Marshfield Clinic

Scientific or Scholarly Validity Review Requirements

1. SCOPE

1.1. System Wide

2. DEFINITIONS & EXPLANATIONS OF TERMS

2.1 Scientific or scholarly validity:

- A study is considered to be scientifically valid or to possess scholarly validity if it meets the following criteria:
  - ◊ The study uses procedures consistent with sound research design;
  - ◊ The research is designed soundly enough to answer the question(s) being posed or yield the expected results; and
  - ◊ If the study involves an investigational product, and/or is subject to ICH-GCP (E6), clinical and non-clinical information on the product is adequate to support the proposed research.

2.2. Minimal risk: Minimal risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

2.3. Greater than minimal risk: Research which involves more than minimal risk to subjects

3. PURPOSE

3.1 Ensuring scientific or scholarly review is a key component in protecting the rights and welfare of human research subjects. The regulations for the protection of human subjects require that all of the Criteria for IRB Approval of Research are satisfied (45 CFR 46.111 (a) & 21 CFR 56.111(a)) including the two criteria that address scientific review:

- Risks to participants are minimized (i) by using procedures consistent with sound research design and which do not unnecessarily expose participants to risks and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.

Marshfield Clinic Research Foundation Institutional Review Board (MCRF IRB), the institution, and the investigator share an obligation to ensure that any research to be

conducted complies with the regulations mentioned above. The IRB Chairperson or designee has responsibility for confirming scientific or scholarly validity of each study before IRB expedited approval may be given or before the new study will be scheduled for review by the convened IRB. This document outlines requirements for scientific or scholarly validity review of research submitted to the IRB.

4. PROCEDURE BODY

4.1 The following types of submissions do not require confirmation of scientific or scholarly validity:

a. Exemption Requests

b. Humanitarian Use Device Applications

c. Expanded Access Applications

d. Applications for Databases or BioBanks

e. Feasibility Data Collection

4.2 For studies that involve **not greater than minimal risk**, the IRB Chair or the IRB's expedited reviewer will determine whether the proposed activity has scientific or scholarly validity at the time of expedited review. The finding will be documented on the reviewer guide.

4.3 For studies of **greater than minimal risk**, the IRB Chair or designee will determine whether the proposed activity has scientific or scholarly validity at the time of pre-review, before the study may be scheduled for review by the convened IRB. Documentation of this determination will be recorded on the Scientific or Scholarly Validity Review form and will be available to all IRB members at the time of IRB review.

4.4 If the IRB Chairperson or designee desires input as to the scientific or scholarly validity of a study, it will be scheduled for review by the Marshfield Clinic Research Foundation Research Committee who will evaluate the proposal using the criteria in this procedure. A copy of the Research Committee minutes documenting its assessment will be provided to the expedited reviewer or convened IRB members.

4.5 If the scientific or scholarly validity of a proposal is disapproved by the IRB Chairperson, designee or Research Committee, the project will not be reviewed by the IRB until the proposal has been revised to satisfy requirements.

5. ADDITIONAL RESOURCES

5.1 References:

- 45 CFR Part 46 – Protection of Human Subjects
- 21 CFR Part 56- Institutional Review Boards
- Association for the Accreditation of Human Research Protections Programs (AAHRPP) [Element I.1.F., II.1.E]

5.2 IRB Form for Convened Review: Scientific or Scholarly Validity Review Form
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6. DOCUMENT HISTORY

Version No.	Revision Description
1.0	New Document in Document Control transferred from Policy & Handbook Library - #934.3 (no changes made)
2.0	Sect. 2 – add definitions of minimal risk and greater than minimal risk. Sect. 3 – add purpose and regulations. Sect. 4.3 add "designee" to perform scientific review if IRB Chairperson is not available or has a conflict of interest. Add name of IRB form to be completed for scientific review.
3.0	

7. DOCUMENT PROPERTIES

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