

**University of Hawaii at Manoa  
John A. Burns School of Medicine  
Course Overview  
Dr. Rosanne C. Harrigan**

**Course Number:** 640

**Course Title:** Introduction to Clinical Research and Informatics Applications in Research

**Course Credit:** 2 credits

**Prerequisite:** MD, PhD, or equivalent doctoral degree or permission of instructor

**Placement in Curriculum:** Spring Semester (first semester)

**Course Description:** This course provides instruction in developing a clinical research question and creating a concise protocol that includes a literature review, study design, subject recruitment and sampling, instruments and other measurement approaches, sample size, consent form, budget and timetable and use of bioinformatics. Each trainee reviews and supports the work of colleagues. The course closely follows the textbook *Designing Clinical Research*, by S. Hulley.

**Course Objectives:** In this course, students will:

- acquire the skills for designing and interpreting clinical research, including appropriate informatics;
- produce a complete concise draft of a research protocol;
- help others in the class to develop these skills and protocols;
- provide feedback that will improve the course and its materials; and in time, contribute to the field by teaching these skills to others.

**Learning Outcomes**

At the conclusion of the course students will be able to:

use of informatics to design and interpret clinical research  
prepare a first draft of a research proposal  
collaborate with other researchers on protocol development  
possess the skills to contribute to the field by teaching basic research skills to others

## **Topical Outline:**

### General Sessions

Getting Started: the anatomy of clinical research  
Conceiving the Research Question  
Choosing the Study Subjects: Specification, Sampling, and Recruitment  
Planning the Measurements: Precision, Accuracy and Informatics  
Getting Ready to Estimate Sample Size: Hypotheses and Underlying Principles  
Estimating Sample Size and Power: The Nitty-gritty  
Designing an Observational Study: Cohort Studies  
Designing an Observational Study: Cross-sectional and Case-control Studies  
Enhancing Causal Inference in Observational Studies  
Designing an Experiment: Clinical Trials I  
Designing an Experiment: Clinical Trials II  
Designing Studies of Medical Tests  
Research Using Existing Data: Secondary Data Analysis, Ancillary Studies, and Systematic Reviews and informatics  
Addressing Ethical Issues  
Designing Questionnaires and Data Collection Instruments  
Data Management and informatics  
Implementing the Study: Pretesting, Quality Control, and Protocol Revisions  
Community and International Studies  
Writing and Funding a Research Proposal

## **Teaching Methods**

Discussions of interest emerging from the previous week  
Illustrations of selected aspects of the readings from current week  
Review of assigned protocol assignments  
Weekly Exercises  
Critique of Protocols  
Submission of protocol by email

## **Required Texts:**

*Designing Clinical Research*, 2nd Ed., (Hulley et al, Lippincott, Williams and Wilkins, 2001; *Biostatistical Analysis*, 2nd Edition (Zar JH, Prentice-Hall Resources: Clinical Researchers).

## **Learning Experiences:**

Lecture, discussion, critique, literature searchers and analysis, protocol development

## **Evaluation:**

Critiques of protocols	10%
Submission of completed protocol	75%
Exercises	10%
Evaluation	5%