1.12 Sponsored Research

1.0 Purpose

The purpose of this policy is to describe the Organization's requirements for research sponsored by an external funding agency or commercial sponsor.

2.0 Policy

It is the policy of the Organization that in sponsored research, both the Sponsor and the Organization have obligations to protect research participants and ensure that the research is conducted in accordance with the Organization's ethical standards, and in full compliance with all applicable HRPP policies, federal regulations for protection of human subjects, state and local laws and regulations, and University of Nebraska Board of Regents By-Laws.

3.0 Definitions

- 3.1. Sponsor is defined as the company (pharmaceutical, device or biotechnology), other non-federal agencies, non-profit foundations, or individual donors providing financial or other support for a research study. Where applicable, the term sponsor also includes agents of sponsors (for example, contract research organizations).
- 3.2. Contract is defined as a study agreement executed between a commercial Sponsor and the Organization and signed by authorized representatives of each of the parties.
- 3.3. A Federal Awarding Agency is defined as a Federal agency that provides a Federal award directly to the Organization.
- 3.4. A Notice of Award is the legal document issued to a non-Federal entity (which would include the Organization) for a Federal Awarding Agency that an award has been made to support the study or project at the non-Federal entity.
- 3.5. A Subaward is an award of financial assistance made under a Notice of Award by a non-Federal entity to the Organization to carry out part of the scope of work or study.
- 3.6. A Subcontract is an agreement made under a contract between a commercial, non-federal agency, or foundation to another entity, which that entity is passing down financial assistance and the terms and conditions of that contract to the Organization.

4.0. Investigator Responsibilities

- 4.1. The investigator is responsible for assuring that all appropriate approvals are obtained from UNeHealth and/or SPA prior to initiating any research interventions, including screening of potential subjects.
- 4.2. The investigator is responsible for assuring all charges for research activities are billed appropriately to the cost center or work order associated with the Contract, Notice of Award, Subaward or Subcontract.
  - 4.2.1. Non-routine patient care costs which result from procedures performed solely for research purposes must be supported by the study budget and not charged to the subject and/or their third-party payors.
- 4.3. The investigator is responsible for promptly reporting to the IRB if they are advised by the sponsor of (1) any findings that could affect the safety of subjects or the willingness of subjects to continue participation in the study (for example, serious adverse events), or (2) any findings that could influence the conduct of the study, or (3) any noncompliance, or (4) any other information important to the IRB's continued approval of the study.
- 4.4. The investigator is responsible for promptly reporting to the IRB if they are advised by the sponsor of any results of on-site monitoring conducted by the Sponsor at UNMC or other sites under the jurisdiction of the UNMC IRB.
- 4.5. The investigator is responsible for promptly initiating any corrective action required by the sponsor.
- 4.6. The investigator will notify subjects if they are advised by the sponsor after completion of the study of any findings that may directly affect the safety or medical care of subjects.
- 4.7. The investigator will complete the Charge for IRB Review of Commercially Sponsored Projects (Full Board and Expedited Review) form within RSS.

5.0. Sponsor Responsibilities

- 5.1. The Sponsor must promptly (no longer than 30 days) report to the Organization and/or PI

any findings that could affect the safety of subjects, the willingness of subjects to continue participation in the study (e.g., serious adverse events), influence the conduct of the study, noncompliance, or other information important to the IRB's continued approval of the study.
- 5.2. The Sponsor must provide the Organization with data safety monitoring reports as well as other routine or urgent reports promptly as indicated in the data and safety monitoring plan approved by the IRB.
- 5.3. The Sponsor must report to the Organization and/or PI any results of on-site monitoring conducted by the Sponsor at UNMC or other sites under the jurisdiction of the UNMC IRB.
- 5.4. The Sponsor must have a plan in place to notify the Organization and/or PI of the results upon completion of the study when the findings may directly affect the safety or medical care of subjects.

