Purpose and Function of the IRB

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1.0 Purpose
To aid in assuring knowledge and compliance of all persons involved in any aspect of
human subject research by documenting the purpose and function of the Board.

2.0 Scope
The SOP applies to all human subject research falling under the purview of the Health
Sciences Institutional Review Board.

3.0 Policy/Procedure
The purpose of the Health Sciences Institutional Review Board is to assure that the rights
and welfare of human research volunteers are adequately protected in research being
conducted in conjunction with the University of Missouri Health Sciences Center and its
affiliates. The principles which govern the IRB in assuring that the rights and welfare of
subjects are protected are those principles embodied in the regulations and the Federal
Wide Assurance. The Board also reviews proposed research for compliance with all
applicable federal, state and local laws.
To accomplish this purpose, a group deliberation process is used to review and approve protocols and related materials (i.e. informed consent document, investigator brochures, recruitment materials, test article information, etc.) to determine:

1) the level of risk category into which each proposal falls

2) that the level of risk is minimized by procedures consistent with sound research design that do not unnecessarily expose the research volunteer to risk

3) that the risks to research volunteers are reasonable and are outweighed by the anticipated benefit and the knowledge that may be expected to be gained

4) the evaluation of risks and benefits considers only the risk/benefits which may result from the research (risk/benefit of standard of care procedures are not taken into account except as relating to research).

5) the risk/benefits are not considered in light of long-range effects of applying research knowledge gained effecting public policy

6) the participant selection pool is equitable

7) the human subject volunteers are adequately informed of the risk and benefits of participation in the research study, what is involved in participation in the research study

8) informed consent is adequate and obtained from each prospective volunteer and appropriately documented in accordance with and to the extent required by federal regulations and HS IRB policies

9) the privacy and confidentiality of each research volunteer and the corresponding data is adequately protected

10) the inclusion of appropriate additional safeguards to protect the rights and welfare of research volunteers who may be vulnerable to coercion or undue influence (those individuals considered as members of vulnerable populations, (e.g. children, prisoners, incompetent persons, or economically or educationally disadvantaged individuals)

The Board carries out the purpose and function in its review of all newly submitted projects, amendment requests, unanticipated problems and continuing review.