UCONN HEALTH

**POLICY NUMBER 2002-42**
**July 12, 2016**

**POLICY: REVIEW AND APPROVAL OF RESEARCH INVOLVING HUMAN SUBJECTS (Human Subjects Protection Program (HSPP))**

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

**DEFINITIONS:**

**Administrative Officers**: For purposes of this policy Administrative Officers include the signatory official and administrator on the institution's Federal Wide Assurance, Vice President for Research, Associate Vice President for Research, Executive Vice President for Health Affairs, Director of the Human Subjects Protection Program, Dean of the School of Medicine, Dean of the School of Dental Medicine Associate Dean for Clinical Research Planning and Coordination, and Associate Vice President for Research Administration and Finance

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

**Engaged in Research**: UConn Health faculty, students, employees or agents, for a research purpose, obtain data through intervention or interaction with individuals, use identifiable private information of living individuals (e.g. medical records), and/or use human tissue to test the safety or effectiveness of an investigational device.

**Non-exempt Research**: The Office for Human Research Protections and the Food and Drug Administration identify in their respective regulations categories of human subject research that may be deemed exempt from regulations. Non-exempt research is any type of human subject research not included in those categories.

**POLICY STATEMENT:**
It is the policy of UConn Health that all research involving human subjects that engages the institution in research, be conducted in accordance with applicable federal regulations including, but not limited to, the following:

- Department of Health and Human Services – Code of Federal Regulations (CFR), 45 CFR 46, Protection Of Human Subjects
- Food and Drug Administration - CFRs, 21 CFR 50, Protection of Human Subjects; 56, Institutional Review Boards; 312, Investigational New Drugs; 812, Investigational Devices
- Office of Civil Rights CFR - 45 CFR 164, Health Insurance Portability and Accountability Act

In accordance with the regulations cited above, UConn Health has established an Institutional Review Board (IRB), whose members are appointed by the Director of the Human Subjects Protection Program (DHSPP) in consultation with the IRB Chairs. The 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 UConn Health are responsible for assuring that all UConn Health 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 UConn Health faculty, staff, agents and students, in accordance with administrative policies and procedures established for this purpose. The IRB shall monitor and conduct continuing review of such non-exempt research at intervals of at least once per year.

The IRB, or 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 risks to subjects. The IRB is authorized to observe, or have a third party observe the consent process and the research. The observer may interact with potential subjects, enrolled subjects, and/or the research team as related to the study being observed.

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. Any of the Administrative Officers may conduct additional review of research, which has been approved by the IRB. An Administrative Officer also has the authority to disapprove or suspend research which has been previously approved by the IRB. Only the IRB may reinstate approval.

UConn Health faculty, staff, agents and students are responsible for familiarizing themselves with the IRB's policies and procedures that are available on the HSPP web site, 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 DHSPP, and the DHSPP shall report to relevant Administrative Officers and agencies (e.g. 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,
- Suspensions or terminations of IRB approved research.

Richard Simon (Signed) 8/1/16

**Richard Simon, M.D.** **Date**
**Director, Human Subjects Protection Program**

Jeffrey Seemann (Signed) 8/10/16

**Jeffrey Seemann, Ph.D.** **Date**
**Vice President for Research**

New Policy: 4/10/02
Revised: 9/01/05, 11/5/07, 8/13/2008, 11/13/12, 8/12/14, 7/12/16