6.0. Organization Responsibilities

- 6.1. All Contracts, Subcontracts, and Subawards are reviewed by UNeHealth, UNMC Sponsored Programs Administration (SPA) or UNO SPA.
- 6.2. In negotiating contracts with commercial sponsors, UNeHealth and SPA will utilize template language which is consistent with requirements in Addendum I (Contract or Funding Arrangement) below, and with AAHRPP accreditation standards.
  - 6.2.1. If a sponsor is unwilling to utilize approved template language, UNeHealth and SPA, in consultation with the Office of Regulatory Affairs, and appropriate legal counsel as needed, will determine whether the substitute language is consistent with requirements in Addendum I below, and with AAHRPP accreditation standards.
- 6.3. The Organization will not enter into a contract or other funding arrangement that does not obligate the sponsor (and/or the investigator) to fulfill its responsibilities as detailed in this policy, or that does not satisfy the requirements of Addendum I (Contract or Funding Arrangement) below.
- 6.4. When the Notice of Award or Contract agreement includes human research activities that will be conducted by investigators who are not employees or agents of the Organization, a Subcontract/Subaward must be executed between the Organization and the collaborating institution.
  - 6.4.1. The Subcontract/Subaward will include the requirement for the collaborating institution to assure compliance with federal regulations for the protection of human subjects in research and to provide documentation of current and ongoing IRB approval.
  - 6.4.2. The collaborating institution must also ensure that key personnel involved in human subject research are in compliance with the NIH policy on education in the protection of human research subjects and provide documentation of education of key personnel to the Organization.
- 6.5. The Organization will comply with the detailed study protocol, HRPP policies, and all applicable federal regulations.

7.0. ORA and/or IRB Responsibilities:

- 7.1. Contract Specialists and the Clinical Research Financial Compliance Specialist interact with Sponsors, investigators, legal counsel, IRB Executive Chair/designee and the IRB analysts to resolve identified issues and concerns.
- 7.2. If the IRB has already reviewed the project and the Contract, Subaward or Subcontract requires a major modification of the IRB application and/or ICFs, the convened IRB will re-review the study. "Major modification" is defined as per HRPP policy 2.4 (Review of Changes in Approved Research).
  - 7.2.1. Minor modifications to the IRB Application and/or ICFs may be reviewed as expedited per HRPP policy 2.3.
- 7.3. The IRB will not issue a final release of commercially sponsored research until a fully executed Contract or Subcontract has been concluded.
- 7.4. The ORA and SPA or UNeHealth will communicate via RSS message portal, email, or another mechanism as appropriate to advise (1) when the Contract or Subcontract is fully executed, and (2) when the ORA has issued final approval and release of the research.

Addendum I

Contract or Funding Arrangement: The contract or funding arrangement must include a clear definition of the Sponsor's responsibility for the payment of medical care for research participants who experience a research related injury, including (1) non-exculpatory limitations the sponsor has imposed on the extent of payment for medical care, and (2) the location(s) where medical care can be obtained. This statement of responsibility must be consistent with the "Compensation in Case of Injury" clause found in the ICF. Indemnification language in the contract must not compromise the rights and welfare of research subjects. The contract must not include a financial bonus or financial penalty specifically linked to subject recruitment efforts (HRPP policy 3.7 Finders Fees and Recruitment Bonuses). The contract must not include any direct personal payments or other form of compensation from the Sponsor to investigators and other study personnel. The contract must not include any requirements which would cause the Organization to violate the HIPAA Privacy Rule. When PHI is provided to the Sponsor the Sponsor must refrain from using PHI to recruit subjects or

advertise additional studies to subjects, refrain from using the PHI for marketing or market research and place the same restrictions on any third party to whom the Sponsor discloses PHI. The contract must not include any prohibition from retaining a copy of the data generated during the study at UNMC or other study sites under the jurisdiction of the UNMC IRB. The contract must not include any restrictions on publication of the results of the research which violate the University of Nebraska Board of Regents Policy (RP-3.2.8 (section 7; page 103)).

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