POLICY
Research - Investigator Responsibilities

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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1. Purpose

The purpose of this policy is to describe the role of the Principal Investigator (PI) and their responsibilities in ensuring that the rights, safety, and welfare of human subjects in research will be protected at Spectrum Health.

2. Responsibilities

The PI plays a critical role in ensuring adequate human subject protections are in place for potential and/or enrolled research subjects. If PI is unable to meet the outlined responsibilities, they may be asked to step down from the role or jeopardize initial or continued approval of other their research by the Spectrum Health IRB (SH IRB). The convened IRB, IRB Chair, and Institutional Official (IO) (when appropriate), have the authority to suspend or terminate IRB approval of research that is not being conducted in accordance with federal regulations, institutional policies, and SH IRB requirements.

There is no guaranteed direct compensation from the institution available for PIs conducting research at Spectrum Health. The PI role is voluntary. Conducting research at Spectrum Health is considered a privilege and can be revoked if the PI fails to follow federal regulations, institutional policies, and/or IRB requirements for protecting human research subjects.

3. Policy

A. Role of the Principal Investigator (PI)

The role of the PI is to follow institutional policies and human subject protection regulations, applicable laws, standards of professional conduct, and good clinical practice. The PI must understand and accept the significance of their role as a **primary protector of research subjects**.

The PI must possess the expertise, time, and commitment to conduct and provide the necessary oversight for all aspects of the study and must be willing to accept full responsibility for the study.

They conduct this role by ensuring:

- Risk to study participants and others are minimized;
- Risk to study participants are reasonable in relation to anticipated benefits and the importance of the knowledge that may be expected to result;
- Selection of subjects is equitable;
- Informed consent is obtained and documented, or waived with appropriate rationale;
- There is adequate provision for monitoring data for potential safety concerns;
- There is adequate provision to protect privacy and confidentiality of study participants; and
- Additional and appropriate protections are incorporated for potential participants who are likely vulnerable to coercion or undue influence.

B. Oversight of Research

The PI is the individual who assumes full responsibility for a research project, including the supervision of any Sub-Investigator(s) (Sub-I) and research personnel. The SH 22IRB only recognizes one institutional PI per study.

The PI must consider the qualifications, training, and experience of the research personnel before delegating responsibilities. All personnel engaged in research activity at Spectrum Health should be listed on the study personnel in the electronic IRB system. All investigators and research staff must be familiar and act in compliance with Spectrum Health and regulatory requirements governing the delegation of responsibilities for obtaining informed consent, dispensing and administering study drugs/devices, and performing other research-related procedures.

The PI must also ensure that their research personnel are adequately trained on the IRB approved protocol as well as all applicable regulatory requirements and Spectrum Health policies. The PI is ultimately responsible for the oversight and supervision of the research conduct.

C. Responsibilities of the PI

1. To follow all applicable Spectrum Health policies and procedures regarding human subject protections.

2. To abide by all applicable federal, state and local laws, regulations and institutional policies regarding human subject protections applicable by funding source and jurisdiction.

3. To demonstrate competency with the principles of the Belmont Report, the regulations governing human subject protections, and ethical considerations in biomedical and social behavioral research, through successful completion, of the online CITI training course in Basic Biomedical Research.

4. To disclose any potential conflicts of interest that may jeopardize study objectivity (potential financial and non-financial gains) for studies submitted to the Spectrum Health IRB by completing the Conflict of Interest disclosure form annually and/or when changes occur.

5. To follow applicable SH IRB Policies and Food & Drug Administration (FDA) regulations, including filing Investigational New Drug (IND) or Investigational Device Exemption (IDE) applications, when the PI takes on the additional sponsor responsibilities of the sponsor-investigator, to develop and investigate the safety and efficacy/effectiveness of an experimental

unapproved drug or device individually (vs. company), or investigate a new route, dosage or use in a new patient population for an FDA approved drug or device that significantly increases the risk associated with the use of the drug or device.

6. Submit all human subject research proposals and requested information for review to the Spectrum Health Office of the IRB per SH IRB application requirements, including verification of exempt status and abide by the determination to approve or disapprove the research made by the SH IRB for all human subjects research. The PI has a right to appeal an IRB action at any time if in disagreement with the committee's decision.

7. If requested, attend a convened IRB meeting to summarize initial research submission and address committee member questions.

8. Avoid enrollment of subjects in research studies without prior review and formal written approval or determination of exempt status by the SH IRB.

9. Ensure all study support staff members are adequately trained for their roles and delegated responsibility appropriately.

10. Be sensitive to and maintain awareness of potential privacy and confidentiality issues with subjects and subject data.

11. Promptly report to the SH IRB any proposed changes to the previously approved research (i.e. protocol revisions, study procedures, informed consent revisions, changes in study personnel, changes in study locations) and not implement the change until reviewed by the IRB or designated reviewers and a determination has been made to approve the changes in writing, except where the change is necessary to eliminate an immediate hazard to subjects.

