

Investigator or Key Personnel Responsibilities  
Policy Number 2876.17



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

**Investigator or Key Personnel Responsibilities**

Policy Number 2876.17

Reviewed by: Michele Reznicek, Campus IRB Compliance Officer  
Reviewed by: Janelle Greening, Quality Assurance Associate  
Reviewed by: Campus IRB Membership

Effective Date: December 12, 2007

Approval Authority:

A handwritten signature in black ink, appearing to read 'Cheryl B. Li'.

Signed  
IRB Chair

Date December 12, 2007

Institutional Approval:

A handwritten signature in black ink, appearing to read 'R. J. Hall'.

Signed  
Associate Vice-Chancellor for Research

Date December 12, 2007

Investigator or Key Personnel Responsibilities  
Policy Number 2876.17

**1.0 Policy**

The Campus Institutional Review Board (Campus IRB) assures that all investigators and key personnel conducting human subject research at the University of Missouri-Columbia shall possess the qualifications and expertise to appreciate the complexities in the research and carry out the proposed activities.

**2.0 Scope**

The guidelines and responsibilities of this policy apply to all investigators and key personnel proposing to conduct human subject research under the jurisdiction of the University of Missouri-Columbia.

**3.0 Purpose**

A qualified investigator or key personnel provides the best opportunity for maximizing the assurance for the protection of human subject participants. The Campus IRB mandates that all investigators and key personnel under its jurisdiction meet the requisite responsibilities and to assure the safety and welfare of human subject participants.

**4.0 Standard Operating Procedure**

Key personnel are defined as “all individuals responsible for the design and conduct of the study.” There are common responsibilities incumbent to any investigator or key personnel engaging human participants in research studies.

Investigator or Key personnel, are not limited to, but shall meet the following responsibilities:

1. Possess the professional qualifications and expertise to adequately appreciate the degree of proposal complexity and risk to human subject research participants;
2. Comply with the Training & Education requirements set forth by the Campus IRB Policies;
3. Comply with ALL policies and procedures of the Campus IRB, the applicable Federal regulations provided through the Department of Health and Human Services codified in (45 CFR 46 and the Belmont Report);
4. Assure that the research proposals submitted to the Campus IRB have been certified for scientific merit and that the study design is in accordance with the ethical standards of their relevant research community;
5. Assure that all submitted applications are complete with the required forms and supportive documentation prior to submission to the Campus IRB;
6. Provide the Campus IRB with documentation of research designs using procedures already being conducted on the participant for non-research purposes. The investigator should provide any supportive reports that provide information regarding the monitoring of such activities.
7. Assure that all human subject research activities being conducted have received prospective review by the Campus IRB;
8. Assure that all modifications of approved human subject research activities have been prospectively reviewed by the Campus IRB;

Investigator or Key Personnel Responsibilities  
Policy Number 2876.17

9. If serving as an Advisor, complete the Advisor Approval Form after reviewing the student or staff member's proposal. Assure that the applicant, and application complies with all requirements set forth by the Campus IRB. The Advisor shall ensure the Campus IRB of the intent to provide continuous oversight of the project. When serving in the role as an Advisor, you must submit the proper documentation to confirm review of the student's proposal.
  - a. Step #1 Complete the Advisor Approval Form in the online system
  - b. Step #2 Confirm receipt with the Campus IRB Office
  - c. Step #3 Comply with all responsibilities set forth in the "Investigator or Key Personnel Responsibilities" Policy
10. Maintain appropriate oversight of the research protocols, research staff, selection and recruitment methods, research study conduct, and appropriately delegate research responsibilities;
11. Timely submit the requisite Continuing Review Report according to the "Continuing Review Process" policy.
12. Comply with "INFORMED CONSENT PROCESS" policy
  - a. Legally effective consent shall be determined by governing Federal, State, and Local Law.
  - b. The Investigator must conduct research in compliance with the Campus IRB "Privacy and Confidentiality" Policy.
13. Protect and maintain the privacy and confidentiality of the participating subject or their data during and after the conclusion of the research in accordance with the "Privacy and Confidentiality" policy;
14. Practice methods and standards that embrace the ethical and professional integrity of the Campus IRB research community;
15. When the proposal involves a "cooperative site" or "multi-center studies," the researcher must comply with the "Research Involving Collaborative Institutions and Multi-Center Sites" policy.
16. Recruit participants in a fair and equitable manner, weighing the potential benefits of the research to the participants against their vulnerability and the foreseeable risks; recruit participants in compliance with the Campus IRB "Recruitment Process."
17. Assure that the research proposes the least risky alternatives, with detailed processes for promptly detecting potential harm; and mitigating potential injuries when research involves greater than minimal risk to participants;
18. Provide the Campus IRB with the plan for data and safety monitoring when relevant;
19. Immediately report (within 5 days) to the Campus IRB any of the following:
  - a. Amendments or Deviations to approved projects;
  - b. Any adverse event or unanticipated problem in approved projects;
  - c. Any conflicts of interest;
  - d. Complaints made in reference to research activities;
  - e. Requests to extend project term periods;
  - f. Known or suspected noncompliance research activities;
  - g. Funding source changes;
  - h. Any suspension or closure of approved projects;
  - i. Any issue that arises that could impact the adequate protection of human subjects involved in research;
20. Cooperate with the Campus IRB, or its approved representatives, or the Campus IRB Audit or Quality Assurance Team during onsite inspections to confirm compliance; verify allegations, including the scope and extent, of suspected wrongful acts;
21. Submit the required "Annual Research Certification of Human Subject Research Activities" document to the Campus IRB upon request;
22. Retain all research records (including but not limited to audio and video tapes, documents, and instruments) for a period of three years after the completion of the research or termination of the project; and

Investigator or Key Personnel Responsibilities  
Policy Number 2876.17

23. Avoid acts that subvert the integrity of the Campus IRB approval process by submitting false information to the board; intentionally withholding information that may impact the decision making process of the Campus IRB; or submitting an application for approval after the project has already been completed.
24. Comply with the Campus IRB “ Noncompliance with Campus IRB Policies and Procedures” policy
25. Comply with the “Application Submission Process” policy

*Revised December 2006*  
*Revised June 2007*  
*Revised November 2007*