



University of Connecticut Health Center

POLICY NUMBER 2002-42

August 13, 2008

POLICY: REVIEW AND APPROVAL OF RESEARCH INVOLVING HUMAN SUBJECTS (Human Subjects Protection Office)

PURPOSE:

To assign authority and responsibility for the review and approval of research involving human subjects.

POLICY STATEMENT:

It is the policy of the University of Connecticut Health Center that all research involving human subjects, conducted by the faculty, staff, agents or students of the Health Center, or research conducted using Health Center facilities, be conducted in accordance with federal regulations including, but not limited to the following:

- Federal Policy for the Protection of Human Subjects (Federal Register, Vol. 56, No. 117, 6/18/91, p.28002.
- Code of Federal Regulations, Title 45 Public Welfare, Department Of Health And Human Services, National Institutes Of Health Office For Protection From Research Risks, Part 46, Protection Of Human Subjects, Revised November 13, 2001, Effective December 13, 2001.
- Code of Federal Regulations, 21 CFR 50, 56, 312, 812, as established by the Food and Drug Administration.

DEFINITIONS:

Administrative Officers: For purposes of this policy Administrative Officers include the signatory official on the institution's Federalwide Assurance, Vice President for Health Affairs, Director of the Human Subjects Protection Office, Dean of Academic Affairs, Dean of the Medical School, Dean of the Dental School, Associate Vice President for Research Administration and Finance, and Director of Research Compliance.

Agent: An individual performing institutionally designated activities or exercising institutionally delegated authority or responsibility

In accordance with the regulations cited above, the Health Center has established an Institutional Review Board (IRB), whose members are appointed by the Director of the Human Subjects Protection Office (DHSPO) in consultation with the IRB Chairs. The Institutional Review Board (IRB) is composed of multiple panels, constituted with individuals of diverse backgrounds and expertise, appointed in accordance with the requirements of the regulations cited above.

The IRB, its staff, and the administrative officers of the Health Center are responsible for assuring that all Health Center faculty, staff, agents and students engaged in research involving human subjects comply with applicable regulations and guidelines.

The IRB shall have the responsibility to review and the authority to approve, require modifications of or disapprove all research involving human subjects conducted by Health Center faculty, staff, agents and students or such research involving the use of Health Center facilities, in accordance with administrative policies and procedures established for this purpose. The IRB shall monitor and conduct continuing review of such research at intervals of at least once per year.

The IRB, or its staff acting on behalf of the IRB, has the authority to inspect research facilities, obtain records and other relevant information relating to projects it has approved. The IRB may suspend or terminate approval of projects it has approved, and take actions that it judges necessary to ensure compliance with federal and other applicable regulations, or to address issues which have been associated with unexpected serious harm to subjects. The IRB is authorized to observe, or have a third party observe, the consent process and the research.

No entity or individual may grant final approval to a project which has not received the review and approval of the IRB or which has been disapproved by the IRB. The Administrative Officers may conduct additional review of research, which has been approved by the IRB, and have the authority to disapprove or suspend research, which has been previously approved by the IRB.

Health Center faculty, staff, agents and students are responsible for familiarizing themselves with the IRB's policies and procedures (available through various published and on-line sources, and on-going IRB training), conducting research involving human subjects in accordance with the terms of approval established by the IRB, and reporting non-compliance and unanticipated problems associated with such research immediately to the IRB.

The IRB shall report to the DHSPO, and the DHSPO shall report to Administrative Officers, and when applicable OHRP and the FDA, and others with an interest in the

research (e.g. funding agencies, Department Chairs) :

- unanticipated problems involving risks to subjects or others
- serious or continuing noncompliance with applicable regulations or IRB requirements; and,
- any suspension or termination of IRB approved research.

Richard Simon, M.D.

8/20/08

Director, Human Subjects Protection Office

Date

Bruce M. Koeppen

8/20/08

Dean, Academic Affairs

Date

Cato T. Laurencin

8/24/08

Vice President, Health Affairs

Date

Replaces Policy: November 5, 2007 (August 31, 2005)