

ETHICS GRAND ROUNDS

Tuesday, February 11, 2014 South Campus D1.602, Noon–1:00, McDermott Plaza Lecture Hall

WHAT MAKES RESEARCH ETHICAL?

DAVID S. WENDLER, Ph.D.

Head, Unit on Vulnerable Populations

Department of Bioethics

NIH Clinical Center

Many believe that informed consent makes clinical research ethical. However, informed consent is neither necessary nor sufficient for ethical clinical research. Drawing on the basic philosophies underlying major codes, declarations, and other documents relevant to research with human subjects, this presentation proposes seven requirements that systematically elucidate a coherent framework for evaluating the ethics of clinical research studies: (1) value; (2) scientific validity; (3) fair subject selection; (4) favorable risk-benefit ratio; (5) independent review; (6) informed consent; and (7) respect for enrolled subjects. These requirements are universal, although they must be adapted to the health, economic, cultural, and technological conditions in which clinical research is conducted.

John Z. Sadler, M.D., Course Director
Program in Ethics in Science and Medicine
For Information Contact
Linda Muncy, 214-648-4959; Linda.Muncy@UTSouthwestern.edu
www.utsouthwestern.edu/ethics

Target Audience: Physicians, faculty, residents, fellows, trainees, students, health care professionals. Educational Objectives: At the conclusion of this activity, the participant should be able to: 1) Recognize perennieal and emerging bioethical problems in clinical practice, research, public health, and health policy arenas. 2) Describe competing/contrasting viewpoints concerning these bioethical problems. 3) Demonstrate increased skills in analyzing and practically handling bioethical problems in the clinical, research, public health, and health policy arenas. Educational Method: Lecture and question-and-answer period. Accreditation: The University of Texas Southwestern Medical Center is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. Credit Designation: The University of Texas Southwestern Medical Center designates this live activity for a maximum of 1 AMA PRA Category 1 Credit(s)™. Physicians should claim only the credit commensurate with the extent of their participation in the activity. The University of Texas Southwestern Medical Center designates this activity for 1 hour(s) in medical ethics and/or professional responsibility. Conflict of Interest: All persons in the position to control the content of an education activity are required to disclose all relevant financial relationships in any amount occurring within the past 12 months with any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on patients. A primary mechanism to resolve identified conflicts of interest is a content review that is prior to the activity. Off-Label Uses: Because this course is meant to educate physicians with what is currently in use and what may be available in the future, there may be "off-label" use discussed in the presentation. Speakers have been requested to inform the audience when off-label use is discussed.