCCR	1 U54 RR014607-06	\$2,326,992
Yanagihara, Richard	Clinical Center of Research Excellence: Pacific Center for Emerging Infectious Diseases Research	NCCR	RR018727-02	\$1,887,843
Total				\$15,565,433

New Recruitment Efforts

Upon his arrival, Dean Edwin Cadman initiated a highly active recruitment campaign designed to attract and retain distinguished, experienced faculty with long-term research experience. In turn, this has drawn junior investigators to join the UH faculty. New faculty members are listed in Table 5.

Institutional Changes and Support for Research Development

JABSOM has strengthened clinical research development through a strong emphasis on productivity as an incentive for promotion, the recruitment of nationally recognized scientists, and the collective decision by JABSOM faculty to earn the reputation as the top medical school with an Asian-Pacific focus. As illustrated below, JABSOM faculty have been highly successful in both scholarly and grants activities.

With Dean Cadman's encouragement and support, the chairpersons of JABSOM's clinical departments have been recruiting new faculty with both clinical expertise and research experience. During his five-year tenure at JABSOM, Dean Cadman was instrumental in accomplishing the following:

- Secured new positions for JABSOM with competitive salaries and start-up packages when negotiating employment terms as Dean;
- Established a new leadership structure at JABSOM by defining roles for new Associate Deans;
- Moved research to the forefront of JABSOM priorities, specifically making research productivity a requirement for tenure promotion;
- Developed a strategic plan for JABSOM that includes educational, training, and research objectives;
- Recruited national and internationally recognized basic and clinical scientists to JABSOM faculty;
- Designed strategies for funding the new Kakaako campus, which includes a new research building with 184,142 square feet of laboratories, offices and support space, and expansion plans that will enable collaboration with biotechnology companies;
- Formed new departments in Native Hawaiian Health, Complementary and Alternative Medicine, Geriatric Medicine, and the Division of Research Support Services (DRSS);
- Created the new Grants Development Office as part of the DRSS to increase JABSOM's competitiveness at obtaining extramural funding from private and public donors;
- Set up an environment in which research funding has increased by 700%.
- Began negotiations for a more realistic indirect cost recovery rate to support future research

Table 3.— Successful Applications Involving Training & Career Development

Submittal Date	Title of Project	RFA Number	Investigators	Total Amount
01/22/01	#3 - Hawaii State Biomedical Research Infrastructure Network (BRIN)	RR-01-005	Kenneth Mortimer, PhD (PI) Martin Rayner, PhD David Easa, MD Stephen Seifred, PhD Kelly Withy, MD	\$5,979,955
08/27/01	#4 - Hawaii Minority Research Infrastructure Support Program	PAR-01-101	Edwin Cadman, MD (PI) Russell Phillips, MD William Holzemer, PhD Todd Seto, MD Deborah Taira, ScD Robert L. Anders, APRN, DrPH Anne Wuerker, PhD, RN	\$1,071,820
09/27/01	#13 - Hawaii Science Training and Education Project (HiSTEP)	PAR-00-036	Kelly Withy, MD (PI) Mary Elizabeth Pateman, MEd, MPH Denise Hayashi-Forman Richard W. Smerz, DO	\$1,947,290
04/16/02	#22 - A Study of Oral Health Disparities in Adult Asian & Pacific Islanders (Planning Grant for Research to Prevent or Reduce Oral Health Disparities)	RFA-DE-02-005	David Easa, MD (PI) Rosanne Harrigan, EdD Mark Greer, DMD, MPH Carolyn Kuba, BS Ho'oipo DeCambra, BA	\$290,553
05/31/02	#12 - John A. Burns School of Medicine First Endowed Chair for the Department of Native Hawaiian Health	RR-01-007	Edwin Cadman, MD (PI) Benjamin Young, MD	\$4,687,000
05/22/02	#24 - Partnerships for Diabetes Related Disparities in Hawaii (Project EXPORT)	MD-02-002	Marjorie Mau, MD, MS (PI) Barbara Howard, PhD (Co-PI)	\$5,595,302
09/02	#26 - Partnership in Community Pediatric Research, Teaching and Service Project	Department of Defense Contract	Chris Derauf, MD (PI)	\$3,823,239
04/22/03	#35 - Masters in Clinical Research	RR-03-007	Rosanne Harrigan, EdD, MS, APRN-RX, FAAN (PI) David Easa, MD (Co-PI) James Davis, PhD (Program Director)	\$2,622,489
01/16/04	#41 - University of Hawaii Research Scientist Award in Molecular Cardiology	HL-03-015	Edwin C. Cadman, MD (PI) David Easa, MD (Project Director)	\$3,535,000
02-24-04	#42 - PhD in Clinical Research	RM-04-007	Rosanne Harrigan, EdD, MS, APRN-Rx (PI)	\$646,134
04-20-04	#45 - Pacific Research Center for Early Human Development (PRCEHD)	NOT-RR-04-003	Kenneth Ward, MD (PI) David Easa, MD (Associate Program Director) Peter Bryant-Greenwood, MD Richard Aillsopp, PhD Lynnae Millar, MD, Charles Neal, MD, PhD	\$10,918,600

