



**Campus Institutional Review Board**  
University of Missouri-Columbia


**Board Membership**

Policy Number 2876.5

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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

Board Membership  
Policy Number 2876.5

**1.0 Policy**

The Campus Institutional Review Board (Campus IRB) is comprised of a diverse membership to assure that all human subject research conducted at the University of Missouri-Columbia is reviewed by a committee with the appropriate expertise to appreciate the scientific merit of the proposal and the foreseeable risks and benefits to the participants. The Campus IRB shall have a qualified IRB chair and membership that are periodically reviewed with the necessary adjustment of the membership and composition of the IRB to reflect the scientific expertise necessary to review research proposals under the jurisdiction of the Campus IRB.

**2.0 Scope**

The scope of the Campus IRB membership applies to all human subject research being conducted under the jurisdiction of the University of Missouri-Columbia.

**3.0 Purpose**

The Campus IRB membership is a committee comprised of respected individuals providing leadership and expertise that supports an ethically sound human subject research culture that is primarily focused on the critical need to ensure the ongoing comprehensive protection of research participants.

**4.0 Standard Operating Procedure**

The federal regulations require an IRB to have the sufficient expertise and diversity to properly evaluate ethical issues involved in research proposals subject to review. The Office of Research is directly responsible for reviewing the composition of the board to determine whether it meets regulatory and organizational requirements. The Office of Research conducts an annual review of the board and updates its FWA annually to assure compliance with organizational and regulatory requirements.

The Campus IRB shall comply with the regulations by assuring the following:

A. Composition of the Campus IRB: The board will be comprised of:

1. At least 5 regular voting members with diverse backgrounds.
2. A committee under the leadership of a single Chair with assistance of an administrative office staff.
3. A committee with no less than 10 members representing the academic profession.
4. At least one member of the scientific community.
5. At least one member of the non-scientific community.
6. At least one member who is not affiliated with the institution.

B. Board Membership Appointments:

1. The Vice Chancellor for Research will solicit and appoint the Board Chair.
2. The Vice Chancellor for Research will solicit and appoint board members and may collaborate with the Campus IRB Compliance Officer.

Board Membership  
Policy Number 2876.5

3. Campus IRB members may be invited to serve a 3 year term.
  - a. At the end of each year, a member may be reappointed to serve an additional year at the discretion of the Vice Chancellor for Research; or
  - b. Members may be invited and serve 2 consecutive 3 year terms followed by a 1 year absence of service, at the discretion of the Vice Chancellor for Research; or
  - c. Members may be reappointed following 2 consecutive 3 year terms, at the discretion of the Vice Chancellor of Research.

C. Categories of Membership

The Campus IRB strives to maintain a diverse membership of the human subject research community so that there is an appreciation of local research standards represented by the member's expertise and efforts to effectuate a more comprehensive review of proposals in specific areas.

1. Scientific Membership: A member who is considered an expert from an Academic Academy within a specific scientific community. The scientific member shall have the relevant expertise to demonstrate an appreciation for the scientific merit of the proposed activities within their respective area. A scientific member shall have a direct affiliation with the University of Missouri-Columbia.
2. Non-Scientific Membership: A member who possesses relevant information in a nonscientific area to assist the board in deliberations, but is not considered an expert from an Academic Academy within a specific scientific community. The non-scientific member does not represent an area of expertise to demonstrate the scientific merit in the respective academic area. A non-scientific member may have a direct affiliation with the University of Missouri-Columbia. A convened IRB Meeting is prohibited from conducting business in the absence of the Non-Scientific Member.
3. Lay Membership: A lay member shall be a member of the community who demonstrates concern for human rights and ethical issues. A lay member shall have no direct affiliation with the University of Missouri-Columbia, but may participate in activities with the University in a non-scientific capacity.
4. Unaffiliated Membership: Each IRB shall include 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.

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 as provided:

1. At least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.
2. 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.
3. Qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender.
4. May NOT consist entirely of members of one profession.

Board Membership  
Policy Number 2876.5

5. At least one member whose primary concerns are in scientific areas
6. At least one member whose primary concerns are in nonscientific areas.
7. 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.
8. 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.

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

E. 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 appropriate reflects the designation for which the member is to serve. The form will be distributed to member candidates prior to their appointment and require self-identification of potential conflicting interests. All members must comply with the "Conflict of Interest" policy.
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.
4. The roster shall be updated each August with the list of current members and reported to OHRP through the Office of Research.

F. 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. See Federalwide Assurance Policy; and Administrative Staff Policy.
2. The roster will be updated to reflect the current membership accordingly in compliance with this policy.

G. Roles and responsibilities of the members includes, but is not limited to:

1. Assure that all University of Missouri-Columbia research involving human subjects complies with the Belmont Report, Federalwide Assurance document, Campus IRB Policies, and the Department of Health and Human Services (DHHS) regulations set forth by 45 CFR 46;
2. Possess the expertise to understand the complexity of the proposed research activities and appreciate the risk(s) to human subject participants.
3. All members are screened prior to their appointment on the board. All members are provided a copy and must comply with the Campus IRB policies. All members are notified of the Conflict of Interest disclosure requirements.
4. Maintain current knowledge of regulatory changes and attend continuing education events to maintain the current professional qualifications and knowledge necessary to assure adequate protection of human subjects involved in research.
5. Attend scheduled board meetings;
6. All members are provided and expected to review:
  - The Initial IRB Application form
  - The Continuing Review IRB Application form
  - The current consent document

Board Membership  
Policy Number 2876.5

- Any newly proposed consent documents

The Primary reviewers are provided and are expected to review in depth:

- The Initial IRB Application form
- The Continuing Review IRB Application form
- The current consent document
- Any newly proposed consent documents
- The complete protocol including any protocol modifications previously approved by the IRB.

