



Campus Institutional Review Board
University of Missouri-Columbia


Community Outreach Activities

Policy Number 2876.42

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

Board Review

Signed 
IRB Chair

Date December 12, 2007

Administrative Review

Signed 
Associate Vice-Chancellor for Research

Date December 12, 2007

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1.0 Policy

The Campus IRB is committed to educating the research community about the IRB process by quarterly evaluates Community Outreach efforts that are designed to enhance the community's understanding of the human subject research process.

2.0 Purpose

The Campus IRB is responsible for enhancing the education of research participants and the community about the IRB process and must assure that researchers employ a procedure that provides a venue for participants to ask questions and voice concerns or complaints.

3.0 Scope

This policy applies to all human subject research conducted under the jurisdiction of the Campus Institutional Review Board (Campus IRB).

4.0 Standard Operating Procedure

The Campus IRB will educate the research community and participants by providing a public venue for educational tools regarding the human subject research and IRB process, and a process for participants to ask questions, voice concerns or complaints to the investigator.

I. COMMUNITY OUTREACH EDUCATION EFFORTS

A. SUBJECT PARTICIPANT

1. Campus IRB Website

The Campus IRB website provides information to the research community and participants about what is human subject research, the rights of a research participant, the IRB process, and who to contact if you have questions, concerns or complaints.

LINK: <http://www.research.missouri.edu/cirb/index.htm>

2. OHRP Website

The Campus IRB provides a link to the Office of Human Subject Research Protection (OHRP), which is the federal agency charged with governing over Institutional Review Boards.

LINK: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116>

3. Education Brochures

- a. Campus IRB "Protecting Human Subject Research Participants"
 - i. Defines human subject research
 - ii. Defines the "Ethical Responsibilities" of the IRB
 - iii. Describes the responsibilities of the IRB to protect participants
 - iv. Defines Informed Consent
 - v. Campus IRB Contact Information if you have questions, concerns or complaints.
 - vi. "Becoming a Research Volunteer" developed by OHRP
- b. Human Subject Research Decision Charts

4. Informed Consent

The Campus IRB requires each research study to provide a venue for participants to ask questions and voice concerns or complaints. All Informed Consent documents must contain contact

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information for the primary or co-investigators, in the event a participant has questions or concerns about the research study. Additionally, the investigator must provide the contact information for the Campus IRB, in the event a participant has questions or concerns about the researcher or the study, and the researcher is not available or the participant is uncomfortable discussing with the research team. All Informed Consent documents must have the official Campus IRB approval and expiration date signed by an IRB official or designee.

B. RESEARCHER

1. Campus IRB Website

The Campus IRB website provides information to the research community and participants about what is human subject research, the rights of a research participant, the IRB process, and who to contact if you have questions, concerns or complaints. The site provides the following educational links, but not limited to, OHRP (federal human subject research protection agencies), AAHRPP (Accrediting Organization), NIH (National Institutes of Health), Office of Research, Conflict of Interest Committee, OSPA (Office of Sponsored Programs).

LINK: <http://www.research.missouri.edu/cirb/index.htm>

2. OHRP Website

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3. Informed Consent

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See SAMPLE CONSENT TEMPLATE located at LINK:

<http://www.research.missouri.edu/cirb/index.htm>

4. Educational Brochures

- a. Campus IRB “Protecting Human Subject Research Participants” (*Developed by Campus IRB*)
 - i. Defines human subject research
 - ii. Defines the “Ethical Responsibilities” of the IRB
 - iii. Describes the responsibilities of the IRB to protect participants
 - iv. Defines Informed Consent
 - v. Defines the Types of IRB Review
 - vi. Campus IRB Contact Information if you have questions
- b. Protecting Human Research Subjects (*Developed by DOE and NIH*)
 - i. Defines “Are you conducting research using Human Subjects?”
 - ii. Requirements for conducting research involving human participants.
 - iii. The Role of the IRB
 - iv. Types of IRB Review
 - v. Defines Informed Consent
 - vi. Contact information for questions, concerns or complaints.
- c. Campus IRB “Online Submission Process”
 - i. Selecting the proper IRB to review your application
 - ii. Pre-requisite: Compliance Training
 1. How to complete Compliance Training BEFORE submitting an application to the IRB
 2. How to submit an application to the IRB

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3. Deadlines for submitting “Full-board” applications
 4. Contact Information for questions, concerns or complaints.
 - d. Human Subject Research Decision Charts
5. Onsite Departmental/Unit IRB Training
- a. The Campus IRB provides onsite live training sessions to the investigator/research community about human subject research activities and the IRB processes.

