



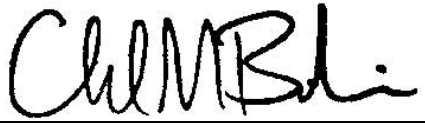
Campus Institutional Review Board
University of Missouri-Columbia

Federal Wide Assurance (FWA)
Policy Number 2876.1

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Reviewed by: Janelle Greening, Quality Assurance Associate
Reviewed by: Campus IRB Membership


Effective Date: December 12, 2007

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 University of Missouri (UM) conducts federally supported research and through its Federal Wide Assurance (FWA), it commits the University of Missouri-Columbia (UMC), and all of its components to a legally-binding agreement to assure that all human subject research complies with the requirements of the governing Federal Department or Agency head and its policies.

2.0 Purpose

Any institution engaged in human subjects research (not otherwise exempt) that is conducted or supported by any agency of the U.S. Department of Health and Human Services (HHS) must have an OHRP-approved assurance of compliance with the HHS regulations for the protection of human subjects.

3.0 Scope

The FWA applies to all human subject research conducted at the University of Missouri-Columbia, regardless of sponsorship. The FWA provides that all human subject research conducted under the jurisdiction of the Campus Institutional Review Board (Campus IRB) is subject to the review and prior IRB approval. All human subject research will be reviewed, prospectively approved, and subject to continuing oversight and review at least annually by the Campus IRB. The Campus IRB has the authority to approve, require modifications, or disapprove any aspect of the human subject research activities.

All human subject activities designated under the Assurance, regardless of funding source, will be guided by the ethical principles in: (a) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research; and (b) all other appropriate ethical standards recognized by Federal Departments and Agencies that have adopted the Federal Policy for the Protection of Human Subjects.

The UMC will comply with the Federal Policy for the Protection of Human Subjects, known as the Common Rule. All federally-supported human subject research will also comply with any additional human subject regulations and policies of the supporting Department or Agency. All human subject research conducted or supported by the Department of Health and Human Services (DHHS) will comply with all Subparts of DHHS regulations as codified in Title 45 Code of Federal Regulations Part 46 (45 CFR 46 and its Subparts A, B, C, and D).

4.0 Standard Operating Procedure

The Office of Research will submit the FWA and all updates to OHRP at least every 36 months (3 years). The Office of Research will assure that the membership is comprised of the appropriate scientific expertise, unaffiliated positioning with the University, a community member or of non-scientific status. The Campus IRB will coordinate with the Office of Research to properly submit the FWA to OHRP. In order to maintain an active Assurance, the Office of Research will update the agreement at least every 36 months (3 years). In an effort to comply with the FWA policy requirements, the Campus IRB in cooperation with the Office of Research will annually assure that:

A. The Campus IRB has established, and will provide a copy to OHRP upon request, written procedures for:

- 1) Providing appropriate training of the institutional signatory officials and designees, IRB Chair and Membership, and the IRB Compliance Officer.

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- 2) Establishing educational and oversight mechanisms and procedures for documenting the training of key personnel.
- 3) Conducting initial and continuing review, approving research, and reporting findings to the investigator, the University of Missouri-Columbia Office of Research, and appropriate federal agencies.
- 4) Determining which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since the previous Campus IRB review.
- 5) Ensuring that changes in approved research protocols are reported promptly and are not initiated without Campus IRB review and approval, except when necessary to eliminate apparent immediate hazards to the subject.
- 6) Ensuring that all collaborating institutions operate under an approved FWA.

B. The Office of Research has established, and will provide a copy to OHRP upon request, written procedures for:

- 1) Providing the Campus IRB with sufficient resources to conduct reviews in compliance with its policies.
- 2) Ensuring prompt reporting to the Campus IRB, appropriate institutional officials, the relevant Department or Agency Head, any applicable regulatory body, and OHRP of any:
 - a. Unanticipated problems involving risks to subjects or others;
 - b. Serious or continuing noncompliance with the Federal regulations and/or Campus IRB requirements; and
 - c. Adverse event or deviation activities that may affect or increase the risk to human subject participants.

C. The Campus IRB will assure that the proper FWA documents are submitted along with all updates to OHRP at least every 36 months (3 years).

Composition of the Federalwide Assurance Document: (See Attachment "A").

Section 1 – Institution Filing Assurance

Section 2 – Institutional Components

Section 3 – Statement of Principles

Section 4 – Applicability

Section 5 – Designation of Institutional Review Boards

Section 6 – Human Protections Administrator

Section 7 – Signatory Official

Section 8 – DHHS Approval

D. Campus IRB Membership Roster

The Campus IRB will be comprised of a diverse membership reflecting the expertise of the human subject research community and meet regulatory requirements set forth in the Code of Federal Regulations Section 46.104 and comply with the "Board Membership Policy." See Policy.

- At least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.
- If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.
- Qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender.
- May NOT consist entirely of members of one profession.
- At least one member whose primary concerns are in scientific areas
- At least one member whose primary concerns are in nonscientific areas.
- At least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
- No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. The member shall comply with the Campus IRB "Conflict of Interest" policy. See Conflict of Interest Policy.

NOTE: The Campus IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB. See Policy "Invitees: Requesting Information from Advocates, Consultants, and Guests."

PROCESS TO DETERMINE THAT A DESIGNATION OF MEMBERSHIP MEETS REGULATORY REQUIREMENTS

1. The Campus IRB Compliance Officer shall be responsible to assure that the roster membership meets the regulatory requirements set forth in CFR 46.104.
2. The Campus IRB Compliance Officer shall complete a Board Membership Screening Form to assure the member meets the expertise for which they were invited to serve. The Compliance Officer will assure that the service purpose appropriately reflects the designation for which the member is to serve. See Campus IRB Member Screening Form.
3. Each Campus IRB Members will be evaluated each July to determine who shall serve on the board. If a member's service ceases, the roster will be updated accordingly in compliance with this policy. See Membership Evaluation Form.
4. The roster shall be updated each August with the list of current members and reported to OHRP through the Office of Research.

PROCESS TO REPORT ROSTER CHANGES TO OHRP

1. The Compliance Officer shall be responsible for assuring the updating of the roster by coordinating efforts with the Office of Research. The Vice-Chancellor for Research shall report the roster changes to OHRP.
2. The roster will be updated to reflect the current membership accordingly in compliance with this policy.

*Revised May 2006
Revised June 2007
Revised October 2007*