

Training Requirements for Individuals Involved in Human Subjects Research

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

All Spectrum Health personnel and applicable consultants who are reviewing, conducting, or supporting human research.

II. Purpose

To demonstrate Spectrum Health's commitment to the protection of the rights and welfare of human research participants by ensuring that all Spectrum Health personnel and applicable consultants who are reviewing, conducting, or supporting human research demonstrate and maintain knowledge of the ethical principles and regulatory requirements governing the protection of human research participants.

III. Specific Policy

A. Determining Applicability

1. Spectrum Health requires all individuals, who are involved in the conduct of human subject research with Spectrum Health patients, or are utilizing the Spectrum Health Institutional Review Board (IRB) as the IRB of record for the research protocol; provide evidence of human subjects research protection training for the researchers and research personnel involved. This includes:

- (a) Spectrum Health employees, IRB members and staff, subcontractors, consultants, students and affiliated personnel involved in research being conducted at Spectrum Health;
- (b) Any individual involved in the conduct of a research protocol, including retrospective studies, which involves direct intervention or interaction with a human research subjects and/or their private health information while conducting the research is subject to human subject research protections training.

2. Training completed at another institution may be acceptable if it is equivalent to the Spectrum Health requirements. A copy of a training certificate, or a signed letter noting the training from a representative of the institution where the training occurred, will satisfy this requirement. Spectrum Health may require additional human research subject protections training if the previous education is not equivalent to Spectrum Health research education standards.
3. 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. Specific Requirement

1. To fulfill the requirement for human subjects research training at Spectrum Health, all researchers and research personnel (as defined in the previous “applicability” section of this policy) must complete the appropriate education course provided by the Collaborative Institutional Training Initiative (CITI), located online at <http://www.citiprogram.org>.
2. Researchers and research personnel are required at a minimum to complete the Basic Biomedical Course.
3. Spectrum Health reserves the right to require additional courses to researchers and research personnel as necessary. Additional courses include Good Clinical Practice, Responsible Conduct of Research and Health Information Privacy and Security.
4. Upon completion of the CITI human subjects training course, a certificate of course completion will be emailed directly to the Spectrum Health CITI administrator via the CITI coordinating center as verification of the individual’s course completion. Documentation of completed human subjects training will be retained by the Spectrum Health Research and Human Rights Committee (IRB).
5. Documentation of completed human subject research protection training must be submitted to the Spectrum Health Research and Human Rights Committee’s (Spectrum Health IRB) **prior** to committee consideration of a research submission. The Spectrum Health IRB may refuse applications that do not include documentation of human subject research protection training for all researchers listed as participants in the conduct of the study.

C. Ongoing Training Requirements

1. All investigators and research personnel who remain engaged in human subjects research at Spectrum Health are required to complete continuing education every 3 years from the date the basic training (CITI Basic Course) was completed. This requirement can be met by completing the CITI Refresher Course which is accessible via www.citiprogram.org.
2. Investigators and research personnel, who do not complete this continuing education requirement within 3 years and 30 days post the date of completion of either the CITI Basic or last Refresher Course, will be placed on the IRB restricted research personnel list. New IRB approvals will not be granted, active protocols may be suspended, and further engagement in research activities may no longer be permitted for individuals placed on the IRB restricted research personnel list. You can be removed from the IRB restricted research personnel list by complete the continuing education requirement.

D. Additional Protections - Principal Investigator's (PI) Role

1. The PI is responsible for assuring all study personnel are informed of their research study responsibilities and are trained and qualified to perform all delegated tasks.

IV. Revisions

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

V. References

www.spectrum-health.org/research; <http://citiprogram.org>

VI. Policy Development and Approval

Document Owner:

Leah Voigt (VP, Chief Privacy Officer)

Writer(s) (formerly Author):

Not Assigned

Reviewer(s):

Alicia Herr (Program Mgr, Subacute Rehab), Bethany Stanisiewski (Mgr, Finance - Research), Curtis Gritters (Dir, Clinical Ops & Perf Impr), Harmony Van Valkenberg (Dir, Office Of Sponsored Progs), Leah Voigt (VP, Chief Privacy Officer)

Approver:

John MacKeigan (EVP/Cmo Spectrum Health System)

VII. Keywords

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