Categories of IRB Review

Full Board Review: In general, protocols are reviewed by the full board when the study involves greater than minimal risk to a population of voluntary participants. The meeting schedule and submission deadlines are available on the IRB web site. After initial approval, protocols must continue to be reviewed by the Board at least annually.

Expedited Review: This typically is granted when there exists no more than a minimal risk to subjects and the research falls into a specified category described in the Common Rule (45 CFR 46) for expedited review. After initial approval, protocols must continue to be reviewed and approved at least annually.

Exempt Review: After initial review, the IRB may provide exemption from further review only when the when the research falls within an exemption category specified in the Common Rule. This type of research often the examination of existing laboratory / pathological specimens or existing data, or use of surveys, tests and interviews.

Questions or concerns related to human subject research should be directed to either:

Institutional Review Board Office
Administrative Coordinator
Phone: 679-1019

OR

Human Subjects Protections Office
Administrator
Phone: 679-3054

UConn Health Center

16 Munson Road.
Mail Code 3926
Farmington, CT 06030-2806

University of Connecticut Health Center

Human Subjects Protections Office

&

Institutional Review Board Office

Employee Orientation Brochure

Remarkable Care Through Research and Education

Ethics in Human Subject Research – the Belmont Report

In 1979, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research published "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," which has become known as the "Belmont Report." The principles of autonomy, beneficence, and justice are the key ethical issues set forth in the report. All research conducted at the Health Center that involves human subjects is to be conducted in accordance with these principles.

Autonomy means that the decision of each person of whether or not to participate in research must be respected. Decisions are to be free from coercive elements or undue influence.

Beneficence obligates the researcher to protect the well-being of study participants by minimizing potential harms in a research design while maximizing potential benefits. Balancing risks and benefits is an important consideration.

Justice requires that the burdens and benefits of human subjects research are distributed fairly.

Regulation of Human Subject Research – the Common Rule

Federal law (45 CFR 46) mandates that the IRB review and approve any research involving human subjects and assure that legally effective informed consent is obtained from study participants, or appropriately waived by the IRB.

Research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information about the individual, e.g. chart reviews.

To safeguard the rights of human subjects, the IRB prospectively reviews protocols to assure that the research activities proposed 1) include no unnecessary risks and 2) minimize the occurrence of those risks that do exist. The IRB determines whether the potential benefits are reasonable in relation to the risks. For example, the IRB considers the importance and significance of the scientific knowledge potentially gained against the risks to study subjects.

While the Common Rule may be the most relevant, there are also other regulations governing human subject research, e.g. FDA and HIPAA regulations.

Human Subject Research Training Requirement

All investigators, key study personnel and individuals obtaining consent must complete training in human subject protections before becoming involved with a study. Information on how to satisfy this training requirement is available on the IRB web site.

IRB Review

All research involving human subjects must be approved by the IRB **before** it is initiated. Applications may be reviewed under one of three review categories. The investigator may request a specific type of review but the IRB makes the final determination.

For more information on IRB policies and requirements visit the IRB web site at:
http://hspo.uchc.edu