REQUIRED ELEMENTS OF CONTRACTS, PROTOCOL AND/OR CONSENT AGREEMENTS FOR THE PERFORMANCE OF HUMAN RESEARCH

POLICY

The rights and welfare of research participants will be protected by requiring specified provisions to be included in contracts, protocols and/or consent agreements for the performance of research involving human subjects.

APPLICABILITY

The policy applies to all contracts, protocols and/or consent agreements for the performance of human subjects’ research which are reviewed by or on behalf of the University of Cincinnati (UC).

PROCEDURE

1. When a project for the performance of research involving human subjects is accompanied by a written agreement, the agreement must comply with each of the requirements of this policy.

2. Where applicable, the requirements set forth in this policy may be met by appropriate language in a protocol, investigator’s brochure, or other documentation when such documentation is incorporated by the parties as a part of the agreement.

3. Each such agreement shall include requirements outlining the ethical responsibilities of the parties involved. This requirement may be met through written assurances concerning at least the following:

   a. Compliance with all applicable laws, including but not limited to, Department of Health and Human Services (DHHS) 45 CFR 46; FDA regulations governing the protection of human subjects (21 CFR 50); and regulations governing clinical investigators as found (21 CFR 312.50 et. seq.); ICH-GCP as applicable to FDA regulations 21 CFR 50 and 56 for industry sponsored protocols;

   b. Compliance with university rules and policies;
c. Approval of all contemplated human research activities by the UC, or UC approved, Institutional Review Board (IRB) or an external IRB as provided in Policy III.01 Review by the Institutional Review Board of Human Subjects Research.

d. Agreement to comply with applicable law regarding privacy, follow procedures for data recording and reporting; to permit monitoring, auditing and inspection; and to retain the clinical trial related essential documents until the sponsor informs the investigator these documents are no longer needed.

4. Each such agreement shall include suitable assurances for the protection of research participants, including terms addressing at least the following:

   a. Research related medical care for participants. Each agreement shall clearly describe the availability of medical care for research-related injuries, including whether such care will be provided, and, if so, who will provide such care and who will be responsible for the cost of such care.

      The following language is recommended for the contract, protocol, and/or consent agreements:

      “Sponsor will reimburse site for the reasonable cost of medical treatment required by participants in the study due to injury or illness caused by that subject’s participation in the study to the extent that such injury or illness is not covered by the participant’s medical or third-party health insurance, and is not caused by the negligence of employees or agents of the site.”

   b. Data ownership. Any such agreement shall comply with the terms of University Rule 10-43-18, “Ownership and Access to the Original Scientific Record.”

      The following language is recommended to include in confidentiality terms in a contract, protocol and/or consent agreements:

      “Nothing herein shall be deemed to prevent the disclosure of the study data and results to participants and their healthcare providers by sponsor or investigator when such disclosure is reasonably necessary to ensure the safety and appropriate medical care for such participants.”
c. **Publication.** Contracts or other agreements will require the sponsor to follow applicable policies and procedures regarding the publication of findings from sponsored research. Contracts, protocols and/or consent agreements may not contain terms which prohibit publication or which require sponsor approval prior to publication of data from a human subjects research project, except as follows:

i. **Sponsor Comment Period:** such agreements may provide for delay of publication, not exceeding ninety (90) days, when requested to permit a sponsor to offer comments or suggestions, provided that such terms shall not include a requirement that the author is bound to accept such comments or suggestions.

ii. **Reviews for Proprietary Information:** any such agreement which requires access to and/or use of a sponsor’s *bona fide* proprietary data or materials will be accepted only if terms regarding access, use, and protection of such data or materials do not unreasonably restrict the dissemination of scholarly findings made within the project.

iii. **Delays for Intellectual Property Protection:** such agreements may provide for delays, not exceeding ninety (90) days, to enable the University and/or sponsor to screen proposed publications for possibly patentable ideas and to commence necessary steps to assure appropriate legal protection for such patentable ideas.

