



**Responsible Conduct of Research
Fall 2010
Childrens Hospital Los Angeles**



Session 3: Protecting Human Research Subjects

Thomas G. Keens, M.D., C.I.P.

Date: September 30, 2010

Time: Thursday: 8:00 AM to 9:30 AM

Location: CLIC Classroom, Childrens Hospital Los Angeles

Overview: Clinical Care requires that the health care professional make decisions solely intended to benefit the patient before him or her. Research, on the other hand, is designed to benefit mankind. Human research subjects, participating in research designed to benefit mankind, may be injured when their welfare is not foremost in the minds of the scientists. Ethical principles have been developed to guide human researchers in performing research which achieves the best science and respects the rights and welfare of human subjects. This session will prompt analysis, discussion and insight into the factors which can encourage investigators to engage misuse of human research subjects through pre-readings on background and the detailed discussion of three hypothetical vignettes.

Reading Assignment:

Participants are asked to read the handout prior to class. This contains:

- (1) Protecting Human Research Subjects, *by Thomas G. Keens.*
- (2) The Nuremberg Code.
- (3) The Belmont Report.
- (4) The World Medical Association Declaration of Helsinki.
- (5) International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS).

Course attendees with disabilities are encouraged to participate. If there are special needs, particularly with respect to participation in the interactive discussions, these should be brought to the attention of the course coordinators (Dr. Keens and Ms. T. Tierney) so that accommodations can be arranged.

Course Objectives: At the conclusion of the session, attendees will:

- (1) Learners will identify the basic ethical principles which underlie human research and protects the rights and welfare of human research subjects.
- (2) Learners will apply ethical principles to case scenarios which illustrate difficulties in protecting human research subjects.
- (3) Learners will understand how independent review of human research can help to protect the rights and welfare of human research subjects.

Expectations: All attendees will:

- (1) Do the pre-readings prior to class.
- (2) Participate actively in the discussions of vignettes during the session.

Contacting Course Instructor:

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