SPECTRUM HEALTH

Authority, Jurisdiction, and Responsibilities of the SH IRB

This Policy is Applicable to the following sites:
Continuing Care, Corporate, Gerber, Outpatient/Physician Practices, Priority Health, Reed City, SH GR Hospitals, SHMG, United/Kelsey, Zeeland

Applicability Limited to: N/A

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Functional Area: Administrative Operations, Research

Department Area: Research

I. Scope

Spectrum Health IRB responsibilities in the protection of human subjects in research conducted under its jurisdiction.

II. Purpose

To state the institutional authority under which the IRB is established and empowered and describe the responsibilities of the Spectrum Health IRB in the protection of human subjects in research conducted under its jurisdiction.

III. Policy

A. Authority and Jurisdiction

A.1. The Spectrum Health IRB is established and empowered under the authority of the Board of Trustees for Spectrum Health and is responsible for reviewing all research projects determined to involve the use of humans as subjects and being conducted at any Spectrum Health entity or utilizing patient tissue/data owned by Spectrum Health and/or utilizing Spectrum Health services for research purposes.

A.2. Spectrum Health IRB review and approval must occur prior to the initiation of any research related activities, including recruitment and screening. Retrospective IRB approval cannot be granted.

A.3. The Spectrum Health IRB acts as the privacy board with relation to HIPAA for research purposes.

A.4. The IRB is charged with the protection of the rights, safety, and welfare of human subjects participating in biomedical and behavioral research under its jurisdiction. The IRB reviews and oversees such research to assure that it meets ethical principles and that it complies with federal regulations that pertain to human subject protection at 45 CFR 46 and 21 CFR 50 and 56, and other pertinent regulations and guidance, as applicable (e.g., GCP, DOD, etc.).

B. Governing Principles

B.1. The SH IRB is guided by the ethical principles applied to all research involving humans as subjects, as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, more commonly referred to as the *Belmont Report*:

B.1.1. **Beneficence** – the sum of benefits to the subject and the importance of the knowledge be gained outweigh the risks to the subjects as to warrant a decision to allow the subject to accept these risks.

B.1.2. **Autonomy –** legally effective informed consent is obtained, unless the requirements for waiver of informed consent are met by adequate and appropriate methods in accordance with the provisions of applicable regulations.

B.1.3. **Justice –** the selection of subjects is equitable and is representative of the group that will benefit from the research.

B.2. Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with good clinical practice and the applicable regulatory requirements.

C. Relationship of the IRB to Spectrum Health Officials and Other Committees

C.1. It is understood that Spectrum Health officials and other committees may be required to review and approve human subject's research.

C.2. While the Spectrum Health IRB may work collaboratively with officials and other committees, the IRB is obligated to function independently of these processes. IRB Members and staff should report any concerns/issues of undue influence to the Spectrum Health Institutional Official. The Institutional Official will work with the appropriate executive leadership and Human Resources to address/mitigate the situation.

C.3. Although a Spectrum Health official or committee may disapprove research that has been approved by the IRB, no official or committee may approve research that has been disapproved by the IRB.

D. The Spectrum Health IRB is obligated to:

D.1. Knowledgeably review human subject's research in accordance with federal, state, and local laws and regulations, and Spectrum Health research and/or Spectrum Health IRB policy(s).

D.2. Approve, disapprove, or require modifications for approval for all human subject research activities.

D.3. Determine that risks to subjects are minimized by utilizing consistent and knowledgeable review of sound research design; determine research does not unnecessarily expose subjects to risk and, that risks to subjects are reasonable in relation to anticipated benefits to the subjects and the importance of the knowledge that may be expected to result; determine selection of subjects is equitable; determine if a consent is needed or waiver of informed consent can be used and accepted.

D.4. When appropriate, determine that the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects; determine that there are adequate provisions to protect the privacy of subjects and the confidentiality of the data; also, determine when subjects may be likely to be vulnerable to coercion or undue influence; and determine that additional safeguards have been included in the research to protect the rights and welfare of these subjects.

D.5. When appropriate, observe or have a third party observe the consent process and the research.

D.6. Suspend or terminate approval of ongoing research that violates the Spectrum Health IRB's requirements or that has been associated with unexpected serious harm to subjects or repeated complaints. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.

D.7. Notify parties in writing of its decisions to approve, disapprove, or require modifications to approve research. If the IRB decides to disapprove a research activity, include in the written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

D.8. Review of all unanticipated problems involving risk to study subjects or others or any serious or continuing non-compliance.

D.9. Conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year.

D.10. Mitigate a review of all reports of alleged noncompliance as it may relate to this policy, federal regulations, requirements or determinations of the Spectrum Health IRB, or any unexpected serious harm to subjects as per requirements.

1. Revisions

Spectrum Health reserves the right to alter, amend, modify or eliminate this policy at any time without prior written notice.

2. Policy Development and Approval

Document Owner:
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Not Assigned

Reviewer(s):
Not Assigned

Approver:
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3. Keywords

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