

Campus Institutional Review Board Reporting Requirements
Policy Number 2876.36



Campus Institutional Review Board
University of Missouri-Columbia

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Reviewed by: Campus IRB Membership

Effective Date: December 12, 2007

Approval Authority:

Signed
IRB Chair

A handwritten signature in black ink, appearing to read 'ChMBLi', written over a horizontal line.

Date December 12, 2007

Institutional Approval:

Signed
Associate Vice-Chancellor for Research

A handwritten signature in black ink, appearing to read 'R. Hall', written over a horizontal line.

Date December 12, 2007

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1.0 Policy

The Campus IRB must ensure prompt reporting to the IRB any unanticipated problems involving risk to human subjects or others. The Campus IRB will institute additional reporting practices to the appropriate institutions officials, and agency heads when warranted, when the board has determined that any of the following actions occur:

- An unanticipated problem or serious adverse events involving risks to participants or others
- Serious or continuing non-compliance
- Suspended or terminated approval of research.

2.0 Scope

The reporting responsibilities of the Campus IRB govern all human subject research activities conducted under the jurisdiction of the University of Missouri-Columbia.

3.0 Purpose

The reporting structure of the Campus IRB is vital to the success and implementation of its efforts in protecting human subject research participants by endorsing an environment premised on an efficient, high quality comprehensive compliance program.

4.0 Standard Operating Procedure

The Campus IRB is integral to the fundamental mission of the University of Missouri-Columbia's objective to create a culture of compliance. This culture is best served by support established throughout the organizational structure. In an effort to exemplify the institution's support for the IRB process, a system for reporting has been developed to create an open line of communication. The Campus IRB will conduct its processes in accordance with the "Campus IRB Review Processes", "Assessing the Level of Risk", and "Privacy and Confidentiality", "Noncompliance", "Deviation", and "Reporting" policies. The investigator must comply with these policies.

A. CAMPUS IRB REPORTING REQUIREMENTS

The Campus IRB must distribute a written report of all unanticipated problems involving risks to participants or others, non-compliance determined to be serious or continuing, and suspensions and terminations of approved research by the IRB to the categories below within (30) days, and in all cases of death within 24 hours:

1. Institutional Officials
The Vice-Chancellor for Research is the designated recipient of the report.
2. Governmental Agencies
The head of any supporting Federal department or agency, OHRP, and any other relevant regulatory entity or unit governing the research shall receive the written report.
3. Sponsors or Coordinating Centers
The head of any coordinating center or sponsor supporting the research may receive a written report upon request.

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B. PROCESS FOR NOTIFICATION OF FINDINGS AND ACTIONS

The Campus IRB shall provide a written report all serious or continuing non-compliance, suspension or termination of IRB approval, and unanticipated problems involving risks to participants or others, it's findings, actions, and rationale for the IRB's decision to within 30 days to the Vice-Chancellor of Research. In cases involving death, the Vice-Chancellor of Research will be notified in 24 hours.

NOTE: For more serious actions, the Compliance Officer may expedite reporting, as deemed necessary to further protect human subjects.

1. METHODS FOR NOTIFICATION

The Campus IRB shall provide a written notification to the Vice Chancellor for Research and any relevant Institutional Officials, agencies or sponsors.

2. PARTIES TO NOTIFY

The Campus IRB shall provide a written notification to the Vice Chancellor for Research and any relevant Institutional Officials, governmental agencies or sponsors in the following manner:

a. VICE-CHANCELLOR OF RESEARCH

- Distributing a written report of all serious or continuing non-compliance, suspension or termination of IRB approval, and unanticipated problems involving risks to participants or others to the recipient within (30) days. In cases of death, within 24 hours.
- The Vice-Chancellor of Research shall have electronic access to the information provided in the report via the eIRB database.

The electronic system provides visible access of all activity fields and processes related to IRB processes and documentation. Such information includes, but is not limited to, research team members and contact personnel, which projects are approved, the date of approval, the Investigator's name, protocol title and number, level of review/approval, actions, suspensions, terminations, compliance breaches, unanticipated problems involving risks to participants or others, Corrective Action Plans, approval status, CRR and CRR interval, Amendments, applicable contingencies or restrictions, supportive documents, training certificates, instruments, permission letters, and internal review comments.

- A copy of all approved IRB Minutes are provided to institutional officials in accordance with the "Reporting" policy to meet the requirements for notification to the organization of IRB findings/actions.
- **ONGOING COMMUNICATIONS:** The Campus IRB Compliance Officer keeps the Office of Research and Vice Chancellor of Research fully apprised of all IRB findings and actions, by oral and written communications. The Campus IRB Compliance Officer meets regularly with the Vice-Chancellor of Research to discuss all CIRB activities. The Vice-Chancellor of Research has electronic access to all IRB projects, review and approval statuses and the eIRB system. All mandated reporting is done in compliance with all policies herein and in coordination with the Office of Research.

b. OTHER MU INSTITUTIONAL OFFICIALS

The Vice-Chancellor for Research has the institutional responsibility for overseeing the IRB human subject research program processes and is responsible for reporting any mandated events or occurrences to the appropriate institutional officials in accordance with University of Missouri policies, to assure human research activities are conducted in compliance with applicable governing regulations and laws.

