

OR 202-C

01/01/07

Sparrow Health System
Institutional Research Review Committee
Office of Research Oversight and Compliance
1215 E Michigan Avenue, Lansing, MI 48912
Phone: 517.364.2150 Fax: 517.364.2763 E-mail: irrc@sparrow.org

Date _____
IRB Member Name/Address _____

IRB: _____

Capacity: _____

Term of Appointment: _____

Introduction and Purpose

The Institutional Review Board is a federally regulated entity with the mandate to review biomedical and behavioral research studies that take place within or under the authority of the Sparrow Health System. The purpose of this review is to determine if the proposed research meets certain established regulatory, policy, and ethical criteria to protect the rights and welfare of the human subjects of such research. The criteria used by the IRB to determine the acceptability of such research is based upon principles discussed in the Belmont Report (attached), which are:

- The sum of the benefits to the subject and the importance of the knowledge to be gained so outweigh the risks to the subjects as to warrant a decision to allow the subject to accept these risks.
- Legally effective informed consent will be obtained from each subject, unless the requirements for waiver of informed consent are met, by adequate and appropriate methods in accordance with the provisions of applicable state and federal regulations.
- The conduct of the study will be reviewed at timely intervals.

Scope of Work

The IRB will review protocol and informed consent forms, and review or delegate the review of Investigator and site qualifications for the purpose of approving, recommending modifications to, or disapproving proposed research involving human subjects as required by regulations of the U.S. Department of Health and Human Services and the Federal Food and Drug Administration. Criteria to be used in reviewing protocols include minimization of risk, equitability of subject selection, adequacy of informed consent and maintenance of subject confidentiality.

As regular member of the IRB, your presence will be used to establish a quorum; therefore you will be expected to attend regularly scheduled meetings, which generally occur once a month. All regular members receive a packet of material pertinent to the proposed research prior to the scheduled meeting. The packet contains the meeting agenda, expedited review information, the protocol(s) and informed consent form(s) and Investigator information submitted for review. You are expected to review this information prior to the meeting and participate in the review and ensuing discussion. You will be expected to serve as part of the three-member primary review team for protocols as assigned.

The responsibilities of the primary reviewer are outlined in the description of reviewer duties (Attachment OR 203-D and SOP OR 203 section 1.3.2).

Requirements

Prior to assuming responsibilities of an IRB member, new appointees will be expected to observe a meeting, and complete the Human Subjects training course. IRB members are required to participate in continuing training and education during the term of their appointment.

Members are expected to agree to recuse themselves if they have a conflict of interest that could bias their consideration of research submitted for review, and to document this agreement at the time they accept appointment to the IRB.

Term

The term for IRB members is two years. This term is renewable. Members who are unable or unwilling to fulfill their duties as IRB members may be removed from the IRB at any time by the IRB Chairperson/Designee). See Member Responsibilities.

Liability Coverage

The E.W. Sparrow Hospital/Sparrow Health System maintains Insurance Warranty for all claims made against IRB members, alternates and consultants.

Please sign below if you agree to the terms described in the above.

IRB Member

Date

IRB Chairperson/Designee

Date