



Institutional Review Board

University of Missouri-Columbia

Standard Operating Procedure

Office of Sponsored Programs Administration/IRB
Coordination

Office of Sponsored Programs Administration/IRB Coordination

Effective Date: June 1, 2006
Original Approval Date: June 1, 2006
Revision Date: June 10, 2010
July 1, 2011
March 1, 2015
July 1, 2015

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Table of Contents

Purpose
Scope
Policy/Procedure

1.0 Purpose

To describe the procedures for coordination between the Office of Sponsored Programs Administration (OSPA) and the Institutional Review Board (IRB) in administering sponsored research agreements at the University of Missouri-Columbia (UMC) to ensure protection of human subjects and conduct of research in compliance with federal, state, and institutional human research protection requirements and the written research protocol.

2.0 Scope

The SOP applies to all human subject research falling under the purview of the University of Missouri Institutional Review Board.

3.0 Policy/Procedure

Both OSPA and the IRB are committed to ensuring the protection of human subjects involved in sponsored research. Sponsors are the agencies, institutions, companies, organizations,

IRB – Office of Sponsored Programs Administration/IRB Coordination

Page 2 of 3

foundations, or individual grantors responsible for the initiation, management, or financing of 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 in carrying out the responsibilities above. All research falling under these types of agreements is considered sponsored research. OSPA and the IRB coordinate activities in significant areas of sponsored research including: Proposal Submission; Negotiation of Award Agreements; Negotiation of Clinical Trial Agreements; Sub-award Agreements for Off-Site Research; Establishing Accounts; and Suspensions, Terminations, and Lapses of Approval.

Sponsored Research Contracts

- Sponsor contracts that are reviewed by the OSPA. The OSPA will review contracts and the IRB and OSPA will share contract and study information as necessary for each sponsored protocol to ensure that protocol, consent, and contract language are consistent.
- Contracts or other funding agreements require the sponsor to promptly (no longer than within 30 days) report to the organization any findings that could:
 - Affect the safety of the participants.
 - Influence the conduct of the study or alter the IRB's approval to continue the study.
- Contracts or other funding agreements require the sponsor to follow the organization's policies and procedures regarding the publication of findings from sponsored research.

Contracts will be reviewed for the following by both the OSPA and IRB:

- The organization will comply with the protocol, applicable regulations and ethical requirements.
- The contract will require the Sponsor to send data safety monitoring reports to the Organization.
- The contract will define the time frames for providing routine data, urgent data and safety monitoring reports to the Organization.
- The contract will specify a time frame after study closure for communicating findings from the sponsor.
- The contract will define who will be responsible for research related injuries.
- If the sponsor will monitor the conduct of the research, the contract will be required to state that if the study monitor uncovers information that could affect the safety of participants or their willingness to continue participation, influence the conduct of the study, or alter the IRBs approval to continue the study, the sponsor will make sure that the information is communicated to the IRB.
- If the sponsor discovers results that could affect the safety or medical care, the sponsor will make sure the IRB finds out, even if the study is closed.

Terminations or Lapses in IRB Approval

1. If the IRB terminates IRB approval of a sponsored project due to noncompliance, the IRB office will provide the Director of OSPA with a copy of the resulting termination letter.

IRB – Office of Sponsored Programs Administration/IRB Coordination

Page 3 of 3

2. OSPA is responsible for taking the appropriate action in accordance with the sponsor requirements.
3. If an IRB approval lapses due to failure of the PI to submit a continuation review application, IRB staff is responsible for sending the PI a lapse of approval letter. The PI is responsible for informing the sponsor of the project that IRB approval has expired, been terminated, and any lapse of approval.

[Return to Table of Contents](#)