Institutional Review Board

University of Missouri-Columbia

Standard Operating Procedure

Reporting Requirements

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1.0 Purpose

The IRB's policy is to comply with all applicable local, state, and federal regulations in the conduct of research studies. Once the IRB has taken any of the following actions, additional reporting to the IRB, appropriate institutions officials, and agency heads may be warranted:

- Determined that an event represents an unanticipated problem involving risks to participants or others
- Determined that non-compliance was serious or continuing
- Suspended or terminated approval of research

Written procedures are required for preparing and sending these reports.

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

A. IRB staff will initiate these procedures as soon as the IRB takes any of the following actions:
- Determines that an event represents an unanticipated problem involving risks to participants or others
- Determines that non-compliance was serious or continuing
- Suspends or terminates approval of research

B. The IRB Director, with input from the Chair, prepares a letter that contains the following information:
- The nature of the event (unanticipated problem involving risks to participants or others, serious or continuing non-compliance, suspension or termination of approval of research)
- Name of the institution conducting the research
- Title of the research project and/or grant proposal in which the problem occurred
- Name of the principal investigator on the protocol
- Number of the research project assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement)
- A detailed description of the problem including the findings of the organization and the reasons for the IRB's decision
- Actions the institution is taking or plans to take to address the problem (e.g., revise the protocol, suspend subject enrollment, terminate the research, revise the informed consent document, inform enrolled subjects, increase monitoring of subjects, etc.)
- Plans, if any, to send a follow-up or final report by the earlier of
    - A specific date
    - When an investigation has been completed or a corrective action plan has been implemented

C. The IRB Chair and the Institutional Official review the letter and modify the letter as needed.

D. The Institutional Official signs the letter and returns it to the IRB Director.

E. The IRB Director sends a copy of the report to:
- The IRB by including the letter in the next agenda packet as an information item
- The Institutional Official
- Legal Counsel, if applicable
- For VA research: VA R&D committee and the Facility Director (The VA Facility Director is responsible for reporting to other VA authorities and

external agencies as required by VA policy) for additional VA reporting requirements see SOP-VA Hospital Research.

- For DoD research: In addition to the reporting required in the Department of Defense/IRB Coordination SOP, the following must be promptly (no longer than within 30 days) reported to the DoD human research protection officer:
    i. When significant changes to the research protocol are approved by the IRB; the results of the IRB continuing review; change of reviewing IRB; and/or when the organization is notified by any federal department, agency or national organization that any part of an HRPP is under investigation for cause involving DoD supported research
- The following agencies:
    i. OHRP, if the study is subject to DHHS regulations or subject to a DHHS federalwide assurance
    ii. FDA, if the study is subject to FDA regulations.
    iii. If the study is conducted or funded by any Federal Agency other than DHHS that is subject to "The Common Rule", the report is sent to OHRP or the head of the agency as required by the agency
    iv. Reporting to a regulatory agency is not required if the event occurred at a site that was not subject to the direct oversight of the organization, and the agency has been notified of the event by the investigator, sponsor, another organization, or other mechanisms.
- Principal investigator
- Sponsor, if the study is sponsored
- Contract research organization, if the study is overseen by a contract research organization
- Chairman or supervisor of the principal investigator
- The Privacy Officer of a covered entity, if the event involved unauthorized use, loss, or disclosure of individually-identifiable patient information from that covered entity
- The Information Security Officer of an organization if the event involved violations of information security requirements of that organization
- Office of Risk Management
- Office of Sponsored Programs Administration
- The IRB Director can provide copies to others as deemed appropriate by the Institutional Official

F. The IRB Director will ensure that all steps of this policy will be completed within 30 days of the initiating action. For more serious actions, the IRB Director will expedite reporting.

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