



Institutional Review Board

University of Missouri-Columbia

Standard Operating Procedure

Maintenance

Maintenance

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July 1, 2015

Approved By: Robert Hall, PhD
Associate Vice Chancellor, Research

Table of Contents

[Purpose](#)

[Scope](#)

[Policy/Procedure](#)

[Review, Revision, Approval of SOPs](#)

[Policy Dissemination and Training](#)

[Forms, Templates and Worksheets](#)

1.0 Purpose

To assure knowledge and compliance by documenting the procedures for creating and maintaining IRB Standard Operating Procedures

2.0 Scope

This SOP applies to all human subject research being conducted which falls under the purview of the University of Missouri Institutional Review Board

3.0 Policy/Procedure

To ensure the rights and welfare of human subjects of research will be overseen and protected in a uniform manner, the IRB has developed Standard Operating Procedures (SOP). The SOPs reflect applicable federal regulations and guidance and also policies and procedures of the University of Missouri – Columbia. SOPs provide the framework for the ethical and scientifically sound conduct of human research, regardless of changes in personnel. Written procedures are in place to ensure the highest quality and integrity

IRB – SOP Maintenance

Page 2 of 3

of the review and oversight of research involving human subjects and for adequate documentation of such oversight.

Review, Revision, Approval of SOPs

Changes to federal regulations, guidelines or research practice, as well as the policies and procedures of the University of Missouri – Columbia and the IRB may require a new IRB SOP or a revision to a previously issued IRB SOP. Any new information, identified by the IRB Administrative Office (through the Food and Drug Administration website, Office of Human Research Protections website, or from any other source as identified) as being pertinent to the protection of research participants, will be disseminated via the IRB List-Serve and the applicable SOP will be provided in the IRB SOPs available on the IRB website

(http://research.missouri.edu/policies/pol_dept.htm).

Policies will be reviewed by the IRB Administrative Office every three years or sooner as necessary. The review will consist of determining the policies accurately describe the procedures as they are enacted in compliance with all applicable federal, state, local and institutional regulations.

All new or revised SOPs require review and approval by the Associate Vice Chancellor – Research in the Office of Research. Documentation of review and approval is by signature of the responsible and authorized individuals.

Policy Dissemination and Training

When new or revised SOPs are approved, notification will be disseminated through the IRB ListServ and the approved SOPs will be added to the policies section of the IRB website.

Educational training and information on each revised policy and/or procedure will be provided to all IRB members and IRB Administrative Office staff. Evidence of training will be documented and filed with the IRB Administrative Office.

Each IRB member or IRB Administrative Office staff will be required to review all applicable SOPs prior to undertaking any responsibility within the IRB. Evidence of training will be documented and filed with the IRB Administrative Office.

Forms, Templates and Worksheets

As a complement to the SOPs and a tool to aid in compliance with the procedures as outlined in the IRB SOPs, various forms, templates and worksheets have been developed by the IRB and are available to investigators, IRB members and IRB Administrative staff through the IRB website.

IRB – SOP Maintenance

Page 3 of 3

These materials will be reviewed by the IRB Administrative Office at the same interval as the IRB SOPs and changes will be made accordingly.