



Institutional Review Board
University of Missouri-Columbia

Standard Operating Procedure

Initial Review

Initial Review

Effective Date:	September 1, 2004	
Original Approval Date:	September 1, 2004	
Revision Date:	December 9, 2005	December 1, 2006
	June 10, 2010	August 12, 2010
	July 1, 2011	March 1, 2015
	July 1, 2015	January 29, 2016
	June 8, 2017	May 3, 2018

Michele Kennett

Approved By: Michele Kennett, JD, MSN, LLM
Associate Vice Chancellor for Research

Table of Contents

Purpose

Scope

Policy/Procedure

General Information

Submission Requirements

Full Board Submission Deadlines

Administrative Processing and Review

Additional Reviews

Expedited Review Process

Full Board Review Process

Setting Approval Dates

Expiration Dates

Approval Notification

1.0 Purpose

To aid in assuring knowledge and compliance of all persons involved in any aspect of human subject research by documenting the procedure for initial review of non-exempt research.

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

General Information

In conducting the initial review of proposed research, IRBs must obtain information in sufficient detail to make the determinations required in 45 CFR 46.111, 21 CFR 56.111 and 38 CFR 16.111.

Submission Requirements:

Materials required to assist the IRB in its review of proposed research, include but are not limited to the following, as applicable to the research project:

- Application form and applicable sub-forms (submitted electronically through the eCompliance system)
- Advisor Approval Form
- PI Assurance Form
- Protocol
- Proposed informed consent documents
- Any relevant grant applications
- Letters of permission or support from other participating institutions
- Authorization Agreements (if there is reliance on our IRB or reliance on another institution's IRB)
- Clinical Investigator's Drug Brochure
- Data safety monitoring plan, if appropriate.
- Any recruitment materials, including advertisements intended to be seen or heard by potential subjects
- Questionnaires, handouts, or any other applicable instruments
- Accounting Services Approval

Full Board Submission Deadlines:

The full board deadline is the 25th of the month for review at the following month's meeting.

Administrative Processing and Review

1. All applications submitted to the IRB office will be reviewed in the order they are received. The IRB administrative office staff will conduct a preliminary review of the submission materials to determine the completeness of the packet; to determine if, in their opinion, the project may qualify for expedited or full-board review; and to request clarifications and/or additional materials so as to provide the reviewer with a complete application that meets regulation and institutional requirements.
2. Any incomplete submissions will be left in returned status until all required materials are received. The principal investigator or designated contact person will be notified via e-mail that the packet is incomplete and a list of the materials necessary to complete the packet. A project that is incomplete will not be forwarded for review by the IRB until all the necessary elements and clarifications have been received.
3. Prior to final approval being granted on any project, the IRB office will determine if all study personnel have completed the required IRB education. IRB approval will be held until the required training has been completed for all key personnel.
4. If the study qualifies for expedited review, it is assigned to a reviewer; otherwise it is placed on the appropriate agenda.
5. The IRB staff will ensure the primary reviewer has the necessary expertise. For any review, if the primary reviewer feels he/she does not have the necessary expertise to review the project he/she may contact the IRB staff and the project will be reassigned to another primary reviewer with the necessary expertise. In addition, if an assigned reviewer has a conflict of interest they should contact the IRB staff and the study will be reassigned.
6. If the IRB staff determines that there is not at least one person on the IRB with the necessary expertise, they will invite individuals (consultants) with competence in that area to assist in the review of issues. (see IRB Membership policy)

Additional Reviews

Several other reviews may be required. Rarely is it necessary to prolong an approval for a study due to an additional review, however, it can occur. Investigators will be informed that research cannot commence until all approvals have been obtained, if applicable. Documentation of each additional review will be entered into the eCompliance database.

1. *Devices* - If the project includes the use of an experimental device, a copy of the application, the protocol and the device information will be sent to the designated device

consultant, if needed prior to review (per 45 CFR 46.107(f)). The device review and recommendation will be sent to the assigned reviewer as part of the review packet.

