

Campus Institutional Review Board Authority
Policy Number 2876.3



Campus Institutional Review Board
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

1.0 Policy

The University of Missouri-Columbia Human Subject Research Protection Program grants the Campus Institutional Review Board (Campus IRB) with the full authority to assure that all human subject research under its jurisdiction complies with the regulations of the Department of Health and Human Services (DHHS) (45 CFR 46.101); Food and Drug Administration (FDA); the Belmont Report; Federalwide Assurance (FWA #00002876) of the University of Missouri-Columbia; and Campus IRB Policies. The University of Missouri Columbia grants the Campus IRB full authority to operate independently of other entities and in the absence of institutional influence.

The Campus IRB shall have the unfettered authority to protect the human subject research review, approval and monitoring processes in the absence of institutional interference.

2.0 Purpose

All human subject research activities must be reviewed, prospectively approved, and subject to continuing oversight (at least annually) by the Campus IRB to assure the safety and welfare of research participants.

3.0 Scope

The University of Missouri-Columbia grants full review and approval authority to the Campus IRB for all activities meeting the DHHS and FDA definition of human subject research. This authority extends to the determination of whether an incident involves an unanticipated problem, adverse event, or any non-compliance, including serious or continuing. It also grants the IRB with the authority to place activities on administrative hold, suspension or termination of IRB approval.

A. Scope of Jurisdiction

The Jurisdiction of the Campus IRB is defined by its binding commitment with DHHS (FWA #00002876) and the University of Missouri-Columbia's institutional policies. The Campus IRB has the authority to review all research involving humans that meets the definition of human subject research in accordance with the Checklist entitled "Determining When an Activity is Human Subject Research" according to DHHS and FDA definitions.

The jurisdiction of the Campus IRB includes all human subject research that is conducted or directed:

- (a) by UMC faculty, staff, students, agents, affiliates, or outside researchers, and occurs on the property of the University of Missouri-Columbia;
- (b) by UMC faculty, staff, students, agents, affiliates, or associated outside researchers, and occurs elsewhere;
- (c) elsewhere by an outside researcher involving UMC faculty, staff, students, agents, or affiliates;
- (d) by UMC faculty, staff, students, agents, affiliates, or outside researchers, and involves the use of the UMC's non-public information to identify and/or recruit human research subjects or prospective subjects;
- (e) by UMC faculty, staff, students, agents, affiliates, or outside researchers and receives funds through the UMC or receives support by internal resources; and
- (f) Involving item(s) "a" through "e" referenced above, and is supported by federal funds or any other external resource(s).

ALL investigators conducting "human subject research" falling in any of the categories listed above in items (a) through (f), IS REQUIRED to submit an application to the Campus IRB for review.

WHICH ACTIVITIES ARE SUBJECT TO FDA REGULATION?

The Campus IRB does have jurisdiction over FDA regulated research. Research falling under the following categories meets the FDA definition of human subject research, and will be transferred to the Health Sciences IRB:

1. The activity involves the use of a drug other than the use of a marketed drug in the course of medical practice.
2. The activity involves the use of a medical device other than the use of a marketed device in the course of medical practice.
3. The results of the activity are submitted to the FDA or held for inspection by the FDA.
4. The tissue specimens are being used to test the effectiveness of a medical device and the information is submitted to the FDA for approval of the device.
5. The activity involves one or more of the following: FDA regulated articles: food or drug dietary supplement that bears a nutrient content or a health claim, a food or color additive for human consumption, infant formula, biological or electronic product for human use, or other article subject to the FD&C Act.

AND

6. Individuals are directed by a research protocol rather than by medical practice, when they are or become participants in research (either as recipients of an FDA regulated product (approved or experimental) or as controls). OR
7. Individuals participate in an investigation either as subjects or as controls where an investigational device is used on them or on their specimens.

WHICH ACTIVITIES ARE SUBJECT TO VA REGULATION?

The Campus IRB does have jurisdiction over VA regulated research. Research falling under the following categories may be subject to VA regulations and will be transferred to the Health Sciences IRB:

1. The researcher or key personnel are employed or associated with the VAMC or VA entity.
2. The research will be conducted at the VAMC or VA entity.
3. The researcher's or key personnel's responsibilities in the proposed activities involve collaboration with the VAMC or VA entity. (i.e. Business Associate's Agreement; Data Use Agreement; etc.)
4. The researcher intends to recruit human subjects or access data under the jurisdiction or auspices of the VAMC or VA entity.
5. The researcher intends to recruit human subjects or access data from the VAMC or VA entity.
6. The research activities fall under the jurisdiction or auspices of any Veteran's Administration regulated entity, organization or agency.

B. Scope of Authority

The University of Missouri-Columbia makes no distinction between the importance of protecting human subject participants involved in Social Science and Biomedical research. Accordingly, the U.S. Department of Health and Human Services (DHHS) regulations that focus on the IRB do not distinguish between the types of human subject research. The Campus IRB will review activities in relation to the ethical standards for human subject research based

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on the risk to research participants, not on the academic field in which research may be classified.

