

Applicability of Federal, State and Local Laws
Policy Number 2876.2



Campus Institutional Review Board
University of Missouri-Columbia

Applicability of Federal, State and Local Laws

Policy Number 2876.2

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 be a stylized name.

Signed _____
Associate Vice-Chancellor for Research

Date December 12, 2007

Applicability of Federal, State and Local Laws
Policy Number 2876.2

1.0 Purpose

The Campus IRB shall conduct its operational activities in a manner that complies with State, Federal, and Local Laws.

2.0 Scope

The applicability of compliance with State, Federal, and Local laws applies to all human subject research being conducted under jurisdiction of the University of Missouri-Columbia Campus IRB.

3.0 Policy/Procedure

The Campus IRB assures that all human subject research conducted at the University of Missouri-Columbia under its jurisdiction complies with the regulations of the Department of Health and Human Services (DHHS) (45 CFR 46.101); the Belmont Report; and the Federalwide Assurance (FWA #00002876) of the University of Missouri-Columbia, and any applicable State, Federal and Local Laws.

The Campus IRB shall conduct its operational activities in a manner that complies with State and Local Laws, and in a manner that does not offend Federal regulations.

- A. Should a question or conflict arise concerning State, Local or Federal Law, and IRB processes, the Campus IRB may:
- a. Consult with Legal Counsel of the University of Missouri-Columbia to:
 - i. Assess the nature of the question or conflict; and
 - ii. Assess the applicability of State, Local, and/or Federal regulation(s) or law; and
 - iii. Apply the appropriate State, Local, and/or Federal Law to IRB processes.
 - b. Consult with OHRP to:
 - i. Assess the nature of the conflict;
 - ii. Request a written determination on the matter;
 - iii. Receive directives; and
 - iv. Request an interpretation of the applicable Federal regulation.
 - c. Notify the Vice Chancellor for Research of the:
 - i. Nature of the conflict; and
 - ii. Impact of the conflict in relation to State, Local, and/or Federal law.
 - d. Place the matter of the next available board meeting Agenda for review.
- B. Should a question or conflict arise concerning the application of laws beyond federal law relevant to research involving humans as participants and IRB processes, the Campus IRB will:
- a. Consult with Legal Counsel of the University of Missouri-Columbia to:
 - i. Assess the nature of the question or conflict; and
 - ii. Assess the applicability of laws beyond federal law relevant to the IRB process; and
 - iii. Apply the appropriate processes to protect the safety and welfare of human subject participants.
 - b. Notify the Vice Chancellor for Research of the:
 - i. Nature of the conflict; and
 - ii. Impact of the conflict in relation to State, Local, and/or Federal law.
 - c. Place the matter of the next available board meeting Agenda for review.
 - d. Other Options:

The Campus IRB may consult with OHRP to:

 - i. Assess the nature of the conflict;
 - ii. Request a written determination on the matter;

Applicability of Federal, State and Local Laws
Policy Number 2876.2

- iii. Receive directives; and
- iv. Request an interpretation of the applicable Federal regulation.

C. The Informed Consent Process

- a. The Campus IRB may consult with Legal Counsel of the University of Missouri-Columbia to:
 - i. Assess the nature of the question or conflict; and
 - ii. Assess the applicability of State, Local, and/or Federal regulation(s) or law; and
 - iii. Apply the appropriate State, Local, and/or Federal Law to IRB processes.Consult with legal counsel for regarding the application of laws beyond federal law relevant to research involving humans as participants.
- b. Legally effective consent shall be determined by governing Federal, State, and local Law;
- c. The investigator must comply with the Campus IRB “Informed Consent Process” policy.
- d. The investigator must comply with the Campus IRB “Privacy and Confidentiality” policy.

Revised May 2006
Revised June 2007
Revised November 2007