



Institutional Review Board

University of Missouri-Columbia

Standard Operating Procedure

Noncompliance

Noncompliance

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1.0 Purpose

The purpose of this policy is to establish procedures for handling reports and findings of noncompliance.

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

In order to demonstrate appropriate oversight of research activities and to comply with federal and state statutes, regulations, policies, guidelines, and applicable University policies and procedures, all reports of research non-compliance will be investigated. Reports of noncompliance will be directed to the appropriate IRB staff and to the IRB for investigation and corrective action.

See Definitions document that defines noncompliance, serious noncompliance, and continuing noncompliance.

Receiving Reports of Noncompliance

1. Anyone inside or outside of the University community who has reason to believe that noncompliance with the HRPP Policies and procedures occurred are required to report to the IRB. These reports, including protocol deviations, complaints or other concerns will be accepted verbally or in writing. Reports of noncompliance may be sent to the IRB Chair, IRB members, IRB Staff, or Research Compliance Office.

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2. Investigators reporting their own noncompliance must submit the Event Report within 5 business days of becoming aware of the noncompliance.

Process for Handling Reports of Non-Compliance

The Director, IRB Chair, or designee will review the report, upon receipt. The review is designed to determine whether noncompliance occurred. The review may include review of files, literature, documents, or communication from the investigator and others.

If the issue was reported by someone outside of the research team, the investigator may be contacted by the Director or designee to discuss the issue and to receive additional information. If the Investigator does not provide a timely response, or offers an unsatisfactory explanation or corrective action plan, the IRB may ask the investigator to meet with the chair or attend an IRB meeting to discuss the issue. During the review, the IRB may impose restrictions to the research study until satisfactory answers are received by the investigator.

The IRB reserves the right to request any appropriate additional consultation and expertise to resolve noncompliance.

If it is determined noncompliance did not occur, no other actions are taken. The outcome of the review will be documented within the file.

If noncompliance occurred and an Event Report has not yet been submitted, the investigator will be asked to submit an Event Report with a Corrective Action Plan for board review. The investigator will be asked to submit this report within 5 business days.

When Expedited Review of Noncompliance is Allowed:

1. If the IRB Director, Chair or designee determine the noncompliance involves a minor error, incident, or deviation, the Event Report can be processed using the expedited procedure.
2. This Event Report will be assigned to a primary reviewer or IRB chair.
3. See possible actions below for outcomes of the review.
4. If the primary reviewer or IRB chair determine the noncompliance may be serious or continuing, the process below for full board review will be initiated. All potential serious and continuing non-compliance requires full board review.

When Full Board Review of Noncompliance is Required:

All incidences of noncompliance that could potentially be serious or continuing will be presented to the IRB for a vote to determine whether the noncompliance was serious or continuing (or defer the decision to a future meeting pending receipt of additional information), and the results of the vote will be documented in the Minutes.

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1. The Event Report is assigned to a primary reviewer by the IRB office.
2. The Event Report will be placed on the next available full board docket.
3. The investigator may be asked to attend the IRB meeting.
4. At a convened IRB meeting, the primary reviewer will present the issue. All IRB members will receive the Event Report, synopses of any communication between the IRB and the investigator, the last approved IRB application or continuing review, the approved consent, protocol, or any other pertinent information.
5. The IRB will determine whether the noncompliance resulted in serious or continuing noncompliance, and whether the corrective action plan is acceptable. See findings and possible actions below.
 - a. If the IRB requests additional information, it is referred back to the IRB office to obtain the requested information. An additional review by the IRB designee may be implemented if there is a need to gather more information about the extent or nature of the noncompliance to determine whether the noncompliance is serious or continuing. The information will be presented at the next available full board docket.

Findings

The results of an IRB review will be communicated in writing by the IRB chair or IRB designee to the Investigator (with a copy to the appropriate file).

Not Serious and Not Continuing Noncompliance: If it is determined by the IRB that the finding of noncompliance is not serious and not continuing, the investigator will be notified in writing with any board action(s).

Serious and/or Continuing Noncompliance: If it is determined by the IRB that the finding of noncompliance is serious and/or continuing, the investigation will be notified in writing with the board action(s). See Reporting below.

Possible Actions May Include:

1. No further action
2. Administrative Hold (in accordance with SOP on Suspension and Termination of IRB approval)
3. Suspension: Suspend enrollment or all research procedures for the specific research study in question (in accordance with SOP on Suspension and Termination of IRB approval)
4. Termination of the research; (in accordance with SOP on Suspension and Termination of IRB approval)
5. Require a response from the investigator with a modified corrective action plan
6. Initiate audits or research tracer team reviews of all or some part of the investigator's active protocols
7. Modification of the protocol
8. Modification of the information disclosed during the consent process
9. Additional information provided to past participants
10. Require a status report within a certain period.

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11. Obtain more information pending final decision
12. Conference with other IRB's involved with the research
13. Require current participants re-consent to participation
14. Provide information to current participants whenever such information might relate to the participant's willingness to continue to part in the research
15. Monitoring of the research
16. Monitoring of the consent process
17. If the event is determined to be research misconduct, the event will be referred to the Research Integrity Officer (see Collected Rule below):

MU Collected Rules -420.010 Research Dishonesty

http://www.umsystem.edu/ums/rules/collected_rules/research/ch420

If the Corrective Action Plan calls for any changes to the previously approved research, an Amendment Form must be submitted. See the Amendment SOP for more information about the Amendment process.

Reporting

All cases of noncompliance which the IRB determines to be serious or continuing will be reported according to the SOP on Reporting.

VA Research and Reports of Noncompliance

If the report of noncompliance involves VA research, the IRB Director and the VA R&D Human Research Compliance Officer will interact to review the report of noncompliance. The resolution of the issue will be discussed between all applicable parties. (See Truman VA Hospital Human Subject Research – Special Considerations SOP for further information.)

References:

Policy Revision Dates Prior to January 21, 2019:

December 12, 2005; December 24, 2009; June 10, 2010; July 1, 2011; March 1, 2015;

July 1, 2015; June 8, 2017