Standard Operating Procedure (SOP) Maintenance

Effective Date: May 15, 2006
Revised Date: December 1, 2006

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

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

2.0 Scope
   This SOP applies to all human subject research being conducted which falls under the
   purview of the Health Sciences 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 HS 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 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 Health Sciences IRB may require a new HS IRB SOP or a revision to a previously issued HS IRB SOP. Any new information, identified by the HS 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 HS IRB ListServe and the applicable SOP will be provided in the HS IRB SOPs available on the HS IRB website (www.research.missouri.edu/hsirb/policies).

Policies will be reviewed by the HS IRB Administrative Office every three years or sooner if determined necessary by the Compliance Officer. 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 HS IRB ListServe and the approved SOPs will be added to the policies section of the HS IRB website.

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

Each IRB member or HS IRB Administrative Office staff will be required to review all applicable SOPs prior to undertaking any responsibility within the HS IRB. Evidence of training will be documented and filed with the HS 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 HS IRB SOPs, various forms, templates and worksheets have been developed by the HS IRB and are available to investigators, IRB members and IRB Administrative staff through the HS IRB website.

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