POLICY
Training Requirements for Individuals Involved in Human Subjects Research

This Policy is Applicable to the following Spectrum Health sites:
Continuing Care, Corporate, Gerber (Newaygo County General Hospital Association), Outpatient/Physician Practices, Priority Health, Reed City (Reed City Hospital Corporation), SH GR Hospitals (Spectrum Health Hospitals), SHMG, United/Kelsey (Spectrum Health United; Spectrum Health Kelsey Hospital), Zeeland (Zeeland Community Hospital)

Applicability Limited to: N/A

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Functional Area: Research

Department Area: Research

1. Purpose

The purpose of this policy is to ensure individuals conducting clinical research at Spectrum Health are appropriately trained and educated, to identify appropriate training mechanisms, and to ensure appropriate documentation of training and education.

2. Responsibilities

All individuals engaged in research at Spectrum Health must demonstrate and maintain knowledge of the ethical principles and regulatory requirements and protections governing human subjects research. The education and training that is provided strengthens the underpinnings of the Human Research Protection Program (HRPP). All those involved in the review and/or conduct of research will maintain continuing knowledge of, and comply with, the following:

- Relevant ethical principles;
- Relevant federal regulations and guidance documents;
- Written Spectrum Health IRB (SH IRB) procedures;
- Federal, State and local laws; and
- Institutional policies for the protection of human subjects in research.

3. Policy

A. Applicability:

Spectrum Health requires all individuals who are engaged in the conduct of human subjects research or are utilizing the SH IRB as the IRB of record for the research protocol, provide evidence of human subjects research protections training. This includes:

(a) Spectrum Health employees, agents, subcontractors, consultants, students and affiliated personnel engaged in research being conducted at Spectrum Health (as defined in policy *Qualifying Engagement in Humans Subjects Research* (#2049);
(b) Any individual involved in the conduct of research which involves direct intervention or interaction with a human research subject and/or their identifiable private health information is subject to human subject research protections training requirements outlined in this policy.

B. Required Education and Training:

B.1 Human Subjects Protections

To fulfill the requirement for human subjects research training at Spectrum Health, all individuals engaged in human subjects research must complete the Basic Biomedical Course provided by the Collaborative Institutional Training Initiative (CITI), located online at http://www.citiprogram.org . This course includes an overview of the history of protections, the applicable federal and state regulations and the three ethical principles outlined in The Belmont Report.

Principal Investigators (PI) are responsible for maintaining documentation of this human subjects protection training for all study personnel and ensure it is renewed accordingly. Human subject research protection training must be completed by all study personnel prior to the Spectrum Health IRB approving a submission.

All investigators and research personnel must complete continuing education in human subjects protection periodically (i.e., at least every 3 years).

If an individual has taken CITI training with another institution, the individual is to "affiliate" with Spectrum Health. Any modules that have been taken that are equivalent to those required by Spectrum Health will populate with the date completed. If additional modules are required by Spectrum Health, the individual will only need to complete the outstanding modules within that course.

Spectrum Health reserves the right to require additional training for researchers and research personnel when working with human subjects when it is deemed to be necessary.

B.2 Good Clinical Practice

Good Clinical Practice (GCP) is required for all research personnel involved in the conduct, management and oversight of a clinical trial. *Clinical trial* is defined by the NIH as “a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.”

All investigators and research personnel must complete continuing education in GCP every 3 years. The PI of the clinical trial is responsible for maintaining documentation of this GCP training for all study personnel and ensure it is renewed accordingly.

GCP principles describe the responsibilities of investigators, sponsors, monitors and IRBs in the conduct of clinical trials. Compliance with these GCP principles provides assurance that the rights, safety and well-being of human subjects are protected, that clinical trials are conducted in accordance with approved plans, and that data derived from clinical trials are reliable.

4. Policy Development and Approval

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5. Keywords

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