development at Kakaako;

- Infused JABSOM with a renewed sense of vigor and enthusiasm, improving faculty and student morale while generating widespread community support for JABSOM efforts;
- Encouraged establishment of a new paradigm of community-based participatory research at JABSOM;

- Strengthened partnerships with the community by fostering an atmosphere conducive to direct collaboration with community health centers, the Hawaii State Department of Health, local hospitals and clinics, and private sector research entities; and
- Ensured that each of JABSOM's new and existing programs is consistent with the goals of Dr. Elias Zerhouni's NIH Roadmap Initiative.

There is no doubt that during his short tenure as Dean, Dr. Cadman made tremendous contributions to the research environment at the university and throughout the state. Indeed, as illustrated by faculty scholarly activity and grants productivity in the academic year 2002-2003 (Table 6) this environment continues to flourish.

Postdoctoral Fellows and Research Associates Involved in Clinical Research at the Institution

There are currently about 30 research associates supporting clinical and translational research programs at JABSOM. The number of JABSOM fellows and their specific disciplines are listed in Table 7.

Hiring of skilled technical personnel

Several new technical personnel are employed by JABSOM through grants, contracts, and institutional support, including the following:

- 88 Administrative and Professional Technicians
- 25 Research Technicians
- 9 Exchange Professors (consultants and collaborators)

Development of new or enhanced research and biotechnological capabilities

The expansion of research capacity over the last ten years has coincided with funding of focused research programs. Most of these programs rely on state-of-the-art cellular, molecular and genomic techniques. Collaborations between JABSOM and biotechnology companies continue to provide a platform for future growth, and many of our investigators are working diligently to improve capability in proteomics and other areas. The following cutting-edge translational and clinical research programs are led by faculty from JABSOM, in conjunction with a variety of nationally recognized collaborators. This is not an all-inclusive list of JABSOM research, but one that serves to illustrate the diversity of research interest and expertise at JABSOM.

NICRR: COBRE: (10.2 million) Center of Biomedical Research Excellence, Pacific Center for Emerging Infectious Diseases Research – Dr. Guliz Erdem has support from the CRC for her expanded studies.
NICRR: INBRE: (13.5 million) Hawaii State IDeA Networks for Biomedical Research Excellence – Will serve as a resource for CRC bioinformatics services.
NICRR: CRECD: (3.5 million) Clinical Research and Career Development Award, UH Masters in Clinical Research – All Masters students have CRC-approved studies.
NINDS: SNRP: (10.2 million) Special Neuroscience Research Program, Emotion and Cognition on Gene, Cell, and Systems Levels – One project on Methamphetamine abuse by Dr. Alicata in the Department of Psychiatry will be conducted in conjunction with the proposed MR Core under Dr. Linda Chang.
NHLBI: (3.5 million) University of Hawaii Research Scientist Award in Molecular Cardiology – Under recruitment, the research cardiologist is expected to work with the CRC as an active clinical investigator and engage in new and existing collaborations.
NHLBI: (3.5 million) Heart Failure Disparities in Native Hawaiians and Pacific Peoples – Expands opportunities for collaborative community-based research studies.
NICRR: CCRC: (10.9 million) The Center for Clinical Research Excellence, The Pacific Research Center for Early Human Development – recently funded, center staff for Phenotyping and Patient Sampling Core is located at KMC CRC facility, CRC resources to support the individual studies of Dr. Lynnae Millar's, with other investigators' project involvement under development.