12. Report within 5 business days to the SH IRB any new information that might meet the definition of an unanticipated problem involving risk to subjects or others encountered during the research per the reporting requirements outlined on the IRB Reportable New Information xForm, available in IRBManager.

13. If appropriate, inform the subject's primary physician about the subject's participation in the trial if the subject has a primary physician and if the subject agrees to the primary physician being informed.

14. Provide adequate time, assistance, equipment, support, and finances to safely conduct the study.

15. Ensure adequate medical care is provided to a subject for any adverse event directly related to the research study.

16. Obtain, document, and maintain records of informed consent for each study subject or each study subject's legally authorized representative, or ensure it is appropriately delegated to study staff (in accordance with Spectrum Health Informed Consent Policy #2053), except when a waiver from the consent requirements has been granted by the SH IRB.

17. As applicable, follow the regulations and SH IRB determinations as they relate to conducting research including vulnerable populations. Vulnerable populations include: children, pregnant women, neonates of uncertain viability, nonviable neonates, adults with diminished decision-making capacity, students, individuals with limited English proficiency, non-readers or visually impaired persons, and hospital volunteers & employees. These additional requirements may include, but are not limited to, use of assent in children and mentally incapacitated individuals when appropriate, use of a legally authorized representative, use of translated documents and an interpreter for non-English speaking subjects, and obtaining parental permission for research with children.

18. When applicable, to follow regulations and SH IRB policies requiring submitting information on the progress of previously IRB approved research for review by the IRB to allow continued approval, at a minimum, annually.

19. Maintain all required research records, including original signed informed consent forms and IRB submissions and approvals, during the study and for 11 years from the date of the submission of the final expenditure report to the funding agency, or per contracted agreement with the study sponsor, or for 3 years post study closure with the SH IRB, whichever is longer.

20. Promptly report research study suspensions or terminations made by the sponsor, other IRBs or regulatory agencies to the SH IRB within 5 business days per the Reportable New Information form available in IRBManager.

21. Recognize the authority of the SH IRB to inspect the contracts, study records and conduct (i.e., observe the informed consent process) for a research study under the jurisdiction of the SH IRB to ensure there are adequate human subject protections in place and followed.

22. Submit the clinical trial agreement (legal contract) to the Office of Research for review when any element of treatment to a research subject will be delivered at a Spectrum Health facility prior to enrolling the first research subject and finalizing the agreement. PIs may not sign representing the institution.

23. Recognize the SH IRB has the authority to suspend or terminate research studies if it determined there is unexpected serious harm or potential serious harm to subjects in continuing the research, the study is not being conducted in accordance with IRB requirements for protecting research subjects, or allegations of research misconduct are founded, as outlined in Spectrum Health System Policy Authority, Jurisdiction, and Responsibilities of the SH IRB.

24. Report the completion and request the closure of a study to the SH IRB.

25. Safely store and track use of investigational drug, biologics and devices.

26. Follow applicable International Conference on Harmonization (ICH) E6 Good Clinical Practice Consolidated Guidance for international clinical research studies or per sponsor clinical trial agreements when applicable. If following ICH E6 GCP, the below additional responsibilities apply to the PI:

(a) Ensure adequate medical care is provided to a subject, during and following the study, for any adverse events, including clinically significant laboratory values, related to the clinical trial.

(b) Follow the clinical trial's randomization procedures, if any, and ensure that the code is broken only in accordance with the protocol. If the clinical trial is blinded, promptly document and explain to the Sponsor any premature unblinding.

(c) Ensure a qualified physician (or dentist, when appropriate), who is a researcher or a co-researcher for the clinical trial, is responsible for all clinical trial-related medical (or dental) decisions.

(d) Inform subjects when medical care is needed for other illnesses of which the research team become aware.

(e) Although a subject is not obliged to give his or her reasons for withdrawing prematurely from a clinical trial, make a reasonable effort to ascertain the reason, while fully respecting the subject's rights.

(f) Provide evidence of qualifications through up-to-date curriculum vitae or other relevant documentation when requested by the Sponsor, SH IRB, or the regulatory authority.

(g) Be familiar with the appropriate use of the investigational product, as described in the protocol, in the current investigator brochure, in the product information, and in other information sources provided by the Sponsor.

(h) Ensure the accuracy, completeness, legibility, and timeliness of the data reported to the Sponsor.

(i) Permit the monitoring and auditing of the trial by the Sponsor and inspection by the appropriate regulatory authority.

(j) Provide written reports to the Sponsor, the SH IRB, and, where applicable, Spectrum Health on any changes significantly affecting the conduct of the clinical trial or increasing the risk to subjects.

(k) Inform Spectrum Health Office of Research, the Sponsor, and the SH IRB if you suspend a clinical trial without prior agreement of the Sponsor.

(l) Promptly notify the Sponsor if the SH IRB terminates or suspends approval of the clinical trial.

(m) Inform the SH IRB with a summary of the trial's outcome upon completion of the trial; and to provide the regulatory authority with any reports required.

4. Revisions

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

5. Policy Development and Approval

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6. Keywords

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