1.0 Purpose:

1.1 This policy ensures that externally funded research is conducted under a written agreement or contract that outlines the responsibilities of both the sponsor and Hartford HealthCare (HHC) in upholding human research protection standards.

2.0 Definitions:

2.1 **Sponsor –** the individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization that takes responsibility for, initiates, manages, or finances a clinical investigation.

3.0 Procedure:

3.1 All externally funded research involving human subjects must obtain Institutional Review Board (IRB) approval prior to initiation. In addition, these studies may not begin until a fully-executed contract is in place.

3.2 The Grants Administrator will review proposed agreements and negotiate any needed revisions with the sponsor. The Grants & Contracts Office and HRPP Staff will maintain an open line of communication, sharing pertinent information related to a protocol and corresponding contract to ensure human subject protection issues are addressed.

3.3 Written agreements should address the following elements:

3.3.1 A statement that both parties agree to conduct the study in accordance with applicable laws, regulations, ethical standards, and the terms of the protocol.

3.3.2 The responsibilities for protection and maintenance of confidentiality of identifiable data.

3.3.3 Research-related medical care for participants (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.

3.3.4 A statement that adverse events will be reported to the IRB in accordance with the HHC HRPP policy for reporting adverse events.

3.3.5 The sponsor's obligation to communicate to both the IRB and the investigator information affects participant safety or medical care both during study and after study closure (e.g. when final results of the study or adverse events occurring after market approval affect safety or medical care) such that the PI may relay this information to former and/or current participants.

3.3.6 The sponsor's commitment to provide the IRB and investigator in a timely manner any information relating to deliberations of data safety monitoring boards or other reviews.

3.3.7 If the sponsor will monitor the conduct of the research, the contract must state the sponsor's commitment to provide directly to the IRB copies of monitoring and/or auditing reports issued to the Principal Investigator when corrective actions are required on the part of the Principal Investigator (i.e., instances of serious and/or continuing non-compliance or other information that could affect the safety of participants or their willingness to continue participation).

3.3.8 Payment in exchange for referrals of prospective participants from physicians ("finder's fees") is not permitted. Similarly, payments designed to accelerate recruitment that are tied to the rate or timing of enrollment ("bonus payments") are also not permitted.

3.3.9 In agreements that stipulate that the sponsor retains ownership of data generated in the study, HHC investigators must retain the right to publish the results of the study, at least for the portion of the data collected by the investigator. The sponsor maintains the right to review, but not "approve" or refuse publication.

3.4 Reviews will ensure consistency between the protocol, informed consent, and contract language.

4.0 Documentation:

4.1 Fully-executed contracts will be maintained by The HHC Research Institute in the specific study file in hard copy for a period of six (6) years after the completion the research. Per HHC policy, all contracts are downloaded and managed on the Meditract system. Thus, they will still be available for more than 6 years to meet regulatory and sponsor retention requirements.

5.0 References:

5.1 45 CFR 46.116(b)(6), 45 CFR 46. 116(b)(7)
5.2 21 CFR 50.25(a)(6), 21 CFR 50.25(a)(7)

6.0 Revision History:

Rev #	Initials	Effective Date	Description of Change(s)
00	CLB	7/1/11	New Issue
01	CLB	3/15/20	General review; update regulatory references

Standard I-8 (I.8.A., I.8.B., I.8.C., I.8.D., I.8.E.)