



Institutional Review Board

University of Missouri-Columbia

Standard Operating Procedure

**Sponsored Programs Administration and
IRB Coordination**

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1.0 Purpose

To describe the procedures for coordination between the Sponsored Programs Administration (SPA) 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 SPA and the IRB are committed to ensuring the protection of human subjects involved in sponsored research. Sponsors are the external entities, such as government agencies, institutions, companies, organizations, foundations, and individual grantors responsible for the oversight and funding 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. SPA and the IRB coordinate activities in significant areas of sponsored research including: Proposal Submission; Just-in-Time documentation of IRB approval of a research plan; Negotiation of Award Agreements; Negotiation of Clinical Trial

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Agreements; Sub-award Agreements for Off-Site Research; Establishing Accounts; and Suspensions, Terminations, and Lapses of Approval.

Sponsored Research Agreements

1. Sponsor agreements are reviewed by SPA. SPA is responsible for the review and negotiation of sponsored activity agreements. The IRB and SPA will share agreement and study information, as necessary, for each sponsored clinical trial to ensure that protocol, consent, and agreement language are consistent.
2. For each sponsored activity agreement which includes human participants, SPA will collaborate with the IRB to ensure an approved IRB project application is available prior to finalization of the sponsored agreement award.
3. Agreements require the sponsor to follow the Institution's policies and procedures regarding the publication of findings from sponsored research.

Clinical Trial Agreements:

The IRB and SPA will share agreement and study information, as necessary, for each sponsored clinical trial to ensure that protocol, consent, and agreement language are consistent.

Clinical Trial Agreements will be reviewed for the following by SPA (IRB as needed):

1. The institution will comply with the protocol, applicable regulations, and ethical requirements.
2. The agreement will require the Sponsor to send data safety monitoring reports to the Institution and Institution's study investigator.
3. The agreement will define the time frames for providing routine data, urgent data and safety monitoring reports to the Institution.
4. The agreement will specify a time frame after study closure for communicating findings from the sponsor.
5. The agreement will define who will be responsible for research related injuries.
6. The agreement will require sponsor to report to the IRB any findings or information that could directly affect the health, safety, medical care, and/or willingness of current (and past) participants to continue to participate in the study; and report to the IRB any findings or information that could influence the conduct of the study or alter the IRB's approval to continue the study.
7. The agreement will require such reporting promptly (no longer than within 30 days).
8. If the sponsor discovers findings, results, or information that could affect the safety or medical care of participants, the sponsor will make sure the IRB finds out, even if the study is closed.
9. For multi-center studies, the agreement will provide Institution the ability to publish results according to Institution's policies and procedures within reasonable timeframe should not multi-center publication occur upon conclusion of the study.
10. The agreement will require that a description of the study be made available on clinicaltrials.gov.

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11. If sponsors are requiring contract language which is not in alignment with current HRPP/IRB policies and no resolution can be reached, it will be elevated to the Institutional Official for a decision on the ability of the institution to participate in the study.
12. Investigators should be working on IRB requirements at the time of proposal submission and budgeting.
 - The Initial Request for MU to be the IRB of Record is an IRB application form in eCompliance that should be utilized to request the MU IRB to be the IRB of Record for your proposed study if you do not yet have a fully developed protocol. This form may also be used if a letter is needed to indicate IRB pending final determination for a sponsored study submission (i.e. grant proposal submission) or for multi-site studies. This form is intended to be submitted preferably at the time of proposal submission to help with budgeting IRB fees and limit delays during Just In Time requests and award process. If the form is not completed, there is potential for (a) MU to not be able to serve as the IRB of Record for certain multi-site projects, (b) increased costs for IRB fees not included in the budget, and (c) possible delays in IRB approval at JIT requests or award time. Investigators will still need to complete the full IRB application prior to enrolling or interacting with human subject participants.
 - IRB fees apply for industry sponsored studies, for profit, private sponsors and multi-site studies where MU is engaged in research.
<https://research.missouri.edu/human-subjects-research/irb-fees>
 - The “Not Yet Open to Enrollment” status means the project has IRB approval for the project design but some institutional requirements are missing like funding information or in some cases a site initiation visit. For externally sponsored research, the project status will be set to Not Yet Open to Enrollment if the IRB project does not reference the PeopleSoft Proposal Number and if applicable the MoCode. The MoCode and Proposal number can be submitted at a later time using the Requested Identification Numbers/Information Form.
 - If the injury language is still being negotiated at the time of IRB approval, the study will be placed in this status until we receive SPA approval. If changes are needed to consent(s), an amendment must be submitted for additional review and approval, then enrollment can begin if all other requirements have been met.
 - The Requested Identification Numbers/Information Form should be utilized to provide Clinicaltrials.gov number, MoCode, proposal number, fiscal contact, or Study Short Name if it was not previously provided on an approved study. Once the missing information is received and ready to be acknowledged, we will update the project status from “Not Yet Open to Enrollment” to “Active-Open to Enrollment” issue the acknowledgement letter showing the updated project status.

Suspensions, Terminations, or Lapses in IRB Approval

1. If the IRB suspends or terminates IRB approval of a sponsored project due to noncompliance, the IRB office will provide the Director of SPA with a copy of the resulting suspension or termination letter.
2. SPA is responsible for taking the appropriate action in accordance with Institution's policy and sponsor requirements.
3. If an IRB approval lapses due to failure of the PI to submit a Continuation Review Report, eCompliance will automatically send an expiration notice. The PI is responsible for informing the sponsor of the project that IRB approval has expired, been suspended or terminated, and any lapse of approval.

References:

Policy Revision Dates Prior to January 21, 2019:

June 1, 2006; June 10, 2010; July 1, 2011; March 1, 2015; July 1, 2015; June 8, 2017