Institutional Review Board

University of Missouri-Columbia

Standard Operating Procedure

Reporting Requirements

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 institutional officials, and agency heads may be warranted:

- Determined an event represents an unanticipated problem involving risks to participants or others
- Determined 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

Non-Federally Sponsored Study, Non-FDA Regulated

If the IRB determined an event on **a non-federally sponsored study and non-FDA regulated study** represents an unanticipated problem involving risks to participants or others, non-compliance was serious or continuing, and/or suspended or terminated approval, the following will take place:

A. The IRB staff, with input from the Director, prepares a determination letter to be sent to the investigators. Any additional corrective actions will be included in the letter.
B. A copy of the letter will be placed in eCompliance for documentation.

Additional reporting on suspensions and terminations:
A. The Director will notify the Institutional Official of the determination.
B. Office of Sponsored Programs Administration (OSPA) will be notified so the sponsor can be notified by OSPA (See OSPA/IRB Coordination SOP)

Federally Sponsored Study

If the IRB determined an event on **a federally sponsored study** represents an unanticipated problem involving risks to participants or others, non-compliance was serious or continuing, and/or suspended or terminated approval, the following will take place:

A. The IRB Director, with input from the Chair and Institutional Official, 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
B. The MU IRB maintains the Federally Sponsored Reportable Events Report within eCompliance as a monitoring tool to highlight all federally sponsored reportable events.

Internal Communication Reporting Regardless of Sponsor

The Director will ensure ongoing communication with the following contacts as applicable to the study type and the event details:

a. The Institutional Official
b. Legal Counsel
c. The Principal Investigator
d. Chairman or Supervisor of the Principal Investigator
e. The Privacy Officer, if the event involved unauthorized use, loss, or disclosure of individually identifiable patient information from that covered entity
f. The Information Security Officer if the event involved violations of information security requirements
g. Office of Risk Management
h. Office of Sponsored Programs Administration
i. The IRB Director will communicate with any additional contacts as deemed appropriate by the Institutional Official.

External Communication Reporting for Federally Sponsored Studies

The Director will ensure appropriate communication with the following agencies as appropriate:

a. OHRP, if the study is subject to DHHS regulations.
b. When following FDA clinical investigation requirements, the IRB will report serious and/or continuing noncompliance, unanticipated problems, and/or suspensions or terminations, to the FDA when:
    1. The board determined an FDA regulated item caused serious, unexpected subject harm; and/or
    2. The board determined the event could not be corrected and the outcome impacted the validity of the data to be submitted to the FDA for initial approval.
        i. Submissions will be made in compliance with this page: https://www.fda.gov/science-research/report-problems-fda/mandatory-irb-reporting-fda-contacts
        ii. When reporting is required by the IRB, suspensions or terminations of IRB approval, the IRB will include the IND or IDE number, the full name of the research protocol, the name(s) of the clinical investigators, and the reason(s) for the suspension or termination.
        iii. All other events not meeting criteria listed under (b)(1) or (2) should be reported to the FDA by the sponsor or sponsor-investigator.

c. 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.
   i. Reporting to a federal 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.

d. For DoD research: The IRB will report promptly (within 30 days) any unanticipated problems, serious noncompliance, continuing noncompliance. suspensions, and/or terminations to the Component Office of Human Research Protections (COHRP). Substantiated allegations related to classified HSR must be reported immediately.
   i. In addition to the IRB reporting requirement, the following must be promptly (no longer than within 30 days) reported to the COHRP by the sponsor and/or sponsor-investigator (DoD 3216.02 section 3.6):
      1. 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
      2. Reports of audits of DoD conducted or supported human participant research by another federal or state agency, official governing body of a Native American or Alaskan native tribe, other official entity, or foreign government.
   ii. DoD Information: https://rt.cto.mil/ddre-rt/dd-rtl/hsd/hrp/
      1. Additional PI Reporting may be required. The PI must ensure all reportable items will be reported according to each component's requirements. For example, the Army:http://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.contact_orp

e. For VA research, 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-Truman VA Hospital Human Subjects Research – Special Considerations.

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. The MU IRB office maintains a report in eCompliance documenting events requiring federal reporting to help monitor reportable events.

When the investigator provides documentation that the appropriate federal agency(-ies) and/or study sponsor has been notified of the event, the IRB will not submit a duplicate report.

AAHRPP Reporting

The MU IRB must report as soon as possible but generally within 48 hours after the organization or any researcher (if the researcher is notified rather than the organization) becomes aware of:

1. Any negative actions by a government oversight office, including but not limited to, OHRP Determination Letters, FDA Warning Letters, FDA 483 Inspection Reports with an official action indicated, FDA Restrictions placed on IRBs or Investigators, and corresponding compliance actions taken under non-US authorities related to human research protections.
2. Any litigation, arbitration, or settlements initiated related to human research protections.
3. Any press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding the Organization's HRPP.

References:

Policy Revision Dates Prior to January 21, 2019:
December 1, 2006; June 10, 2010; July 1, 2011; March 1, 2015; July 1, 2015; June 8, 2017