



Campus Institutional Review Board
University of Missouri-Columbia


Research Involving Collaborative Institutions and Multi-Center Sites

Policy Number 2876.33

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Board Review:


Signed
IRB Chair

Date December 12, 2007

Administrative Review:


Signed
Associate Vice-Chancellor for Research

Date December 12, 2007

1.0 Policy

The Campus IRB is receptive to a research community built upon collaboration with multiple sites, and appreciates the growing need to gain knowledge of the compliance requirements within the various venues. The Campus IRB will assure that there is at least one site that can be designated as the primary institution, which will be responsible for documenting IRB assurances from the other institutions.

2.0 Scope

The Campus IRB will apply its policies and procedures to all human subject research activities conducted at collaborative institutions or multiple sites.

3.0 Purpose

The Campus IRB is responsible for ensuring that MU investigators conducting research at other facilities (or external researchers conducting research at MU) are appropriately trained to perform those activities in compliance with the policies and procedures governing the IRB research community. The Campus IRB must assure that all investigators performing research under its jurisdiction have the expertise to perform scientifically sound research in compliance with the tenets of ethical research conduct.

4.0 Standard Operating Procedure

When multi-center sites participate in human subject research, an IRB must assure that measures are in place to hold the designated primary institution accountable. The Campus IRB will provide a comprehensive review of the project benefits in relation to the risks, and therefore believes that participants are best protected if all organizations and research team members involved share equally in that responsibility. The review process may be modified, but not relaxed, to accept documentation from other sites assuring that safety measures are in place to address the risks, confidentiality and data storage.

The Campus IRB takes its guidance from the regulations set forth in Title 45 Chapter 46 Section 114, which provides: "Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the department or agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort."

The Campus IRB will not interfere with the external site's review processes, but will expect any researcher under its jurisdiction to meet all applicable MU standards governing human subject research. More to the point, the research team should strive to maintain a culture of compliance by embracing a "seamless" communication system with the Campus IRB. Maintaining "open lines of communication" will be the key to optimally protecting subject participants.

A. Investigator Requirements

1. The investigators should assure that the basic tenets for acquiring "Human Subject Research Training" requirements have been met by all "key personnel"
2. May need to provide the Campus IRB with the supportive documents and any previously IRB approved documents.
3. Maintain the high ethical standards and a level of research integrity necessary to properly protect human subject research participants.
4. When the investigator is the lead investigator of a multi-center study, or the organization was the lead site in a multi-center study:

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- i. Provide information about whether management of the information obtained in the multi site research could be relevant to the protection of research participants, such as:
 1. Unanticipated problems involving risks to participants or others.
 2. Interim results.
 3. Protocol modifications.
5. When the investigator participates in “cooperative site” or “multi-center studies” the Campus IRB must receive:
 - i. Assurance that written permission is received to conduct or participate in research at the site
 - ii. Assurance that Campus IRB standards are practiced
 - iii. Report unanticipated problems or adverse events to the Campus IRB in accordance with its policies
 - iv. Report information about interim study results
 - v. Report any research methodology modifications
 - vi. Evaluation of whether the management of information obtained in multi-site research that could be relevant to the protection of research participants was adequate.
 - vii. Assure methods are in place to protect the data acquired during the process.
 - viii. Meet all of the “Reporting” requirements set forth by the research agreement.
6. Comply with all Campus IRB policies.

B. IRB Requirements

When human subject research is conducted at multiple sites, the Campus IRB is required to maintain communications between the investigator and IRB of the external site. The IRB will be responsible for determining:

1. Whether the site granted permission for the research to be conducted.
2. Whether the site has an IRB.
3. Whether previous IRB approval had been granted to the investigator. The Campus IRB must review the approval documentation to assure that the MU IRB standards will be met by the institution and for the applicant who is applying for Campus IRB approval.
4. If the site had an IRB, whether the IRB had approved the research to be conducted by the investigator, or planned to defer review to the organization’s IRB.
5. A description of the specific arrangements for who will be the IRB of record. Complete all relevant documentation.
6. Systematically evaluate whether the management of information obtained in multi-site research that could be relevant to the protection of research participants was adequate.
7. Contact information for the site.
8. Review all documentation submitted by the investigator.
9. Reviewers must complete the “Stage III Checklist.”

NOTE: The Campus IRB Chair, Compliance Officer, or designee will be responsible for assuring the review process meets these requirements and are conducted in compliance with the “Record Keeping” policy. See Policy.

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