

Campus Institutional Review Board Purpose and Functions
Policy 2876.4



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University of Missouri-Columbia


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Approval Authority:


Signed _____
IRB Chair

Date December 12, 2007 _____

Institutional Approval:


Signed _____
Associate Vice-Chancellor for Research

Date December 12, 2007 _____

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1.0 Policy

The Campus IRB is responsible for the prospective review and approval processes of research activities involving the use of human subjects and must engage in deliberations that function to adequately provide a comprehensive review of the proposed activity, assess the risk to the subjects, assure the research is conducted ethically in an ongoing manner, and maintain communications with the key research personnel.

2.0 Scope

The Campus IRB's prospective review and approval authority applies to all human subject research activities conducted under the jurisdiction of the University of Missouri-Columbia.

3.0 Purpose

The Campus IRB is charged with the duty to adequately protect the rights and welfare of human subject research participants under the jurisdiction of the University of Missouri-Columbia. The Campus IRB's mission is to influence the conduct of research by protecting the rights and welfare of research subjects in a culture of respect for the IRB process. The IRB reviews and monitors the research to assure it meets ethical principals and complies with federal regulations that pertain to human subject protection as promulgated in 45 CFR 46, any other applicable federal regulations, and state and local laws.

4.0 Standard Operating Procedure

The University of Missouri-Columbia requires all research projects involving humans as subject participants, human material, and human data be reviewed and approved by the Campus IRB prior to initiation of any research related activities, including recruitment and screening activities. The Campus IRB of the University of Missouri-Columbia is under the authority of the Vice Chancellor of Research. The Campus IRB is charged with engaging in deliberations that functions to comprehensively review the proposed human subject research activity, assess the risk to the subjects, and render a decision to the investigator regarding the status of the proposed research activities. It is the responsibility of the Campus IRB to carry out its purpose in all review processes, but particularly the "Initial" and "Continuing Review" processes.

GOVERNING PRINCIPLES: The Campus IRB is guided by the ethical principles regarding all research involving humans as subjects as set forth in the report of the National Commission for the Protections of Human Subjects of Biomedical and Behavioral Research entitled "Ethical Principles and Guidelines for the Protections of Human Subjects of Research ("The Belmont Report"). These principles are defined in the Belmont Report as follows:

1. **BENEFICENCE:** The sum of the benefits to the subject and the importance of the knowledge to be gained so outweigh the risks to the subjects as to warrant a decision to allow the subject to accept these risks.
2. **AUTONOMY:** Legally effective informed consent is obtained, unless the requirements for waiver of informed consent are met by adequate and appropriate methods in accordance with the provisions of applicable regulations.
3. **JUSTICE:** The selection of subjects is equitable and is representative of the group that will benefit from the research.

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- A. PURPOSE: The Campus IRB review processes must assure that:
1. The level of risk is minimized by procedures consistent with sound research design and scientific merit;
 2. The potential risks to human subjects are reasonable and are outweighed by the anticipated benefits of participating in the research;
 3. The risks and benefits of the standard of care procedures are taken into account as related to the proposed research;
 4. The target population selection and recruitment processes are equitable, absent of coercion and undue influence;
 5. Informed consent is obtained from each prospective subject and appropriately documented in accordance with the requirements set forth by 45 CFR 46 and the Campus IRB policies, including, but not limited to:
 - a. Assurance that participants are adequately informed of the research process requirements, the risks and anticipated benefits, and approximate time commitment;
 6. Research data, private information and corresponding data collected is kept confidential and adequately protected in compliance with the regulations set forth in 45 CFR 46 and Campus IRB policies;
 7. Private health information and corresponding data is kept confidential and adequately protected in compliance with HIPAA regulations and Campus IRB policies;
 8. Appropriate safeguards are in place to protect the rights and welfare of human subjects.
 9. The Campus IRB will apply human subject protection measures to all research activities meeting the federal definition of “human subject research”, regardless of sponsorship.
 10. The Campus IRB operates under the FWA, and through the Office of Research shall require a written agreement with the sponsor providing:
 - a. That IRB procedure will be followed, and medical care will be provided for participants encountering a research related injury.
 - b. When a sponsor monitors the conduct of research, the sponsor should promptly report findings that could affect the safety of participants or their willingness to continue participation, influence the conduct of the research, or alter the IRB’s approval to continue research.
 - c. If the results of research directly affect the safety of a participant, the sponsor should notify the IRB of the results; the agreement should include a plan to communicate results to the participant.
 11. The Campus IRB will communicate with the Health Sciences IRB to assure consistent application of IRB review principles and educational programs. The Campus IRB Compliance Officer will meet regularly with the Associate Vice-Chancellor of Research and the Health Sciences IRB Officer. Every effort will be made to meet quarterly with both IRB Offices to discuss new regulatory developments, interpretative guidelines or institutional policy changes.
 12. The Campus IRB will communicate regularly with the General Counsel’s office to assure proper application of state and federal requirements for human research protections.
 13. The Campus IRB conducts outreach activities designed to enhance understanding of human research by participants, prospective participants, or their community, when appropriate.

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- B. FUNCTIONS: The functions of the Campus IRB include, but are not limited to:
1. Determination about whether an activity meets the criteria for research involving human participants subject to IRB review. If an activity does NOT meet the federal definition of human subject research, the decision will be communicated in writing to the individual seeking a decision about whether the activity was research involving human participants. If the activity meets the federal definition of human subject research, the decision will be communicated in writing to the individual who will be instructed to complete a Campus IRB Application Form. (See Policy 2876.41 “Activities Requiring Campus IRB Review”.)
 2. Protect the rights and welfare of human subjects involved in research projects under the jurisdiction of the Campus IRB;
 3. Review, approve, require modification to secure approval, or disapprove research activities involving the use of human subjects under the jurisdiction of the Campus IRB;
 4. The Campus IRB shall have the authority to approve, require modifications to secure approval, and disapprove all research activities overseen and conducted by the organization.
 5. The Campus IRB shall have the authority to suspend or terminate approval of research not being conducted in accordance with the Campus IRB policies or associated with unanticipated serious harm to participants.
 6. The Campus IRB shall have the authority to observe, or have a third party observe, the consent process and the conduct of research activities.
 7. Prior approval of changes in previously approved research under the jurisdiction of the Campus IRB;
 8. Provide continuing review of all human subject research activities under the jurisdiction of the Campus IRB.

<p><i>Revised December 2006</i> <i>Revised June 2007</i> <i>Revised October 2007</i></p>
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