SPECTRUM HEALTH

Research - Investigator Responsibilities

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

Purpose: The purpose of this policy is to describe the role of the investigator and to describe their responsibilities in ensuring that the rights, safety, and welfare of the human subjects will be protected at Spectrum Health.

The investigator plays a critical role in ensuring adequate human subject protections are in place for their potential and/or enrolled research subjects. If a lapse or inability to meet the role occurs, he or she may be asked to step down from the responsibility of investigator or jeopardize initial or continued approval of their research by the IRB Committee. The IRB Committee or IRB Chairs (when appropriate), has the authority to suspend or terminate approval of research that is not being conducted in accordance with institutional and IRB requirements.

There is no guaranteed direct compensation available for investigators conducting research at Spectrum Health from the institution. The investigator role is voluntary. Conducting research at Spectrum Health is considered a privilege and will be removed if the institutions and IRB requirements are not met for adequately protecting volunteer research subjects.

Policy Content:

I. Role of the Investigator

A. The role of the investigator is to follow institutional commitments and regulations, applicable law, and standards of professional conduct and good clinical practice. The investigator must understand and accept the significance of their role as a **primary protector of the research subjects**. They conduct this role by ensuring:

1. Risk to study participants are minimized

2. Risk to study participants are reasonable in relation to anticipated benefits and the importance of the knowledge that may be expected to result

3. Selection of subjects is equitable

4. Informed consent is obtained and documented or appropriately waived

5. There is adequate provision for monitoring data for potential safety concerns

6. There is adequate provision to protect privacy and confidentiality of study participants

7. Additional and appropriate protections are incorporated for potential participants who are likely vulnerable to coercion or undue influence

8. Having appropriate education, training and experience

II. Responsibilities of the Investigator

A. To follow all applicable Spectrum Health policies and procedures regarding human subject protections, available at www.spectrum-health.org/researchpolicies. For questions regarding locating policies or concerning policy content, please contact the Office of the IRB at 616-486-2031

B. To abide by all applicable federal, state and local laws, regulations and institutional policies regarding human subject protections applicable by funding source and jurisdiction (i.e. HHS 45 CFR Part 46 Protection of Human Subjects, FDA 21 CFR Part 50 Protection of Human Subjects).

C. 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, defined as a cumulative score of 85% or greater, of the online CITI training course in Basic Biomedical Research available at www.citiprogram.org. Further instructions are available on the IRB website, www.spectrumhealth.org/citi

D. 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 initially and/or when changes occur. The form and additional information are available at www.spectrum-health.org/coi.

E. To follow applicable Spectrum Health IRB Policies and Food & Drug Administration (FDA) regulations, including filing Investigational New Drug (IND) or Investigational Device Exemption (IDE) applications, when the investigator takes on the additional sponsor responsibilities, sponsor-investigator, to develop and investigate the safety and efficacy/effectiveness of a experimental non-FDA approved 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. Contact the Office of Research for assistance with the regulatory requirements for conducting this unique research proposal, 616-391-3050.

F. To submit all human subject research proposals and requested information for review to the Spectrum Health Office of the IRB per IRB application requirements, including verification of exempt status and abide by the determination to approve or disapprove the research made by the Spectrum Health IRB committee or designated IRB committee member for research qualifying for

expedited review. You have a right to an appeal an IRB action, at anytime you are in disagreement with the committee's decision.

G. To provide a 5-10 minute presentation summarizing the initial research proposal for full-board research proposals at the scheduled Spectrum Health IRB meeting and address committee members questions, if requested.

H. To avoid enrollment of subjects in the research studies prior to review and formal written approval or verification of exempt status by the Spectrum Health IRB.

I. To ensure all study support staff members are adequately trained for their roles and delegated responsibility appropriately.

J. To be sensitive to and maintain awareness of potential privacy and confidentiality issues with subjects and subject data.

K. To promptly report to the Spectrum Health IRB any proposed changes to the previously approved research (i.e. protocol revisions, study procedures, informed consent revisions, changes in Sub-I, support staff, changes in study locations) and not implement the change until reviewed by the IRB or IRB Chairs 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.