2. *Radiation or Biosafety* - If the project includes radiation safety or biosafety, a copy of the application, consent, and the protocol will be sent to the radiation or biosafety office prior to review by the full board. The review and recommendation will be sent to the assigned reviewer as part of the review packet and is required prior to IRB approval being granted. Radiation safety or biosafety may require additional reviews by their respective boards. If further review is needed, IRB approval may be delayed until approval from radiation or biosafety is received.

3. *Investigational Drug Services (IDS)* – Pharmacy (IDS) controls the storage, dispensing, labeling, and distribution of investigational medications. If the project includes the use of medication(s), the IRB office will forward a report to the Investigational Drug Pharmacist. Trials involving the dispensing of investigational medications must be reviewed and approved by the IDS before being granted IRB approval. All trials must receive IRB approval prior to Pharmacy's dispensing any medications pursuant to that protocol.

4. *Accounting* – If the project plans to provide compensation to subjects, it must receive approval from accounting prior to IRB approval being granted.

5. *Conflict of Interest* – If a conflict of interest is identified with the investigator and/or study staff and the proposed research, review by the Conflict of Interest (COI) committee is required. The investigator and the Office of Research will be notified about the possible conflict. The investigator may be required to submit additional paperwork for review by the COI committee. Depending on the level of conflict and the degree to which it impacts the proposed study, IRB approval may be delayed until a resolution or management of the conflict has been developed.

6. *Veterans* – If the proposed research plans to recruit veterans and/or use VA resources and/or staff, review by the VA Research and Development Committee is required. VA R&D approval is required prior to conducting any portion of the proposed research at the VA Hospital. See the VA policy for more information.

7. *Tissues/Specimens* – If a proposed study is using tissue samples or excess tissue samples, additional reviews will occur in conjunction with pathology/laboratory supervisors and approved biorepositories.

8. *Coverage Analysis* – If a proposed study is a clinical trial or will result in charges in a hospital or clinical setting, investigators must provide an initial coverage analysis/billing grid detailing charges according to standard of care or research only criteria. A final, Medicare coverage analysis will be performed by the Human Subjects Research Protections Program (HRPP) to ensure compliance with CMS guidelines.

9. Study Type/Department Specific – In certain circumstances, the nature of the study will require additional approval by a committee or department chair or supervisor. The IRB application system will provide a mechanism for these approvals to be acknowledged.

When needed, General Counsel for the University will be consulted on legal issues, to include interpretation of State law and to resolve conflicts between federal, national, and other applicable laws.

Expedited Review Process

Only appropriately trained IRB members may conduct reviews using the Expedited procedure. See IRB Membership policy regarding primary reviewer eligibility and experience. The IRB staff will select and assign a primary reviewer based on their qualifications, education and expertise with the type of research under review.

1. The primary reviewer documents compliance with the applicable regulations permitting expedited review (45 CFR 46.110, 21 CFR 56.110 and 38 CFR 16.110).
2. The review is generally completed within two weeks of receipt of the materials and the review recommendation is sent to the IRB administrative office for final processing. The primary reviewer always has the option to contact the IRB staff and request that the project be reviewed at the next full board meeting if the reviewer determines the project does not meet the requirements for expedited review or if the reviewer is more comfortable having the project reviewed by the full board.
3. The reviewer determines and documents the following:
 - All applicable criteria are met and all research activities fall into one or more categories of research allowing review by the expedited procedure.
 - Any other determinations required by the regulations, including protocol specific findings that justify those determinations.
4. The primary reviewer will determine the study is approved, approved with minor modifications or requires substantive clarifications.
 - a. If the primary reviewer requests any **minor modifications* or clarifications** requiring simple concurrence by the investigator, the IRB office will notify the investigator. This request and the written response will be documented in the file. The IRB staff will review, for completeness, the clarifications or documented changes when they are received.
 - b. For clarifications that they are directly relevant to the expedited determinations under 45 CFR 46.110, 21 CFR 56.110 and 38 CFR 16.110, the IRB staff will contact the investigator and request the modifications or

clarifications in writing. The request and response will be documented in the file. The primary reviewer will re-review the study once the modifications have been made and determine the approval status.