C. INSTITUTIONAL REVIEW BOARD MEMBERS/STAFF

1. Campus IRB Website
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2. OHRP Website
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LINK: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116>
3. Campus IRB/Staff Training
 - a. Members and Staff receive training on an ongoing basis regarding IRB regulations, interpretative guidelines, regulatory updates, AAHRPP accreditation standards, and CIRB policy revisions. Training includes activities to enhance the education of the subjects and research community.
 - b. Members serve as IRB educational ambassadors to the research community.
 - c. Staff members serve as IRB educational ambassadors to the research community
 - d. Human Subject Research Decision Charts

D. RESEARCH COMMUNITY

1. Campus IRB Website
The Campus IRB website provides information to the research community and participants about what is human subject research, the rights of a research participant, the IRB process, and who to contact if you have questions, concerns or complaints. The site contains sample TEMPLATES, IRB recommendations, IRB Decision Chart Templates, and FAQs to facilitate an understanding of the IRB process. The site provides the following educational links, but not limited to, OHRP (federal human subject research protection agencies), AAHRPP (Accrediting Organization), and NIH (National Institutes of Health).
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2. OHRP Website
The Campus IRB provides a link to the Office of Human Subject Research Protection (OHRP), which is the federal agency charged with governing over Institutional Review Boards.
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3. Regulatory Agency/IRB Partnerships
The Campus IRB members and staff partner with other IRBs and representatives from the Office of Human Research Protections to participate in community outreach activities such as conferences, public forums, and IRB Industry Newsletters.
4. Cooperative Community Partnerships: Campus IRB representatives participate in community driven conferences to field questions about the IRB process. Organizations, agencies or departments serving the

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extended community and research participants coordinate educational opportunities for potential research participants with the IRB to enhance the communities understanding of the human subject research and IRB process.

II. EVALUATION OF COMMUNITY OUTREACH EFFORTS

A. PERIODIC EVALUATION OF OUTREACH ACTIVITIES.

1. Quarterly Reviews of Outreach and Educational Offerings

The Campus IRB will assess the effectiveness of its Community Outreach efforts on an ongoing basis with quarterly reviews of educational opportunities offered. The evaluation will be conducted by the Campus IRB Compliance Officer, Campus IRB Chair or Quality Assurance Associate or designee of the Campus IRB.

2. Training Evaluations

Feedback forms evaluating the trainer of each “Live Training” session will be distributed and reviewed on an ongoing basis. The evaluation will be conducted by the Campus IRB Compliance Officer, Campus IRB Chair or Quality Assurance Associate or designee of the Campus IRB.

3. Online Training

Feedback forms evaluating the eIRB online Campus IRB “Human Subject Training” are submitted individually from investigators accessing the system. All evaluations are dependent upon the participant’s submission, and will be reviewed on an ongoing basis. The evaluation will be conducted by the Campus IRB Compliance Officer, Campus IRB Chair or Quality Assurance Associate or designee of the Campus IRB.

4. Participant Outreach Evaluations

The Campus IRB will assess the effectiveness of its Participant Outreach efforts on an ongoing basis. The participant, at their discretion, may submit the evaluation forms individually when accessing the website. All evaluations are dependent upon the participant’s submission, and will be reviewed on an ongoing basis. The evaluation will be conducted by the Campus IRB Compliance Officer, Campus IRB Chair or Quality Assurance Associate or designee of the Campus IRB.

5. Organizational Periodic Evaluation of Outreach Activities

The Campus IRB along with the Human Research Protections Office will annually evaluate the quality and effectiveness of community outreach activities. Improvements will be made as needed based on this evaluation to promote continual improvement of community outreach activities.

Revised June 2007
Revised November 2007
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