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 allegations 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.

Collected Rules -420.010 Research Dishonesty
http://www.umsystem.edu/ums/rules/collected_rules/research/ch420

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 allegations of research non-compliance will be investigated. Allegations 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 non-compliance, and continuing non-compliance.

Receiving Reports of Noncompliance

Research staff or anyone inside or outside of the University community who has reason to believe that noncompliance with the IRB Policies and procedures occurred are required to report allegations of noncompliance to the IRB. These allegations, including protocol deviations, complaints or other concerns will be accepted verbally or in writing.

Allegations of noncompliance may be reported to the IRB Chair, IRB members, IRB Staff, or Research Compliance Office.

Process for Handling Allegations of Non-Compliance

The Director, IRB Chair, or designee will investigate the alleged noncompliance, upon receipt. The investigation is designed to determine whether the allegations of noncompliance can be substantiated. The investigation may include review of files, literature, documents or communication from the investigator and others, which could serve to validate or dismiss the allegation. The investigator may be contacted by the Director or designee to discuss the allegation of noncompliance and to receive additional information to assist with the investigation.

If the Investigator does not provide a timely response to the investigation, 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.

*NOTE: During the investigation, 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 non-compliance.

Possible Outcomes of an Investigation are:

- The allegation of noncompliance has no basis in fact
- The allegation of noncompliance is substantiated

If the allegation of noncompliance is determined to have **no basis in fact**, no other actions are taken. The outcome of the investigation will be documented within the file.

If the allegation of noncompliance is substantiated, the following process is used for handling incidents of non-compliance:

1. The IRB staff will communicate the results of the investigation in writing to the Investigator (with a copy to the IRB chair). This communication will notify the Investigator that the allegation of noncompliance was substantiated.
2. The investigator may 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.
3. The investigator may be asked to respond in writing to the finding of non-compliance and provide additional information prior to submitting the Event Report and Corrective Action Plan.

When Expedited Review of Non-Compliance Permitted

1. If the IRB Director, Chair or designee determine the non-compliance 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 Actions below for possible outcomes of the review.
4. If the primary reviewer or IRB chair determine the non-compliance may be serious or continuing and is not a minor issue, the process below for full board review will be initiated. All potential serious and continuing non-compliance requires full board review.
5. If the expedited process was used, the matter will be placed on the next available agenda as an informational item.

Full Board Review of Non-Compliance

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.

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 investigation report, synopses of any communication between the investigators and the investigator, the last approved IRB application or continuing review, the approved consent, protocol or any other pertinent information.

5. All members attending the IRB meeting will review all the documents and either:
    - Determine the allegation of noncompliance has no basis in fact and no further action is required.
    - Confirm that the allegation of noncompliance is substantiated. If the board has sufficient information for review, the board will determine if the noncompliance is serious and/or continuing.
    - Request more information and defer to a subsequent meeting pending receipt of additional information.

If the IRB determines the allegation of noncompliance is substantiated and the board requests additional information, it is referred back to the IRB office to obtain the requested information. An additional investigation 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.

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 Non-Compliance: 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 Non-Compliance: 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).

Actions

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 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. Modification of the continuing review schedule
11. Obtain more information pending final decision
12. Conference with other IRB’s involved with the research
13. Requirement that 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

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 Allegations of Non-Compliance

If the allegation of noncompliance involves VA research, the IRB Director and the VA R&D Human Research Compliance Officer will interact to determine whether the allegations of research noncompliance can be substantiated and which entity should take the lead in the investigation of the issue. The resolution of the issue will be discussed between all applicable parties. (See VA Hospital Research – Special Considerations SOP for further information.)