5. If the investigator is unwilling to make requested modifications, the project will be placed on the agenda for the next full board meeting along with the justification from the investigator. The board will deliberate and decide to approve or disapprove. See Full Board Review Process below.
6. During an expedited review, if the primary reviewer determines the application cannot be approved by expedited procedures, the application will be placed on the next available full board docket. A research project will not be disapproved without convened IRB review at which a majority of the members of the IRB are present. (45 CFR 46.108(b))

Full Board Review Process

1. The applications for full board review are conducted using a primary reviewer system of review. The primary reviewer documents compliance with regulatory requirements as applicable including, but not limited to 45 CFR 46.116, 21 CFR 56.116 and 38 CFR 16.116. All board members are expected to have a working knowledge of all submitted materials and be able to engage in a meaningful discussion. (See Board Meeting Procedure policy for further information)
2. Once all discussion has ceased on a project, a vote on the motion on the table will be taken. All motions, discussions and actions taking place during the convened Board meeting will be documented in the written minutes of the meeting. (See Board Meeting Procedure and Minutes policy for further information)
3. The convened board will determine if the study is approved, approved with minor modifications or requires substantive clarifications, or disapproved.
 - a. If the board requests any minor modifications* or clarifications requiring simple concurrence by the investigator, the IRB office will notify the investigator. This request and the written response will be documented in the file. The clarifications are subsequently reviewed and approved by the primary reviewer or another designee in a timely fashion.

***Minor Modifications or Clarifications:**

- Those modifications or clarifications that do not involve potential for increased risk or decreased benefit to the human subjects.
- Protocol revisions that entail no more than minimal risk to participants are considered “minor” modifications.
- Changes to informed consent documents that do not affect the rights and welfare of study participants, or do not involve increased risk, or significant changes in the study procedures
- New or revised recruitment advertisements or scripts.

- b. When the convened IRB requests **Substantive Clarifications or Modifications** regarding the protocol or informed consent documents that are directly relevant to the determinations required by the IRB for research under 45 CFR 46.111, 21 CFR 56.111 and 38CFR 16.111, the convened IRB must review the revisions.
 - i. The project will be re-reviewed with the documented modifications at the next convened board meeting to determine approval status.
 - ii. The investigator may request to attend the meeting to discuss the study under review and answer questions or provide explanation. In addition, the board may request that the investigator attend the meeting to address concerns of the study.
4. If the study is disapproved by the convened board, the Principal Investigator will be notified in writing and the decision will be documented in the Minutes. The letter will include the reason(s) for disapproval and recommendations, if any, on how to proceed in an attempt to have the study approved. The investigator will be given the opportunity to respond. (See Appeals policy)

Setting Approval Dates

1. When the IRB Reviews and Approves Research ***Without Conditions:***
 - For expedited review, the approval date is the date the primary reviewer approved the study.
 - For full board review, the approval date is the date of the board meeting in which the convened board approved the study.
2. When the IRB Reviews and Approves Research ***With Minor Modifications or Clarifications:***
 - The approval date is set to the date of the board meeting in which the convened board approved the modifications or the date on which the primary reviewer or IRB designee reviewed and accepted all clarifications.
3. When the IRB Reviews and Defers Approval requiring ***further review by the IRB at a subsequent convened meeting:***
 - If the study is approved at the subsequent convened meeting without conditions, the approval date is the date of the boards meeting in which the convened board approved the study.
 - If the study is approved with minor modifications, the approval date is set to the date of the board meeting in which the convened board approved the modifications or the date on which the primary reviewer or IRB designee reviewed and accepted all clarifications.

- If the study is deferred once more, step 3 will repeat until the study is either approved or disapproved.

Expiration Dates

1. For expedited studies, the initial expiration date is set to one year after the date the primary reviewer approved the study, but cannot extend past that one year interval. Shorter continuing review intervals may be requested, as necessary.
2. For full board studies, the expiration date is set to one year after the date of the IRB meeting at which the research project was initially approved. Shorter continuing review intervals may be requested, as necessary.

The expiration date is defined as the first day that the protocol is no longer approved without continuing review and approval by the IRB.

Approval Notification

The IRB will notify investigators in writing of its decision to approve the proposed research activity, the risk level assigned, the consent requirements, and the continuing review interval within the final approval letter. A copy of the approval letter and attached documents will be documented in the eCompliance database.

[Return to Table of Contents](#)