

UConn HEALTH

POLICY NUMBER 2004-02

July 23, 2018

POLICY: AUTHORITY OF THE HUMAN SUBJECTS PROTECTION PROGRAM

PURPOSE:

To ensure adequate protections are in place for participants in research studies by assigning responsibility to the Director of the Human Subjects Protection Program (HSPP) for the oversight of 1) the Institutional Review Boards and staff, 2) the Scientific Review Committee, 3) the Research Compliance Monitor(s), 4) the Education and Development Specialist(s) and 5) all IRB approved studies; and by empowering the Director of the HSPP to create, change, and implement departmental policy that will ensure such protections; and to create and propose such policy at an institutional level to the Institutional Policy Committee; and to ensure effective communications between the HSPP and other ancillary areas related to human subject research (e.g. Pharmacy, Office of Research Safety, Conflict of Interest Committee).

POLICY STATEMENT:

1. It is the policy of UConn Health that all human subject research approved by the Institutional Review Boards, conducted by the faculty, staff, agents (as defined in Policy 2002-42, [Review and Approval of Research Involving Human Subjects](#)) or students of the Health Center, will be subject to the oversight of the Human Subjects Protection Program (HSPP).
2. The Director of the HSPP has the responsibility to:
 - Ensure compliance with Federal regulations, State laws and internal policies governing the involvement of human subjects in research;
 - Ensure that studies involving human subjects that are conducted at UConn Health or affiliated sites, comply with Federal regulations, State laws and internal policies governing the protection of human subjects in research;
 - Ensure that all research involving human subjects is conducted in accordance with the ethical principles of respect for persons, beneficence and justice as set forth in the [Belmont Report](#);
 - Annually ensure that the HSPP, including the IRB, has adequate resources to operate, conduct reviews, conduct audits, and provide educational opportunities; and to advise leadership of any resource needs;
 - Provide guidance to the Institutional Review Boards, Scientific Review Committee and Research Compliance Monitor(s) and Education Specialist(s);
 - Ensure the IRB is keeping accurate and complete records;
 - Develop outreach activities to inform and educate research personnel and research subjects;

- Ensure key study personnel, reviewers, IRB staff and HSPP staff have completed required training in human subjects protections;
 - Solicit suggestions for improving the protections afforded to human subjects;
 - Respond to allegations of non-compliance with IRB requirements or federal regulations that pertain to human subjects research;
 - Respond to concerns expressed about the protections being afforded to human subjects;
 - Ensure effective communication between the IRB and ancillary areas related to human subject research (e.g. Pharmacy, Office of Research Safety, Conflict of Interest Committee);
 - Continually assess and seek to improve the efforts made to protect human subjects;
 - Develop and maintain detailed operating policies and procedures related to the protection of human subjects, the operations of the IRB and the operations of the HSPP.
3. The Director of the HSPP is authorized to:
- Create, change, implement or deactivate departmental policy pertaining to the protection of human subjects, the operation of the Institutional Review Board, adverse event reporting, the operation of the Scientific Review Committee, the auditing of approved studies, and the training requirements for all individual who conduct, administer or review studies involving human subjects;
 - Appoint the IRB members and chairs and to observe convened IRB meetings;
 - Audit any approved study and to inspect facilities to ensure compliance with regulations, laws and policies pertaining to the protection of human subjects;
 - Conduct audits to investigate allegations of inappropriate investigator conduct relating specifically to human subject protections;
 - Observe the informed consent process with the consent of the subject;
 - Terminate or suspend previously approved studies due to unexpected or increased risks to subjects or serious or continuing issues of non-compliance;
 - Contact subjects, who have consented to be contacted by the HSPP, for purposes of quality improvement programs.
4. To ensure the independence and operation of the IRB in an environment that is free from undue influence the Director of the HSPP may not approve any research that has not been approved by the IRB.
5. It is the policy of UConn Health that the Director of the Human Subjects Protection Program (DHSPP) is the primary individual responsible for the daily operations of the human subject protection program and for reporting the termination or suspension of studies, unanticipated problems involving risk to subjects or others and/or issues relating to serious or continuing non-compliance, as applicable, to the Office for Human Subjects Protections, the Food and Drug Administration, administrative officers defined in Policy 2002-42, and as applicable, other entities with an interest in the research (e.g. funding agencies, Department Chairs). In the absence of the Director of the HSPP, one of the administrative officers defined in Policy 2002-42, or an individual designated by the DHSPP, may fulfill the reporting obligations.

6. The Institutional Official (IO), as designated by the Vice President for Research, signs the Federal-Wide Assurance (FWA) and holds ultimate responsibility for the institution as a whole regarding human subject's protections. Through the FWA, an institution commits to HHS that it will comply with the requirements in the HHS Protection of Human Subjects regulations at 45 CFR part 46. The IO appoints the Director of the HSPP, as a direct report, and delegates daily operational aspects of the human subject projection program to the Director HSPP. In addition to any action taken by the Director of the HSPP, the IO may take actions necessary to protect human subjects and/or ensure compliance that the DHSP is not authorized to do. Such actions may include but are not limited to; forbidding an employee to conduct research at this institution, taking actions that affect employment status, or reallocating resources.

Richard Simon (Signed)

8/10/18

Richard Simon, M.D.
Director of Human Subjects Protection Program

Date

Radenka Maric (Signed)

7/31/18

Radenka Maric, Ph.D.
Vice President for Research

Date

New Policy: 8/13/04

Revised: 8/13/08, 11/13/2012, 8/13/13, 7/23/2018