iv. **Multicenter Clinical Trials:** A delay for up to twelve (12) months following the conclusion of a multi-center clinical trial is acceptable when necessary to permit a first publication from the trial to represent the work from all sites. Any term reflecting this delay must affirmatively provide for the ability of the faculty member to publish site-specific results if no multi-site publication has occurred within the twelve (12) month period.

v. **Publication Restrictions:** In any circumstance in which a publication restriction appears in a written agreement, the appropriate office of sponsored programs in coordination with the office of general counsel and the principal investigator shall promptly confer with the sponsor in an effort to remove or modify such restriction. If such efforts are unsuccessful, such restriction or delay may be approved only upon written request of the Principal Investigator subject to approval by the Vice President for Research, who shall retain records of all such approvals.
d. **Compensation/Budget**

   i. **Finders Fees**: No contract, protocol and/or consent agreement shall include terms under which compensation is paid to any person in exchange for referrals of potential participants. This does not include compensation normally paid to the Investigator or organization for the conduct of the study.

   ii. **Bonus Payments**: No contract, protocol and/or consent agreement shall include terms under which payments are made to the organization or research staff designed to accelerate recruitment that are tied to the rate or timing of recruitment.

   e. **Communication of Findings**

   Contracts or other funding agreements will require the sponsor to promptly report any findings that may affect the safety of participants or influence the conduct of the study or alter the IRB’s approval to continue the study. Contracts or other agreements will require the sponsor to send data and safety monitoring plans and reports. Contracts or other funding agreements will specify the time frame for providing routine and urgent data and safety monitoring reports as indicated in the data and safety monitoring plan approved by the IRB.

   vi. **Patient Safety or Medical Care.** Each such agreement shall describe a method under which study findings which may directly affect participant safety or medical care are promptly communicated to affected subjects.

   vii. **Results of Monitoring.** In addition, in any study in which a sponsor or other funding source will perform routine monitoring or oversight, the agreement shall include an associated plan under which the monitoring body causes any of the following findings to be promptly reported to the IRB of record:

   1. Findings which may affect the willingness of subjects to continue participation;

   2. Findings which may influence the conduct of the study;

   3. Findings which may alter the IRB’s approval to continue the study.
Contracts or other agreements will describe the steps followed to communicate findings from a closed research study when those findings directly affect participant safety. Contracts or other funding agreements will specify a time frame after closure of the study during which the sponsor will communicate such findings (e.g., two years). This will be based on the appropriate timeframe for each individual study.

f. **Manufacture of Test Articles.** Each such agreement for an investigational test article shall contain assurances that the manufacture and formulation of investigational or unlicensed test articles conform to federal regulations.

g. **Indemnification.** UC requires indemnification for UC, its Board of Trustees, and its Institutional Review Board for any clinical trial sponsored by a commercial firm for which it is the IRB of record. The Office of General Counsel has the authority to waive indemnification, and may do so when requested by the principal investigator if the Office of General Counsel’s review of the contract, protocol and/or informed consent agreement demonstrates that the risk is reasonable.

**ENFORCEMENT**

This policy shall be administered by the Office of General Counsel, the Office of Sponsored Research Services, and the authorized Contracting Officer for Research. Exceptions to the policy may be granted by the Vice President for Research in consultation with the Office of General Counsel.

**RELATED UC POLICIES**

HRPP Policy II.01 *Obtaining Informed Consent in Human Subjects Research*
HRPP Policy II.02 *Reporting Unanticipated Problems in Human Subjects Research*
HRPP Policy II.03 *Treating Injuries of Participants in Human Subjects Research*
HRPP Policy III.01 *Review by the Institutional Review Board of Human Subjects Research*
University Rule 10-43-18 *Records: Responsibilities and rights concerning ownership, access to and maintenance of original scientific records.*
University Rule 10-30-02 *Research Publication restrictions in sponsored research*
Applicable regulations

45CFR46
21CFR50
21 CFR56
21 CFR312.50 et. seq.

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Date Adop ted  March 2015  Signature  signed copy on file