Office of Research Services

13. Sponsored Research

13.1 Policy

UMKC's Office of Research Services (ORS) is responsible for ensuring that negotiations between UMKC and sponsors relative to research that will take place under the purview of UMKC's Institutional Review Board (IRB) follow all relevant Federal and State laws, rules and regulations and Institutional policies and procedures.

Researchers cannot commence research involving human subjects and/or otherwise enroll subjects until the IRB has approved the study and, to the extent that the activity is sponsored, a fully executed sponsor agreement is in place between the sponsor and the University.

Since Truman Medical Center (TMC) and Children's Mercy Hospital (CMH) also serve as sites for sponsored University research, to the extent that research under the purview of UMKC's IRB takes place at TMC or CMH, specific coordination takes place between the UMKC ORS, the IRB, TMC's Office of Research Administration and CMH's Office of Research Administration and Project Management.

13.2 Definitions

Principal investigator (PI): is an Individual who conducts research or under whose immediate direction research is conducted; or, in the event of an investigation conducted by a team of Individuals, is the responsible leader of that team. While the FDA considers a PI and an investigator to be synonymous, this document does not.

Proposal: a proposal is a description of the work University personnel propose to complete on a sponsored project. The details included in a proposal depend on the project's scope and who will read the document. Ideally, the proposal will persuade readers to support the proposed project. Proposals are usually discipline and funding-source specific.

Self-sponsored (or "investigator-initiated," "investigator-sponsored," or "unsponsored"): refers to a situation in which the Individual investigator is a UMKC investigator and is the holder of the Investigational New Drug (IND) or Investigational Device Exemption (IDE) and therefore assumes the duties of the sponsor of the clinical investigator under the applicable US food and drug administration (FDA) regulations.

Sponsor (or "sponsored"): is any governmental or private agency, institution, company, organization, foundation, or person or party that provides funding for a research study. The term *sponsor* is understood to include any intermediaries, such as contract research organizations or coordinating centers, acting as agents of the sponsor. All research falling under these types of agreements is considered *sponsored research*. The funding mechanism may be through a grant, contract or cooperative agreement.

Sponsored project: the characteristics of a sponsored project are:

- Funded for a specific purpose,

- An exchange transaction where the sponsor receives value in return for the funding provided to the University,
- Executed by an Award, Contract, Cooperative Agreement, Memorandum of Understanding, or other formal mechanism,
- For the purpose of supporting any research, scholarly, instructional or public service activity,
- The sponsor may retain some claim (option or otherwise) to intellectual property that may be developed as a result of a sponsored project,
- The sponsor may have a direct interest in the development and ownership of the intellectual property resulting from the activity, and the project may have restrictions requiring regulatory compliance.

13.3 Specific Policies

13.3.1 PI Responsibilities

It is the responsibility of the PI to:

- Know and adhere to the specific limitations and restrictions of the sponsor and of the award documents;
- Know and adhere to all administrative and financial compliance requirements of sponsors, regulators, and the University;
- Know and adhere to all technical reporting and deliverable requirements; and
- Comply with Federal, state and University policies relating to human subjects and other similar policies as appropriate.
- Submit a copy of the grant proposal or clinical protocol as part of the initial IRB application, regardless of funding source.

13.3.2 ORS Review

The ORS is responsible for the formal negotiation and administration of extramural support for University contract agreements sponsored by government and non-government agencies. The University Institutional Official (IO) is the designee authorized to bind the University. ORS is responsible for securing authorized signatures on awards with sponsors. To this end, ORS serves as the intermediary between a sponsor and the PI for purposes of negotiation, budget changes, modifications to an award, award date extensions, and other administrative matters. In consultation with the PI, ORS reviews the award terms and conditions and the budget before obtaining authorized signatures. ORS and the PI are responsible for ensuring University compliance with the terms and conditions of the award, as well as any applicable Federal, State, and University regulations and guidelines.

13.3.3 IRB Review

For commercially sponsored clinical trials under the purview of UMKC's IRB, when subject consent must be obtained, the IRB or IRB staff will confirm the following with TMC or CMH:

- That sponsor agreements contain language reflecting:
    - UMKC's commitment to the protection of human subjects involved in research;

- That UMKC and the sponsor will follow the protocol, applicable laws and regulations and ethical standards.
- Who is responsible for payment with respect to research-related injuries?
- Sponsor Indemnification, as appropriate, for the research undertaken, for subject injury and use of research data and results.
- A summary of the study's scope and a description of services to be provided by UMKC, if applicable TMC, a study budget, and the reporting obligations of the parties.
- If the sponsor discovers results that could affect the safety or medical care for the subjects, then the sponsor will make sure the IRB is notified.
- If a study monitor is used to monitor the research and the study monitor uncovers information that could affect the safety of subjects or their willingness to continue participation, influence the conduct of the study, or alter the IRB approval to continue the study, then the sponsor will communicate such information to the IRB as soon as reasonably possible.

- That a fully executed sponsor agreement is in place between UMKC, TMC or CMH and the sponsor, which is a condition that must be met, in addition to IRB approval, before any subject enrollment can occur.

The appropriate institution's staff will review sponsored agreements and study information as necessary for each sponsored protocol to ensure that the consent and sponsored agreement language are consistent. Inconsistencies will be relayed to the PI. It is the ultimate responsibility of the PI to edit the consent and ensure that it is consistent with the sponsored agreement.

13.3.4 IRB Fees

Payment of the IRB administrative fee is regarded as a contractual responsibility of the sponsor. The investigator should inform the sponsor that IRB administrative fees are the sponsor's responsibility and are not contingent upon research approval, subject enrollment, or early termination of research.

The IRB administrative fee is consistent with current IRB fees levied by other institutions. The IRB administrative fee schedule is subject to periodic review and revisions.

The IRB administrative fees apply to all non-governmental, non-affiliated sponsored research under the purview of the UMKC IRB. Institution supported research and research determined to be exempt from IRB review under Federal regulations are not subject to IRB review fees. The ORS reserves the right to waive IRB administrative fees. Waiver of fees will be considered by the ORS on a case-by-case basis for unfunded studies.

13.4 Procedures

The IRB, directly or through the Truman Medical Center Research Administration Office, will invoice for IRB fees as follows:

- The sponsor will be invoiced for initial review and continuing review to cover the IRB review of sponsored research. These fees are not contingent upon IRB approval, subject enrollment, or other sponsor and investigator actions.

- The investigator will be responsible for payment of the IRB administrative fee if the sponsor does not pay.

- An investigator may submit a written request of waiver of the IRB administrative fee to the IRB administrative office. Waiver of fees will be considered on a case-by-case basis by the ORS.

Approved by: Lawrence Dreyfus, PhD

Name of University Institutional Official

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Signature of University Institutional Official Date