

**John A. Burns School of Medicine
University of Hawaii At Manoa
Dr. R. Rudoy**

Course Number:641

Course Title: Legal and Regulatory Issues and Bioethics and Institutional Review Board

Course Credit: 2 semester credits

Prerequisite: MD, PhD, DDS, other clinical doctorate or permission of instructor

Placement in Curriculum: Spring Semester

Course Description:

Students learn through case discussions how to identify and resolve common ethical dilemmas that arise in clinical research, how research on human subjects is regulated by the federal government, and what constitutes research misconduct. Trainees resolve the ethical considerations involved in the research protocol they develop in the Designing Clinical Research course. This course meets the NIH requirements for training in research ethics.

Learning Outcomes

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

Apply concepts related to the HIPAA Privacy Rule to the development of clinical protocols

Apply concepts related to stem cells to enable and accelerate the pace of stem cell research by identifying rate limiting resources (both material and human) and develop initiatives to enhance these resources and seek the advice of scientific leaders in stem cell research about the challenges to moving the stem cell research agenda forward and strategies to overcome these challenges in clinical research

Possess practical skills necessary for developing a successful research program, and

Apply an understanding of key issues in research including research ethics, IRB, disseminating findings, and recruiting research participant

Apply concepts related to data safety monitoring to the development of clinical protocols

Apply general ethical principles to the decision-making process

Implement the precepts of professional ethics into practice and research

Achieve NIH Human Subjects Certification

Topical Outline:

General ethical principles
Precepts of professional ethics
Ethical principles and clinical research
HIPPA privacy rules and human research
Data safety monitoring and clinical research
Stem cell research ethical Implications
Development of ethical research programs
Public policy and ethics
Cultural competence an ethnical essential
Cultural competence and clinical research
Development of ethical, culturally competent consent forms
Completion of the NIH grant application related to human subjects and data safety monitoring

Required Texts: Dr. Bernard Lo's *Resolving Ethical Dilemmas*, 2nd ed., Lippincott, Williams & Wilkins, 2000

Numerous web sites such as those listed below will be used to provide additional resources for students

http://ohrp.osophs.dhhs.gov/irb/irb_guidebook.htm

www.air.org/cccm/progress/npac_summary.pdf

www.omhrc.gov/clas/Baltgeneralcomments.htm

www.judgehora.com/cultural.html

www.georgetown.edu/research/gucdc/nccc/ncccexnov19994.html

Learning Experiences: Lecture, Case Studies, Discussion, Participation

Evaluation::

Completion of Human Subjects Section of the NIH Application	40%
Preparation of Informed Consent	20%
Data Safety Monitoring Plan	20%
Participation	10%
Evaluation	10%