Institutional Review Board

University of Missouri-Columbia

Standard Operating Procedure

Purpose and Function of the IRB

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Effective Date:	January 22, 2001
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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 University of Missouri Institutional Review Board (MU IRB).

The following applications are reviewed by the MU IRB:

a. The Principal Investigator is employed at any of the following:

- University of Missouri-Columbia including all colleges, schools, and departments

- Howard A. Rusk Rehabilitation Center
- Missouri Rehabilitation Center
- Thompson Center for Autism and Neurodevelopmental Disorders
- University of Missouri Hospital and Clinics (MU Health Care), including
- Women's and Children's Hospital, Ellis Fischel Cancer Center, Missouri Orthopaedic Institute, and Missouri Psychiatric Center
- Harry S. Truman Memorial Veterans Hospital
- Missouri Institute of Mental Health

b. The subject population includes patients (either inpatients or outpatients) in any of the institutions listed above;
c. The research involves physical stress to the subjects (e.g., exercise physiology projects);
d. The research involves any collection of human tissue or blood,(above the amount qualifying for Expedited review);
e. The research involves fetuses.

3.0 Policy/Procedure

The purpose of the 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 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 (only research related risk/benefit is considered instead of standard of care procedures 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 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)

Research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by the IRB.

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