



# University of Connecticut Health Center

**POLICY NUMBER 2004-02**

**August 13, 2008**

## **POLICY: AUTHORITY OF THE HUMAN SUBJECTS PROTECTION OFFICE**

### **PURPOSE:**

To assign responsibility to the Human Subjects Protection Office for the overall protection of human subjects through oversight of the Institutional Review Boards and staff, Research Adverse Events Committee, Scientific Review Committee, Research Compliance Monitors and approved IRB studies, and to empower the Human Subjects Protection Office to create and implement policy that will ensure such protections.

### **POLICY STATEMENT:**

1. It is the policy of the University of Connecticut Health Center 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, or using Health Center facilities will be subject to the oversight of the Human Subjects Protection Office (HSPO).
2. The HSPO 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 UCHC or affiliated sites, are in compliance 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 HSPO, including the IRB, has adequate resources to operate, conduct reviews, conduct audits, and provide educational opportunities; and to advise the Dean for Academic Affairs of any resource needs;
  - Provide guidance to the Institutional Review Boards, Research Adverse Events Committee, Scientific Review Committee and Research Compliance Monitors;
  - Ensure the IRB is keeping accurate and complete records;
  - Develop outreach activities to inform and educate research personnel and subjects;
  - Ensure key study personnel, reviewers, IRB staff and HSPO 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;
  - Respond to concerns expressed about the protections being afforded to human subjects;

- Ensure effective communication between the IRB and the Office of Research Safety, Office of Research Compliance and Office of Research Administration and Finance;
  - 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 HSPO.
3. The HSPO is authorized to:
- Assure creation and implementation of policy pertaining to the protection of human subjects, the operation of the IRB Office and Committees, the operation of the Research Adverse Events Committee and 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 HSPO, 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 HSPO may not approve any research that has not been approved by the IRB.
5. It is the policy of the University of Connecticut Health Center that the Director of the Human Subjects Protection Office is the primary individual responsible 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 and 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 HSPO, one of the administrative officers defined in Policy 2002-42 may fulfill the reporting obligations.

Richard Simon, M.D.

8/20/08

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**Director of Human Subjects Protection Office**

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**Date**

Bruce Koeppen

8/20/08

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**Dean for Academic Affairs**

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**Date**

Cato T. Laurencin

8/24/08

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**Vice President for Health Affairs**

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**Date**

**Replaces Policy of 8/13/2004**