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

**Institutional Review Board Office**
Administrative Coordinator
Phone: 679-1019

**Human Subjects Protections Office**
Administrator
Phone: 679-3054

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