7. Review the agenda and proposed activities prior to board meetings;
8. Timely review proposed activities or reports as follows:
  - a. Full board activities: Serve as a primary or secondary reviewer on assigned activities by assessing the proposal for the level of risk, appropriate Informed Consent procedures, and compliance with the regulations governing human subject research. The reviewer shall make a determination of whether the information submitted is sufficient enough to allow the board to make an informed decision about the recommended course of action;
  - b. Expedited activities: Serve as the reviewer on assigned activities by assessing the proposal for the level of risk, appropriate Informed Consent procedures, and compliance with the regulations governing human subject research. The reviewer shall make a determination of whether the information submitted is sufficient enough to make an informed decision and recommend a course of action;
  - c. Exempt activities: Are conducted internally by CIRB Staff under the direction of the Compliance Officer and Board Chair.
9. Process for Determining IRB members have the experience to conduct initial, continuing or amendment reviews of research

The IRB members are invited to serve on the board because of the expertise they possess either in the Academy of Science of their profession/education, or due to the experience they have in a specific area. The process to determine if the member may conduct initial, continuing, or amendment reviews is as follows:

- a. The members are assigned files that fall within their field of experience or expertise. All members receive extensive human subject training regarding IRB regulatory requirement, review processes and eIRB navigation. Each new member receives a mentor assignment during their first year. The Campus IRB Chair identifies which members have the expertise and IRB training to conduct expedited review and certifies same on the "Member Review Authority" form. Staff check this form list when assigning reviewers accordingly.

Criteria used to determine whether IRB members were considered experienced for the initial review, continuing review and amendment reviews of research.

1. The member must possess an expertise in the academic field for the project they are selected to review.
  2. The member must successfully complete the CIRB Human Subject Research Training requirement.
  3. The member must successfully complete the CIRB Membership Training Requirement for completion of initial, continuing or amendment review processes.
- b. All file assignments for review are determined by the Campus IRB Chair and CIRB Compliance Officer.

Board Membership  
Policy Number 2876.5

- c. When the board does not have at least one person on the IRB with the appropriate scientific and scholarly expertise to conduct an in-depth review of the protocol, the Compliance Officer is charged with the responsibility to assure an evaluation of each protocol has been conducted to determine whether there was at least one person on the IRB with the necessary expertise, and if not, invite individuals with competence in that area to assist in the review process. The Compliance Officer will communicate with the Campus IRB Chair to assure the proper consultant is identified, and the reviewer has the information necessary to proceed with the CIRB Review Process. No reviewer will be required to review a file that they do not have expertise to conduct a review on.
  - d. The Campus IRB is permitted to identify, invite and request information or presentation from the relevant visitors who may be an advocate, consultant, or guests who can provide an opinion about the matter before the board
  - e. File assignments for the expedited review procedure provides that the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in 46.108(b).
  - f. If a member is qualified to conduct an initial review, they will also have the qualifications to conduct continuing or amendment reviews on that file.
  - g. The Review activities shall be conducted in compliance with the CIRB Review Process Policy.
10. Assure that all proposals, regardless of sponsorship, are reviewed in accordance with Campus IRB policies and the "Review Checklist" with a sufficient amount of information to support scientific merit.
  11. Must complete the Review Checklist before approving any proposal.
  12. Take every precaution necessary to adequately safeguard the protection of human subjects involved in research by prospectively reviewing and approving Human Subject Research activities under the jurisdiction of the Campus IRB.
  13. Assist with the review, inspection or auditing activities associated with any human subject research activity or project under the jurisdiction of the Campus IRB to investigate or verify a) proper IRB compliance; b) allegations of noncompliance; c) issues regarding risks to human subjects; or c) to safeguard the welfare and rights of human subjects involved in research.
  14. Voting: A member shall cast a vote and recommend an action regarding proposals in accordance with the Federal regulations, Federalwide Assurance, and Campus IRB Policies unless a conflict of interest is present. If a conflict of interest is present, the member should abstain from the voting activities in compliance with the Campus IRB policies and will remove themselves from the room, abstain from review of the file except to provide information requested by the convened board.
  15. Confidentiality: The member shall maintain confidentiality of all information and materials associated with the Campus IRB processes, which includes but is not limited to, submitted proposals, research activities, proposals, consultation, guest appearances, internal Office of Research or IRB communications or correspondence, issues or discussions, deliberations, and decisions at the board meetings. Failure to maintain confidentiality issues will be forwarded to the Office of Research, Director of Compliance.

Board Membership  
Policy Number 2876.5

H. Performance Evaluation The Campus IRB membership will be periodically reviewed with the necessary adjustment of the membership and composition of the IRB to reflect the scientific expertise necessary to review research proposals under the jurisdiction of the Campus IRB.

1. Each member and chairperson is invited to serve on the board because of their expertise and ability to serve in the respected role as a Campus IRB member.
2. The Office of Research will perform periodic evaluations and annual performance reviews of the board chair and members to assure optimal IRB operations embrace a competent human subjects protection program.
  - a. The evaluation process will be initiated by the Office of Research annually.
  - b. The member and chair will review the evaluation report with the Office of Research in collaboration with the Compliance Officer.
  - c. The Office of Research will determine if the member and chair will be invited to continue to serve on the board.

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