Name	Department	Research Area
R. Yanagihara	Pediatrics	Virology & Emerging Pathogens
M. Berry	Cellular and Molecular Biology (CMB)	Selenium & Selenium Proteins
L. Chang	Medicine	Neuroscience & Imaging
K. Ward	Obstetrics & Gynecology	Early Human Development & Perinatology
S. Ward	IBR	Early Human Development
H. Rubin	Medicine	Health Services Research
M. Mau	Native Hawaiian Health	Diabetes
R. Harrigan	Complementary & Alternative Medicine	Health Disparities Research
D. Gubler	Tropical Medicine	Emerging Pathogens
M. Gerschenson	Medicine	Mitochondrial Research
J. Kim	Medicine	HIV Immunology
J. Spiess	CMB/Psychiatry	Neuroscience & Molecular genetics
T. Ernst	Medicine	Neuroscience & Imaging
C. Neal	Pediatrics (Neonatology)	Early Human Development
V. Andrew Stenger	Medicine	MR, Physics, Bioengineering
Molecular Cardiologist	Medicine	Recruitment underway
Chair	Department of Medicine	Recruitment underway

- The molecular epidemiology of tropical infectious diseases and emerging pathogens (Yanagihara)
- Neurodegeneration and dementia in AIDS (Shikuma)
- The effects of anxiety and stress in health and disease (Speiss)
- Health services research and quality improvement programs (Haya Rubin)
- Brain activation studies in HIV: Brain chemical changes in substance abuse (Chang, Ernst)

- The mechanisms and mediators of premature labor and delivery (Bryant-Greenwood and Millar)
- Community-based participatory diabetes research (Mau)
- Advanced genetics and clinical proteomics core laboratory facilities
- Periodontal disease in preterm labor and delivery (Millar)
- The role of selenium and selenium proteins in health and disease (Berry)
- The study of mechanisms and proteomics of preeclampsia (Bryant-Greenwood)
- Disorders of early human development that affect perinatal and neonatal health (Ward)
- Asian/Pacific Islander Youth Violence Prevention Center (Mark, Crim)
- Pacific People's Mental Health Research Support Program (Andrade)
- Methamphetamine Clinical Trials Group (Haning)
- Collaborative Alcohol Research Development and Planning (Goebert)

Each year, our medical school departments host several visiting scientists who conduct seminars and provide consultation for research activities. In addition, international experts frequently conduct seminars for JABSOM faculty, and several distinguished faculty from mainland institutions offer consultation and guidance on various research programs. Junior faculty members supported by career development funds also interact with esteemed mentors in Honolulu and elsewhere.

JABSOM Grants Development Office as a Resource

The JABSOM Grants Development Office was established in 2003 to facilitate the grants preparation and submittal process for CRC-affiliated investigators. The office works in close collaboration with the Dean's Office, the Fiscal Office and the Office of Research Services (ORS). The ORS retains responsibility for policy interpretation and institutional signatory authorization on all outgoing proposals. As part of the DRSS, the Grants Development Office is responsible for designing and administering effective procedural systems that help increase the probability of success.

SCHOLARLY ACTIVITIES	
Journal Articles	83
Abstracts Printed	73
Books/Chapters Published	35
Editorials Published	10
Other Media: videos, audios, etc.	29
Presentations	91
RESEARCH/TRAINING GRANTS/CONTRACTS	
Extramural Grants	128
Intramural Grants	23

	2000-01	2001-02	2002-03	2003-04
Family Medicine	1	1	1	-
Geriatric Medicine	11	13	12	11
Internal Medicine	-	-	4	1
Obstetrics-Gynecology	-	-	-	-
Pediatrics	3	3	3	3
Psychiatry	10	10	12	12
Sports Medicine	-	-	-	1
Surgery	7	9	8	6
TOTAL	32	36	40	34

The office reviews proposals, collaborative agreements, and financial and personnel requirements, and assists with budget preparation, grants writing, and a host of other activities. After a project is funded, the office ensures that all requirements are met prior to actual implementation.

Conclusion

Over the last ten years, JABSOM has expanded the depth and breadth of its clinical research capacity. The CRC has been only one of a myriad of factors contributing to the tremendous growth in biomedical research throughout the university. Through the above resources and with continued institutional support, the CRC will continue to provide the research infrastructure required for investigators to conduct innovative studies that will directly benefit Hawaii's communities. To be sure, greater interdisciplinary collaboration is fundamental to our progress. As we work together, JABSOM's leaders and devoted faculty strive to enhance current research programs as we invite greater community involvement in conducting and participating in meaningful research that will ultimately lead to a reduction of health disparities among Hawaii's diverse populations.