

Fairview Health Services

Corporate Compliance

Subject:	Fairview Research Scientific Review Committee
Purpose:	To provide a scientific peer review mechanism for research conducted by Fairview investigators.
Scope:	Applies to all Fairview employed researchers and community researchers privileged to practice at Fairview. The policy specifically excludes researchers who are faculty members of the University of Minnesota's Academic Health Center as they have internal resources for scientific review.
Policy:	It is the policy of Fairview that the Research Scientific Review Committee will review the scientific merit of a clinical research protocol to ensure the relevancy of the scientific question and to determine whether the study design appropriately answers that question. The Research Scientific Review Committee will provide scientific peer review of local and national clinical research protocols to be conducted on patients who are treated within Fairview Health Services. Scientific review applies to all applications submitted to the Health and Biological/Medical Review Committee of the Institutional Review Board unless it will be reviewed by another appropriately convened peer review committee (e.g. Nursing Research Council). Scientific review does not apply to exempt or expedited review studies.
Definitions:	<p>Institutional Review Board: A committee formally designated to approve, monitor, and review biomedical and behavioral research involving human subjects with the aim to protect the rights and welfare of the human subjects.</p> <p>Principal Investigator: The individual who conducts research (i.e., under whose immediate direction the research activity occurs).</p> <p>Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge</p>
Procedures:	<p>The Institutional Review Board (IRB), has chosen to delegate the scientific review component of human subjects protections to other committees, effective 7/1/07. Therefore, research involving human subjects is to be reviewed for scientific validity and appropriateness <u>prior</u> to IRB review.</p> <p>Fairview Research Administration is responsible for convening the Research Scientific Review Committee, facilitating Committee activities and coordinating the review process. Fairview Research Administration</p>

will maintain the proper documentation of the review process, including dates, participants, method of review and discussion, and decision.

Research Scientific Review Committee:

The Research Scientific Review Committee shall consist of physicians, nurses, pharmacists, and statisticians. The committee will include a minimum of 4 members. The Research Scientific Review Committee shall review the clinical research protocols according to the review criteria set forth below and shall attest to: (1) maintaining confidential or proprietary information; (2) disclosing a conflicted interest in the sponsor funding the research; and (3) providing notification of receipt of review materials in a timely manner.

Scientific Review Criteria:

The Research Scientific Review Committee shall review the clinical research protocols by determining adherence to the following review requirements: (1) Is the rationale for the study clearly stated and is the rationale scientifically sound?; (2) Are the aims and corresponding hypothesis clearly stated?; (3) Is the primary outcome (and secondary outcomes, as appropriate) clearly defined?; (4) Are there adequate preliminary data in the literature (or from the investigator) to justify the proposed research? Has an adequate literature review been done to support this study?; (5) Is the question or hypothesis being tested providing important knowledge to the field?; (6) Is the design of the study appropriate for the questions being posed?; (7) Have the validity and reliability of measures been established or are there methods proposed for establishing the validity and reliability?; (8) Is the proposed study population appropriate?; (9) Are statistical considerations, including sample size and justification, estimated accrual and duration, and statistical analysis clearly described and adequate to meet the study objectives?; (10) Are all the proposed tests or measurements requested necessary to answer the scientific question?; (11) Are the investigators qualified to conduct this study?

Review Process:

1. The Principal Investigator (or designee) shall submit a clinical research protocol to Fairview Research Administration with the IRB application packet.
2. Fairview Research Administration will receive protocols that warrant review and will distribute to the appropriate committee members within 1-2 business days.
3. Committee members shall submit an attestation form in which they agree to (1) maintain confidential or proprietary information; (2)

	<p>disclose any relevant conflicts; and (3) provide notification of receipt of review within 1-2 business days from receiving review items.</p> <p>4. Committee members will review and email comments to the committee within 7 business days. Research Administration will facilitate telephone conference discussion if person-to-person dialog is warranted.</p> <p>5. Committee members will reach consensus regarding the scientific validity of the project by determining whether the study is approved, approved with stipulations, or not approved. Committee decisions are expected within 10 business days of the receipt of protocol, unless the committee members have requested additional information.</p> <p>Fairview Research Administration will document and communicate committee decisions to the Principal Investigator.</p>
External Ref:	<p>Research Subjects' Protection Program, University of Minnesota Institutional Review Board. (http://www.research.umn.edu/irb/); Minnesota Statute 146.61-67; 45 CFR 46.101(b); 45 CFR 46.111; 21 CFR 56.111</p>
Internal Ref:	
Source:	System Director, Research Administration
Approved by:	Research Institutional Official
Date Effective:	7/1/2007
Date Revised:	5/29/2012
Date Reviewed:	5/29/2012