



Campus Institutional Review Board
University of Missouri-Columbia


Assessment of Scientific Merit

Policy Number 2876.26

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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

1.0 Policy

The Campus IRB will assess of human research proposals under its jurisdiction to assure the ethical conduct of researchers in the protection of human subject participants by ensuring that the proposal has undergone a scientific review by either 1) Requiring documentation from the respective Department certifying scientific merit; or 2) Conducting the scientific review.

All research proposals reviewed by the Campus Institutional Review Board (Campus IRB) shall undergo a rigorous review to assess the scientific quality, importance of the research to increase knowledge, and the appropriateness of the study methodology to answer a precisely articulated scientific question. The Campus IRB Scientific Members will provide the membership with their review of the scientific merit and feasibility of the proposal.

The Campus IRB shall review the scientific design in relationship to the risk and benefits of the proposal as a criterion for IRB approvability. 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, a consultant or guest may be invited to provide information to the board in compliance with the “Requesting Information from Consultants or Guests” policy.

2.0 Scope

This policy shall apply to all research submitted to the Campus IRB.

3.0 Purpose

The Campus IRB must feel confident that the scientific merit of the proposed research justifies a risk/benefit determination and subject participation. The Campus IRB employs an assessment process to determine that the proposed methodology is consistent with sound research design and minimizes the risks to subjects. While the Campus IRB recognizes the academic community encourages research as a learning opportunity for students in certain disciplines, the IRB will not relax its standards of protecting human subjects for the sole purpose of creating a pedagogical environment.

The Campus IRB may distinguish the objectives between scientific and academic review when assessing the level of risk to subjects. The Campus IRB will not make generalized assessments regarding risk allocations for academic research processes and will conduct a case-by-case review of the proposed activities.

The Campus IRB’s charge includes the responsibility of assuring that the study design is in accordance with the ethical standards of the investigator’s area of expertise in the relevant research community.

4.0 Standard Operating Procedure

The Campus IRB shall ensure that the proposal design minimizes bias and has the potential to generate data that will answer the scientific question outlined in the research methodology. The Campus IRB will review the proposed submissions in concert with the investigator’s responses to determine assure the proposed activities has scientific or academic merit, and are conducted in compliance with the “Campus IRB Review Process” and “Assessing the Level of Risk” policies. The investigator should strive to address each of the elements provided below prior to submission to the Campus IRB to avoid delays in the review process. If the proposal does not address the items listed below, the review process will be substantially delayed until the Campus IRB receives documentation assuring satisfaction of all of the elements certifying scientific merit.

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A. ELEMENTS OF SCIENTIFIC REVIEW

1. Importance and novelty of the scientific question
2. Strength of the scientific design and methodology
3. Feasibility of the research as designed
4. Appropriateness of the statistical analysis plan
5. Estimate of the probability of meeting the enrollment goals
6. Need for a Data and Safety Monitoring Board and Committee
7. Assessment of the thoroughness of the proponent's evaluation of the relevant literature and previous studies, if available.
8. Strength of the qualifications of the investigator to carry out the proposal
9. Appropriateness of the inclusion and exclusion criteria
10. Dissemination plan

B. DEPARTMENTAL RESPONSIBILITIES

1. Academic departments have an institutional responsibility to cultivate an environment with the highest standards in scientific conduct and respect for human subject research.
2. The Campus IRB will respect all departmental requirements set forth for their faculty, staff, and students conducting research. The Campus IRB will interface with departmental heads to assure they are kept apprised of the federal requirements necessary to comply with the regulations and standards governing human subject research.
3. The Campus IRB will respect all departmental restrictions placed on researchers, so long as it doesn't interfere with the review processes conducted by the IRB.
4. The Campus IRB encourages the department to assure that student and junior researchers assure that an integral component of their research program will include a Mentoring program that will foster quality research among its members.
5. The Application Submission process will require the applicant to describe the scientific merit of the proposed activities, or the academic merit of student based research. The reviewer must review the investigator's responses, which includes but is not be limited to, the following items:
 - a. Assurance that the investigator or advisor has the requisite expertise and qualifications to carry out or monitor the protocol.
 - b. Assurance that the investigator has the necessary resources, qualified staff, and adequate facilities to support the scientific design as proposed.
 - c. A determination that the importance of the scientific questions is sufficient to merit the inclusion of human participants and the proposed risks imposed upon them.

Additionally, the reviewer must assure answers to the following questions:

- Is the scientific design sufficiently described and adequately justified? What is the strength of the scientific design and methodology?
- Is the scientific design adequate to answer the research question?
- An assessment of the practical feasibility of the research design.
- Are the research objectives likely to be achievable within the proposed time period?
- An estimate of the probability of meeting the goals of enrollment.
- In activities greater than minimal risk that meets the Campus IRB criteria for monitoring data by a Data Safety Monitoring Board/Committee, are adequate provision in place to monitor the data to ensure the safety of participants?
- Assurance that the relevant literature and previous studies, if available, have been taken into account by the PI and that, if necessary, experts in the field have been consulted.

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C. ACADEMIC MERIT REVIEW

The University of Missouri's mission is to provide a venue for research that is in compliance with the State, Federal and Local laws. It recognizes that research may be conducted for academic purposes only, but requires it to undergo a risk/benefit assessment to assure the methodology is appropriately designed to achieve the aim of the research. All academic research will require the advisor to certify academic merit for the purposes of assuring proper oversight of the student and activities to further protect human subject participants. The advisor or the advisor's designee must certify academic merit of the proposed activities by providing electronic signature for the proposed application. The electronic signature is conducted through the "Advisor Approval Form." The form certifies that the advisor has reviewed the proposal and agrees to monitor the human research activities in compliance with Campus IRB policies.

Revised May 2006
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