

Master's Degree in Clinical Research **Rosanne C. Harrigan**

Overview

The MS concentration in clinical research is a two year course of study intended for fellows and faculty who want to master clinical research methods and pursue independent research careers. Course work includes biostatistics, outcomes research and decision analysis and cost-effectiveness analysis. Requirements of the program include a presentation at a regional/national meeting, a systematic review of the literature, and publication of a clinical research report. Students (herein referred to as Scholars) will work closely with mentors in their home departments and preceptors chosen from the graduate faculty.

Objectives

- Acquire a mastery of a broad set of clinical research methods
- Plan and implement one or more clinical research projects
- Present research findings at one regional/national meeting
- Write a systematic review and publish one first-authored peer-reviewed original research paper.

Admission Requirements

- Admission to University of Hawaii Graduate Division
- Possession of an MD, PhD, DDS, Pharm D or the appropriate doctoral degree (exceptions considered)
- Ability to devote at least 50% time to this program and to the conduct of one's own research study
- Established relationship with a research mentor (can be accomplished after acceptance to the program)
- [TOEFL: Test of English as a Foreign Language:](#)
 - Paper-based Test Score of 600

or

 - Internet-based Test Score of 80, with the following minimum section requirements:
 - Reading: 19
 - Speaking: 20
 - Listening: 17
 - Writing: 21

Program of Study

36 Semester hours are required. Students will take the majority of their course work in the first year allowing for focus on independent research during the second year

Required Courses

Adult learning theory and problem-based learning will be used to ensure that graduates develop the skills to become self-directed learners. The five competency domains include research, professionalism/ethics, culturally competent leadership and communication, interdisciplinary collaboration, and self-directed learning. Traditional graduate course evaluations will be complemented by outcome evaluation criteria developed to determine whether students have met competency requirements.

Competency-Based Curriculum

Didactic Component (20) credits	Semester Credits
Introduction to Clinical Research and Informatics Applications in Research	2
Legal and Regulatory Issues, Bioethics and the Institutional Review Board	2
Applied Biostatistics in Clinical Research	3
Applied Clinical Epidemiology and Biostatistics	3
Bioanalytical Methods in Clinical Research	2
Clinical Research Protocol Development and Scientific Writing	3
Seminar	5
Research Practicum	8
Thesis	3
Elective course opportunities	5

Note: One semester credit is equivalent to fifteen contact hours in a semester.

Students must earn grades of B or better in all courses for successful completion; courses that do not result in a grade of B or better will not be counted toward the degree. An overall B average must be maintained to continue in the MS program.

Research Component (11 credits) - equivalent to a one-year research practicum. Requirements for completion are as follows:

- Approval of a research proposal.
- Receipt of IRB approval.
- Completion of a clinical research project.

- Preparation and presentation of an abstract for an oral or poster presentation at a regional/national scientific forum/meeting/congress.
- Preparation of a manuscript for submission to a peer-reviewed scientific journal.
- Completion of a thesis

Seminar Component (5 credits) - Enrollment in a one-credit seminar each semester during the curriculum will be required. Requirements for completion include:

- Consistent attendance at meetings.
- Acceptance of responsibility for all assigned seminar presentations.
- Satisfactory peer evaluations.
- Submission of self-evaluation portfolio describing learning outcomes.

Description Masters of Science in Clinical Research Competencies

Masters of Science in Clinical Research Competencies	Objectives
<p>Research: Develop and implement ethically and culturally appropriate clinical research that addresses health disparities in Asian, Pacific Islander, and Filipino populations.</p>	<ul style="list-style-type: none"> • Conduct clinical research with cultural competence. • Analyze and synthesize literature to ascertain state of the science in regard to selected areas of clinical research, especially health disparities in Asian, Pacific Islander, and Filipino peoples. • Use the Internet to access clinical research information. • Apply appropriate research methodologies to answer clinical research questions. • Demonstrate successful scientific writing skills by producing scholarly works and writing an approved clinical research proposal. • Make correct inferences from data. • Apply clinical research findings by implementing and monitoring an action plan based on relevant data.
<p>Professionalism/ethics: Conduct ethically responsible and culturally competent clinical research</p>	<ul style="list-style-type: none"> • Demonstrate knowledge of laws, regulations, and policies related to clinical research on the development and implementation of protocols. • Apply ethical principles in the design and conduct of clinical research, especially with disadvantaged and underserved populations.
<p>Culturally competent leadership and communication: Establish community- based research networks in selected area of clinical research interest</p>	<ul style="list-style-type: none"> • Communicate in a culturally competent manner with persons from diverse cultural, socioeconomic, educational, and professional backgrounds and with persons of all ages and lifestyle preferences. • Communicate effectively in writing and voicing demographic, statistical, and scientific information for professional and lay audiences.
<p>Interdisciplinary collaboration: Work collaboratively, interdependently and effectively with other members of the clinical research team</p>	<ul style="list-style-type: none"> • Manage clinical research project, including budget. • Recruit and supervise necessary staff for clinical research project. • Demonstrate the ability to manage research team task assignments. • Demonstrate good interpersonal skills, including the ability to work interdependently with other clinical research team members.
<p>Self-directed learning: Demonstrate the skills for self-directed learning</p>	<ul style="list-style-type: none"> • Be able to obtain appropriate feedback, consultation, and/or review before, during, and after a research project. • Conceptualize and synthesize the state of the science related to selected clinical research questions.

RESEARCH ACTIVITIES AND TRAINING EXPERIENCES

Students will participate in a seminar series, attend courses, and complete a mentored research project. Seminars will explore health issues in Hawai'i, focusing particularly on health disparities, and will enable students to interact with leading clinical researchers in Hawai'i. Courses will provide the methodological foundation and the practical tools that will prepare students to conduct clinical investigations. The mentored projects will facilitate in-depth learning that will enable students to become leaders in their chosen fields.