L. To report within 5 business days to the Spectrum Health IRB any unanticipated problems involving risk to subjects or others encountered during the research per the reporting requirements outlined on the IRB Reportable New Information Form , available on the Office of the IRB website under IRB Forms and Templates, www.spectrumhealth.org/irbforms

M. To 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, where appropriate.

N. To provide adequate time, assistance, equipment, support, and finances to safely conduct the study.

O. To ensure adequate medical care is provided to a subject for any adverse event directly related to the research study.

P. To 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, except when a waiver from the consent requirements has been granted by the Spectrum Health IRB, in accordance with HHS 45 CFR Part 46 regulations and IRB policies.

Q. To follow the Spectrum Health IRB additional requirements for conducting research in potential vulnerable populations as applicable. Vulnerable populations include: children, pregnant women, neonates of uncertain viability, diminished decision making capacity individuals, students, limited English proficiency individuals, hospital volunteers & employees. These additional requirements may include, but are not limited to, use of assent in children and mentally limited 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.

R. To follow the HHS 45 CFR Part 46 regulations and Spectrum Health 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.

S. To maintain all required research records, including original signed consent forms and IRB submissions and approvals, during the study and for 10 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 Spectrum Health IRB, whichever is longer, per the IRB Investigator Manual, available on the IRB website under IRB Forms and Templates, www.spectrumhealth.org/irbforms.

T. To promptly report research study suspensions or terminations made by the sponsor, other IRBs or regulatory agencies to the local Spectrum Health IRB within 5 business days per the Reportable New Information form available on the research website under www.spectrumhealth.org/irbforms

U. To recognize the authority of the Spectrum Health 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 Spectrum Health IRB to ensure there are adequate human subject protections in place and followed.

V. To submit the clinical trial agreement (legal contract) to the Office of Research, Research Finance Manager/Director, 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. Investigators may not sign representing the institution. For further information on forwarding research contracts, call the Office of Research at 616-391-3050.

W. To recognize the Spectrum Health 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 SH-ADMIN-RES 001 Authority, Jurisdiction, and Responsibilities of the Spectrum Health IRB.

X. To report the completion and request the closure of a study to the Spectrum Health IRB,.

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

Z. To follow applicable International Conference on Harmonisation (ICH) E6 Good Clinical Practice Consolidated Guidance for international clinical research studies or per sponsor clinical trial agreements when applicable. For questions reqarding ICH E6 GCP and/or whether it applies, please contact the Office of the IRB at 616-486-2031 or the Office of Research contracts at 616-391-3050. If following ICH E6 GCP is applicable, the below additional responsibilities apply to the investigator:

Z.1 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.

Z.2 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 documents and explain to the Sponsor any premature unblinding.

Z.3 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.

Z.4 Inform subjects when medical care is needed for other illnesses of which the research team become aware.

Z.5 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.

Z.6 Provide evidence of qualifications through up-to-date curriculum vitae or other relevant documentation when requested by the Sponsor, Spectrum Health IRB, or the regulatory authority.

Z.7 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.

Z.8 Ensure the accuracy, completeness, legibility, and timeliness of the data reported to the Sponsor.

Z.9 Permit the monitoring and auditing of the trial by the Sponsor and inspection by the appropriate regulatory authority.

Z.10 Provide written reports to the Sponsor, the Spectrum Health IRB, and, where applicable, Spectrum Health on any changes significantly affecting the conduct of the clinical trial or increasing the risk to subjects.

Z.11 Inform Spectrum Health Office of Research 616-391-3050, the Sponsor, and the Spectrum Health IRB if you suspend a clinical trial without prior agreement of the Sponsor.

Z.12 Promptly notify the Sponsor if the Spectrum Health IRB terminates or suspends approval of the clinical trial.

Z.13 Inform the Spectrum Health IRB with a summary of the trial's outcome upon completion of the trial; and to provide the regulatory authority with any reports required.

1. Revisions

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

2. References

www.spectrum-health.org/research; www.spectrumhealth.org/hrpp www.citiprogram.org; www.spectrum-health.org/researchpolicies; www.spectrum-health.org/irbforms; 45 CFR 46; 21 CFR 50; 21 CFR 312; 21 CFR 812; ICH GCP E6; System Policy – SH ADMIN-RES-010 -Training Requirements for Individuals Involved in Human Subject Research; System Policy – SH-ADMIN-RES-017 - Research Conflict of Interest: www.hhs.gov; www.fda.gov

3. Policy Development and Approval

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Not Assigned

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