

Grant Number: 5T15AI07558-02

PI Name: MACKLIN, RUTH

Project Title: EMBEDDING ETHICS IN A CLINICAL RESEARCH TRAINING PROGRAM

Description:

This course in research ethics is developed as an integral part of a new Training Program in clinical Research Methods for clinicians (all are MDs) at Albert Einstein College of Medicine. The course is required in the first year for scholars in the Training Program, which offers a Master of Science degree. The twelve-week course comprises two separable modules, Basic Research Ethics and Advanced Research Ethics, which can be adapted for use separately or together in other settings. The overall program also includes elective courses on special topics in research ethics for participants in the second year of the degree program. Evaluation of the course is carried out by the Director of the Office of Educational Research and Evaluation. Approximately 12-14 scholars enroll each year in the program.

Topics covered include risk-benefit assessments; informed consent; privacy and confidentiality of research subjects and data; ethical issues in epidemiological, social and behavioral research; responsible conduct of scientific research; the role and functions of Institutional Review Boards; vulnerable populations of research subjects; issues in AIDS and human genetics research; inclusion of women and minorities in research; and international research conducted in developing countries. All classes are taught in seminar fashion, using interactive teaching methods, including internet-based formats. One session is devoted to a "mock" IRB meeting, in which scholars review actual research protocols. Another asks scholars to assign risk levels to various procedures commonly used in biomedical research. Assignments between course sessions are posted electronically and designed for participants' comments and critique. Three of the six sessions in the Advanced Module are devoted to presentations by the scholars on ethical issues arising in the research projects they are designing as a requirement of the Master's Program, followed by group discussion. The Basic Module has a take-home examination, and the Advanced Module requires a short paper based on a revised version of the oral presentations made by scholars.

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