

Attachment I

Background

In the late fall of 1996 following the tragic death of a University of Rochester undergraduate in a normal volunteer study, Jay H. Stein, M.D., constituted a "blue ribbon" committee to make recommendations regarding the conduct of human subject research at the University. The Committee's report included a recommendation that all investigators at the University be informed adequately, and on a continuing basis, of the fundamental requirements, responsibilities and ethical issues related to the conduct of human subject research. The Committee recommended that this be accomplished in the setting of a formalized educational program and that a reasonable effort be made to assess the understanding of the information conveyed. The Human Subject Protection Program and the Ethical Principles in Research Program have been developed as a result of this mandate.

HUMAN SUBJECT PROTECTION PROGRAM (HSPP)

Program Content

This is a self-study program consisting of a manual and an examination. The manual was developed by UR faculty and staff and reviewed by an external (national) advisory committee. The advisory committee included government regulators, renowned clinical researchers (biomedical and behavioral) and bioethicists. The program was then piloted by 20 UR clinical researchers with varying levels of research experience and revised based on their input. It will take approximately 4 hours to read the manual and take the examination. Health care professionals successfully completing the program may apply for CME credit or Nursing Contact Hours.

Human Subject Researchers' Responsibilities

As of January 1, 2001, the principal investigator, co-principal investigator, sub-investigator(s), study coordinator(s) and any other person obtaining consent must successfully complete the program before the IRB will approve a new or ongoing study, which is **greater than minimal risk**.¹ You will receive a pass/fail notification within 72 hours of submitting the exam. Reminders of this requirement will be included in the RSRB and WIRB application forms and continuing renewal notices.

ETHICAL PRINCIPLES IN RESEARCH PROGRAM (EPRP)

Program Content

This is a self-study program consisting of the Belmont Report and a brief examination. The Belmont Report identifies the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects. It provides guidelines which should be followed to assure that such research is conducted in accordance with those principles.

Human Subject Researchers' Responsibilities

As of January 1, 2001, the principal investigator, co-principal investigator, sub-investigator(s), study coordinator(s) and any other person obtaining consent must successfully complete the program before the IRB will approve a new or ongoing study, which is **not greater than minimal risk**. You will receive a pass/fail notification within 72 hours of submitting the exam. Reminders of this requirement will be included in the RSRB and WIRB application forms and continuing renewal notices. NOTE: For human subject researchers who conduct both minimal risk and greater than minimal risk studies, it is only necessary to complete the HSPP program since this program includes the ethical principles contained in the Belmont Report.

Program Initiation

- The HSPP program is currently available.
- The EPRP program will be available on September 29, 2000.

¹ According to Federal regulations, minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Examples of minimal risk procedures include electrocardiography, collection of blood by venipuncture from healthy adults who are not pregnant, moderate exercise testing, and administration of psychological tests involving a minor level of stress.

- Both programs are mandatory after January 1, 2001.

HSPP program materials can be obtained by calling Anne Marini at 273-4127. The EPRP program will be available after September 29th on the web at www.urmc.rochester.edu/urmc/rsrb/belmont.htm. Please call Anne if you do not have web access and need a hard copy.