



Campus Institutional Review Board
University of Missouri-Columbia

Privacy and Confidentiality

Policy Number 2876.24

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Effective Date: December 12, 2007

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 Campus Institutional Review Board (Campus IRB), when appropriate, shall assure that adequate provisions are available to protect the privacy of subjects and to maintain the confidentiality of data.

2.0 Scope

This policy applies to all human subject research under the scope of Campus IRB jurisdiction.

3.0 Purpose

Maintenance of privacy and confidentiality of a human subject participant and their data to protect research participants from a variety of potential harms.

4.0 Standard Operating Procedure

In order to approve research, the Campus IRB must determine that the research plan makes adequate provisions to protect the privacy interests of participants.

A. DEFINITIONS:

Privacy can be defined in terms of having control over the extent, timing, and circumstances of sharing oneself with others.

Confidentiality is defined as the treatment of information that an individual has disclosed in a relationship of trust, and with the reasonable expectation that it will not be disclosed to others in ways that are inconsistent with the understanding of the original disclosure without permission. In research, confidentiality refers to the agreement between the investigator and the participant in how data will be managed and used.

B. STANDARD

The standard for determining this policy is that of a *reasonable member of the research community*, and if that individual would consider the information collected in the research to be private.

C. INVESTIGATOR RESPONSIBILITIES

1. The investigator must provide the IRB with specific details outlining the methodology for maintaining a research subject's privacy, and confidentiality of their data.
2. The investigator may choose to store data in a locked box or closet.
3. The investigator may choose to assign identifiers. The code should be kept in a separate area.
4. Researchers should educate staff and exercise caution when gathering sensitive information in the applicable process.
5. The investigator should assure that the proposed research consent processes comply with the Informed Consent policy. (See Informed Consent Process Policy).
6. If the proposal shall involve Private Health Information, the project must be reviewed under the HIPAA regulations.
7. Every application submission requires the investigator to complete a HIPAA assessment.

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8. If the research activities involve private health information, the Investigator must comply with HIPAA regulations to protect the privacy interests of the subject and confidentiality of their data.
 - a. Any issues regarding HIPAA and IRB activities are resolved under the collaboration between the Compliance Officer and Privacy Officer.
9. The investigator should propose provisions for protecting the privacy of subject participants which may include, but not be limited to:
 - a. Deidentification data
 - b. Coding procedures
 - c. Anonymity
 - d. Business Associates Agreements
 - e. Limited Use Agreements
 - f. Aggregate Reporting practices

10. MANDATORY REPORTING

Investigators must comply with Missouri Laws regarding Mandatory Reporting requirements of Section 210.115.1 (Child Abuse Reporting Statute) of Missouri Revised Statutes.

Section 210.115.1 (Child Abuse Reporting Statute) of Missouri Revised Statutes provides:

“For any research taking place in Missouri in which a mandatory reporter under Section 210.115.1, may obtain reasonable cause to suspect that a child has been or may be subjected to abuse or neglect or observes a child being subjected to conditions or circumstances which would reasonably result in abuse or neglect, that person shall immediately report or cause a report to be made to the division in accordance with the provisions of sections 210.109 to 210.183. As used in this section, the term “abuse” is not limited to abuse inflicted by a person responsible for the child’s care, custody and control as specified in section 210.110, but shall also include abuse inflicted by any other person.”

IRB RESPONSIBILITIES

1. The Campus IRB must review the all research protocols with the aim of protecting the privacy of subject participants
 - a. To assure the subject’s privacy is maintained, the reviewer must complete the checklist which determines the confidentiality was maintained
2. The Campus IRB may request information from a consultant or guest who possesses the desired expertise.
3. The Campus IRB will assure that the project complies with all aspects of the Campus IRB policies.
4. The Campus IRB will assure that applications accessing are screened to determine if private health information will be accesses and are subject to HIPAA regulations.
5. The Campus IRB will assure that applications accessing private health information comply with the HIPAA regulations.
6. Immediately report any violations of privacy rights in accordance with the “Reporting” policy.
7. Comply with the “Campus IRB Review Process”, “Assessing the Level of Risk”, “Noncompliance with Campus IRB Policies and Procedures”, “Deviation Review Process”, and “CIRB Reporting Requirements” policies.

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Revised December 2006
Revised June 2007
Revised December 2007