Seminar series

The seminar series will provide a broad overview of research, health and health disparities topics in Hawai'i. The series will invite participation of leaders from both research and community settings. Seminar topics will include ethnic disparities in health research, Native Hawaiian health, childhood research initiatives, fitness and obesity research, social and cultural factors related to health outcomes, and ethical aspects of research. The seminar series will cover both studies of clinical outcomes and health services. As small group discussions, seminars offer a forum for exchange of ideas and nurturing of students' relationships with instructors, many of whom may also serve as mentors for students' individual projects.

As an extension of the seminar series, the UCSF consultants, Stephen Hulley, Charles McCulloch, Bernard Lo, Deborah Grady, and Jeff Martin, will conduct an annual two-day teaching seminar, focusing on current issues in clinical epidemiology, biostatistics, and bioethics.

Course offerings

Required courses will utilize the "learn by doing" and "just in time" approaches so effectively promoted in the UCSF program. Small class sizes will encourage learning by participation, and didactic teaching will be incorporated as needed into active discussion format. At least 50% of class time will focus on interactive exchange, and whenever possible, courses will incorporate individual trainee projects. For example, each student will analyze his or her own clinical dataset as part of the Biostatistics course.

- The first semester will introduce students to clinical research, methods in epidemiology and biostatistics, regulatory issues, and bioethics. Bioethics will be introduced early in order to instill ethical principles into all aspects of students' work. Two first semester courses cover biostatistics: one teaches introductory statistical methods; the other, statistical methods in epidemiology. The Applied Clinical Epidemiology and Biostatistics course will emphasize observational studies and randomized trials. For their class project, each trainee in the clinical epidemiology course will design a study he or she might choose as a practicum project. By the end of the first semester, the students will be able to grasp basic processes of building patient-oriented research studies, understand biostatistics and clinical epidemiology, and analyze bioethical issues in clinical research.
- The second semester will build upon the foundations laid in the first semester. In biostatistics, students will learn regression methods for continuous, binary, count, and time-to-event data. As their course project, students will perform analyses of secondary datasets. "Learning by doing" is especially important in biostatistics where abstract concepts must be applied to real clinical problems. The second semester will also introduce bioanalytic methods in clinical epidemiology. Students will learn the rationale, applications, and limitations of clinically relevant methods. Topics will range from an introduction to molecular genetics and gene mapping to methods for detecting gene and protein expression. In the second semester, students will also be offered their first elective course, and will be encouraged to build individual strengths and pursue unique interests. By the end of the summer, students should be able to analyze research data

with limited supervision, and should know how to apply bioanalytic methods in clinical research.

- In the third semester, students will learn protocol development and scientific writing. This training is “just in time” in that students must present protocols to their research committees by the end of the semester. Students will write their protocols as a class project. In the third semester, the students will also take one or two elective courses. Students can select courses in epidemiology or biostatistics, qualitative or survey methods, basic science, genetics, or other areas of interest. By the end of the third semester students will be prepared to start their independent mentored projects.

Accomplishment of the Following

Presentation at a National Meeting: This requirement involves submission of a first-authored abstract to a regional/nationally recognized scientific meeting/conference within the scholar's academic field and acceptance of the abstract for either poster or oral presentation. The abstract should describe a formative study and not simply a case report or case series. While the topic of the abstract is expected to be closely related to the scholar's systematic literature review, the abstract should not solely consist of a systematic review or meta-analysis.

Preparation of a systematic review: Using unbiased means of identifying studies, the scholar will compose a comprehensive review of the literature pertinent to his or her research question. This review should take the form of either a 3-5 page report similar in format to the "Background and Significance" section of an NIH proposal or an "Integrative Review Paper" suitable for submission to a peer reviewed journal. If appropriate the scholar will use meta-analysis techniques to quantitatively summarize the available literature and to describe, integrate and consolidate any controversial aspects. . All scholars will present their review during a session of the Seminar. This requirement should be completed by the end of the first year of the program. It is anticipated that many, if not all scholars will submit their review for publication.

Publication as first author of a peer-reviewed clinical research report: Using data analyzed during residence in the MS program, the scholar will prepare and submit a first- authored manuscript for publication in an approved peer-reviewed journal. It may be acceptable in selected cases, upon approval of the student's Committee to submit a publication related to a research project that was initiated prior to the student's enrollment in the program but completed during the program. The manuscript should describe a formative study and not simply a case report or case series. The manuscript may be a comprehensive extension of the work submitted in abstract form to a regional/national meeting, but may not consist solely of a systematic review or meta-analysis (although scholars are encouraged to submit integrative reviews for additional publications). Achievement of this requirement will be considered complete upon satisfactory review by the scholar's Master's Committee and upon written correspondence indicating receipt of the manuscript by an approved peer-reviewed journal.

Instructional Experience in Clinical Research

All scholars will be required to serve as instructional assistants for one semester for one of the courses in the program. This experience will typically involve leading a group of 10-15 student for 3 hours a week for 15 weeks. Scholar's will work with their Master's Committee to choose the most appropriate venue for their instructional experience, based on their previous experience, interests and strengths and weakness. Scholar's will receive feedback on their performance from both the Course Instructor and from students, who will be polled anonymously using the web-based course evaluation system.

Master's Committee

A complete description of the process for establishing your committee is provided in the Graduate Division Manual. The web site for the manual is listed below.



<http://www.hawaii.edu-graduate-download-manuals-gdmanual.pdf.url>

See Graduate Division Manual at this web address.