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The Vice-Chancellor for Research may delegate the report preparation responsibility to the Campus IRB. The Campus IRB Chair and Compliance Officer, or designee shall assure the aforementioned report contains the following information:

1. 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)
2. Name of the institution conducting the research
3. Title of the research project and/or grant proposal in which the problem occurred.
4. Name of the principal investigator on the protocol
5. Identifying IRB Number of the research project assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement)
6. A detailed description of the problem including the findings of the organization and the reasons for the IRB's decision
7. 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.)

Examples:

- The Privacy Officer of a covered entity, *when applicable* (if the event involved unauthorized use, loss, or disclosure of individually-identifiable patient information from that covered entity) Office of Risk Management
- Office of Risk Management
- Office of Sponsored Programs Administration

c. GOVERNMENTAL AGENCIES/SPONSORS

A written report will be distributed to all governing agencies in compliance with their applicable mandatory reporting requirements.

- (1) OHRP, if the study is subject to DHHS regulations or subject to a DHHS federal-wide assurance.
- (2) 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.
- (3) 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.

d. PRIVATE SPONSORS

A written report may be distributed to the private sponsor upon request. The IRB shall coordinate activities with the investigator to assure the request is related to IRB activities, and the records appropriately reflect the activities being conducted.

e. OTHER OFFICIALS

The Vice-Chancellor for Research, in coordination with the Campus IRB Compliance Officer and IRB Chair will notify, when appropriate, the individuals and/or agencies overseeing the research activities that require mandatory reporting of such events.

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3. DOCUMENTATION

- i. The Compliance Officer or designated Campus IRB staff will initiate the reporting process in accordance with its policies, once it has received notice and within 30 days of the final determination by the convened board of any of the following:
 - An unanticipated problem or Adverse Event involving risks to participants or others in accordance with the “Unanticipated Problems or Adverse Events Review Process” policy.
 - Serious or Continuous Non-compliance in accordance with the “Noncompliance with Campus IRB Policies and Procedures” policy.
 - Suspension or termination of approval of research in accordance with the “Suspension and Termination of IRB Approval” policy.
- ii. The Campus IRB Compliance Officer in cooperation with the Campus IRB Chair will create a file history report and initiate an investigation into the matter and maintain communication with the Principal Investigator.
- iii. The Campus IRB Compliance Officer in cooperation with the Chair will prepare the Report and send to the Vice Chancellor of Research which shall include:
 - The category of the event
 - Name of the institution(s) where the research is being conducted
 - Name of the principal investigator
 - Title of the research project
 - Grant proposal Number
 - Name of sponsor
 - Copy of the approved application
 - Copy of any applicable supportive documents (i.e. Cooperative Agreement, Corrective Action Plan)
 - A detailed description of the problem
 - The findings, actions, and rationale of the Campus IRB’s decision
 - 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
- iv. If a signature from the institutional official is required, the Vice Chancellor of Research will sign the letter, retain a copy and return a duplicate to the Campus IRB Compliance Officer for record keeping purposes. The Campus IRB Compliance Officer will coordinate with the Vice Chancellor to assure a copy of the report is sent to the appropriate agencies.

C. REPORTING ACTIONS TO MEMBERSHIP

1. **EXPEDITED APPROVALS:** The CIRB shall comply with the reporting methods for keeping all board members advised of research proposals and activities which have been approved under the expedited procedure as provided in the “CIRB Review Process Policy” by providing a written copy of all expedited approvals monthly at the convened meeting. In the event a meeting is not held, a written copy of the approvals will be emailed to the membership. All members will have electronic access to the eIRB database that contains the information in the written report.
2. **FULLBOARD ACTIVITIES:** Members receive a electronic written copy of all actions taken and reported by the Campus IRB. The actions are reflected in the minutes in accordance with the “Minutes” policy.

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3. RESTRICTED ACCESS: Members are expected to self-report any conflict of interest in compliance with the “Conflict of Interest” policy. Any member with a Conflict of Interest on a specific proposal is prohibited from accessing the eIRB records for the project.

D. RECORD KEEPING

The Campus IRB Compliance Officer will assure that the appropriate documentation is recorded in the IRB records and maintained for a period of 3 years after withdrawal, closure of research activities, expiration of approval, or the cessation of activities.

Revised December 2007

Revised February 2008