The Office of Research, through the University of Missouri-Columbia, is the official signatory for the institution for IRB purposes, through the Federalwide Assurance Agreement #00002876.

The institution grants the Campus IRB the authority to do the following:

1. Make a determination of whether an activity meets the criteria for research involving human participants subject to IRB review in accordance with the “Activities Requiring Campus IRB Review” Policy. (See Policy). The activity is reviewed to determine if it meets the DHHS or FDA definition of human research. If an activity does NOT meet the DHHS or FDA 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 institution’s 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
2. The Campus IRB will have the authority, through its policies and procedures, to provide continuing oversight and review of all human research activities under its jurisdiction without institutional interference or undue influences of the IRB members and staff.
 - a. Any member or staff shall report incidents of undue influence directly to the Campus IRB Compliance Officer/and or the Campus IRB Chair
 - b. The Campus IRB Compliance Officer or Chair will report incidents of undue influence to the Associate Vice Chancellor of Research; who will report the matter to the Vice Chancellor of Research. The Vice Chancellor shall have the authority to limit or remove an investigator’s privilege to conduct research. The Vice Chancellor may report the activities to the appropriate Departmental authorities in compliance with University of Missouri-Columbia policies.
3. The authorized Campus IRB administrative staff will have the unfettered authority to make the determination of whether the proposed activities meet the criteria for human subject research subject to IRB review and make the exemption determination, if applicable, in accordance with Campus IRB policies and specifically, “Activities Requiring Campus IRB Review”; “Campus IRB Review Process”; “Assessment of Scientific Merit”; and “Assessing Level of Risk” policies.
4. The Authority conveyed to the Campus IRB may also include, but is not limited to, the following:
 - (a) 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.
 - (b) The Campus IRB shall have the authority to suspend or terminate approval of research not being conducted in accordance with the Campus IRB requirements or that had been associated with unexpected serious harm to participants.
 - (c) The Campus IRB shall have the authority to observe, or have a third party observe, the consent process and the conduct of the research.
 - (d) Prospectively review all systematic investigations, data collection, or activities involving human subjects designed to develop or contribute to generalizable knowledge;
 - (e) Review all research activities involving human subjects prior to the recruitment phase;
 - (f) Review all research activities involving human subjects prior to the initiation phase of the study;
 - (g) Audit any activities under the jurisdiction of the Campus IRB to assure compliance with the Federalwide Assurance, the Belmont Report, Campus IRB Policies, and the regulations and laws governing human subjects’ research;
 - (h) Monitor change in the risk/benefit ratio to research participants;
 - (i) Investigate adverse events, deviations, and noncompliance issues as outlined in the Campus IRB Policies.

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5. The Campus IRB shall have the authority to review, revise and approve policies and procedures governing human subject research.
6. The Campus IRB shall have the authority to identify and disseminate information to the research community through any educational venue appropriate for learning. Such venues can be via email, websites, in-person, teleconference, written dissemination, classroom activities, and any other method it deems necessary to educate the research community.
7. The Campus IRB will transfer activities regulated by the Food & Drug Administration (FDA) or the Veterans Administration or Veterans Affairs Medical Center (VAMC) to the Health Sciences IRB.

4.0 Standard Operating Procedure

The Campus IRB has full prospective review and approval authority for all human subject research activities conducted under its jurisdiction. Investigators conducting human subject research should submit their application to the appropriate forum for proper review.

A. Choosing the Appropriate Forum

The Campus IRB is the proper forum for review of ALL human subject research conducted under the jurisdiction of the University of Missouri-Columbia campus EXCEPT for those studies involving participants under the jurisdiction of the Health Sciences IRB (Item #1 below), the use of Animals (Item #2 below).

1. Applications requiring submission to the Health Sciences Institutional Review Board:

a. The Principal Investigator is employed at any of the following:

- Children's Hospital
- Ellis Fischel Cancer Center
- Howard A. Rusk Rehabilitation Center
- Missouri Rehabilitation Center
- University Hospital and Clinics
- Columbia Regional Hospital
- School of Medicine
- School of Health Professions
- Charles and Josie Smith Sinclair School of Nursing
- School of Veterinary Medicine
- Harry S. Truman Memorial Veterans Hospital
- Missouri Institute of Mental Health

b. The subject population includes patients (either inpatients or outpatients) in any of the institutions listed above;

c. The research involves physical stress to the subjects (e.g., exercise physiology projects);

d. The research involves any collection of human blood, tissue, or bodily fluids;

e. The research falls under the regulation of a Veteran's Administration entity

f. The research falls under the regulation of the Food and Drug Administration (FDA).

g. The research involves a delivered fetus, the delivery process, placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, or hospitalized neonates.

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NOTE: Other areas that may be under the jurisdiction of the Health Sciences IRB includes, but is not limited to, The University Physicians, Green Meadows Clinic, Public Health Clinics, any clinic or healthcare organization with the primary focus of medical treatment.

2. Applications requiring submission to The Office of Animal Care Quality Assurance:
 - a. Any research activities involving the use of animals.

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