

UConn HEALTH

POLICY NUMBER 2004-05

November 13, 2012

**POLICY: WRITTEN AGREEMENTS FOR SPONSORED/FUNDED RESEARCH
INVOLVING HUMAN SUBJECTS (Human Subjects Protection Office)**

PURPOSE:

To ensure that research sponsored/funded directly by any for-profit institution, or any private not-for-profit institution or organization, is conducted under a written agreement that outlines the responsibilities of the sponsor or funding agency and UConn Health in the protection of human subjects.

POLICY STATEMENT:

1. It is the policy of UConn Health that all externally-supported research studies involving human subjects receive approval from the Institutional Review Board prior to initiation, and be conducted under a written agreement between the research sponsor or funding agency and the Health Center that defines the responsibilities of each party in protecting human subjects throughout the conduct of the study.
2. Written agreements should address elements including, but not limited to:
 - a) A statement that the UConn Health and the sponsor agree to conduct the study in accordance with applicable laws, regulations, ethical standards and the terms of the protocol.
 - b) Provisions for research-related medical care for participants also referred to as subject injury. In most cases sponsors will be required to provide payment for care for a research related injury. Examples of when this may not apply include injuries due to investigator noncompliance with protocol, Phase 4 studies, or investigator initiated studies.
 - c) The sponsor's obligation to be first payer for subject injury for Medicare or Medicaid patients.
 - d) Data ownership and the responsibility for protection of confidentiality of identifiable data.
 - e) The sponsor's obligation to communicate to both the IRB and the investigator information that bears on participant safety or medical care both during study conduct and after study closure (e.g. when final results of the study or adverse events occurring after market approval bear on safety or medical care) such that the PI may relay this information to former and/or current participants.
 - f) The sponsor's commitment to provide the IRB and investigator in a timely manner any information relating to deliberations of data safety monitoring boards, other reviews or significant information about the study.
 - g) For device studies, the sponsor's commitment to submit progress reports to the IRB at least yearly.

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- h) A statement that adverse events will be reported to the IRB in accordance with the UConn Health policy for reporting adverse events.
 - i) A statement that relatedness of subject injury to the research intervention will be determined jointly by the Principal Investigator and the Sponsor.
3. In agreements that stipulate that the sponsor retains ownership of data generated in the study, UConn Health investigators must retain the right to publish the results of the study, at least for that portion of the data collected by the investigator.

Richard Simon (Signed)

11/19/12

Richard Simon, M.D.
Director, HSPO

Date

Peter Albertsen (Signed)

11/27/12

Peter Albertsen, M.D.
Associate Dean Research Planning and Coordination

Date

Frank Torti (Signed)

1/8/13

Frank M. Torti, M.D., M.P.H.
Executive Vice President for Health Affairs

Date

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Replaces Policy dated: June 15, 2005