POLICY
Authority, Jurisdiction, and Responsibilities of the SH IRB)

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 (Administrative Operations)

Department Area: Research

1. Purpose

The purpose of this policy is to establish the assurance, authority and responsibilities of the Spectrum Health Institutional Review Board (SH IRB) in the protection of human subjects in research conducted under its jurisdiction.

2. Policy

A. Federalwide Assurance (FWA) for the Protection of Human Subjects

It is the policy of Spectrum Health that it will comply with its Federalwide Assurance (FWA) with the Office for Human Research Protections (OHRP).

- Federalwide Assurance: FWA00000058
- IRB Organization (IORG) #: IORG0000551
- HHS Registration #: IRB00000883

A.1. Terms of the Spectrum Health FWA:

All human subjects research activities, regardless of whether the research is subject to the U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule) at Spectrum Health is guided by a statement of principles governing the discharge of its responsibilities for protecting the rights and welfare of human subjects research conducted at or sponsored by Spectrum Health. This statement of principles includes the Spectrum Health Code of Conduct and the statement of ethical principles outlined in the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

These terms apply whenever Spectrum Health becomes engaged in human subjects research conducted or supported in whole or in part by any U.S. federal department or agency that has

adopted the Common Rule, unless the research is otherwise exempt from the requirement of the Common Rule. The terms of this FWA will not apply if a U.S. federal department or agency conducting or supporting the research determines that the research shall be conducted under a separate assurance.

Spectrum Health renews its FWA every five years, even if no changes have occurred, in order to maintain an active FWA with the U.S. Department of Health and Human Services (HHS). Spectrum Health will update its FWA within 90 days after changes occur regarding the legal name of the Institution, the Human Protections Administrator, or the Signatory Official (Institutional Official). Any renewal or update that is submitted to, and accepted by, OHRP begins the new 5-year effective period. Failure to renew or update an FWA appropriately may result in restriction, suspension, or termination of OHRP's approval of the Spectrum Health FWA.

A.2. U.S. Institutions

When Spectrum Health becomes engaged in research to which the FWA applies, Spectrum Health and the Institutional Review Boards (IRBs) upon which it relies for review of such research will comply with the Common Rule.

Federal Departments and Agencies which have adopted the Common Rule include:
7 CFR §1c – Department of Agriculture
10 CFR §745 – Department of Energy
14 CFR §1230 – National Aeronautics and Space Administration
15 CFR §27 – Department of Commerce
16 CFR §1028 – Consumer Product Safety Commission
22 CFR §225 – Agency for International Development
24 CFR §60 – Department of Housing and Urban Development
28 CFR §46 – Department of Justice
32 CFR §219 – Department of Defense
34 CFR §97 – Department of Education
38 CFR §16 – Department of Veterans Affairs
40 CFR §26 – Environmental Protection Agency
45 CFR §46, subpart A – Department of Health and Human Services
45 CFR §46, subpart A – Central Intelligence Agency (by Executive Order 12333)
45 CFR §46, subpart A – Department of Homeland Security (by federal statute)
45 CFR §690 – National Science Foundation
49 CFR §11 – Department of Transportation

A.3.Non-U.S. Institutions

When Spectrum Health becomes engaged in research to which the FWA applies, Spectrum Health and the IRBs upon which is relies for review of such research at a minimum will comply with one or more of the following:

- The Common Rule;
- The U.S. Food and Drug Administration (FDA) regulations at 21 CFR §50 and §56;
- The current International Conference on Harmonization E-6 Guidelines for Good Clinical Practice;
- The current Council for International Organizations of Medical Sciences International Ethical Guidelines for Biomedical Research Involving Human Subjects;
- The current Canadian Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans;

- The current Indian Council of Medical Research Ethical Guidelines for Biomedical Research on Human Subjects; or
- Other standard(s) for the protection of human subjects recognized by U.S. federal departments and agencies which have adopted the U.S. Federal Policy for the Protection of Human Subjects.

If a U.S. federal department or agency head determines that the procedures prescribed by the Institution afford protections that are at least equivalent to those provided by the Common Rule, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided above, consistent with the requirements of section 101(h) of the Common Rule.

A.4. U.S. and Non-U.S. Institutions

For any research to which the FWA applies, Spectrum Health also will comply with any additional applicable human subjects regulations and policies of the U.S. federal department or agency which conducts or supports the research and any other applicable federal, state, local, or institutional laws, regulations, and policies. When Spectrum Health is engaged in non-exempt human subjects research conducted or supported by HHS, Spectrum Health will comply with the requirements of subparts B, C, and D of the HHS regulations at Title 45 Code of Federal Regulations §46 (45 CFR §46) , when applicable, for research involving pregnant women, fetuses, and neonates; prisoners; and children, respectively.

Human subjects research conducted or supported by each U.S. federal department or agency listed above will be governed by the regulations as implemented by the respective department or agency. The head of the U.S. federal department or agency retains final judgment as to whether a particular activity conducted or supported by the respective department or agency is covered by the Common Rule. If Spectrum Health needs guidance regarding implementation of the Common Rule and/or other applicable U.S. federal regulations, Spectrum Health will contact appropriate officials at the U.S. federal department or agency conducting or supporting the research.

For U.S. federally-conducted or –supported research covered by the FWA, the U.S. federal department or agency that conducts or supports the research retains final authority for determining whether Spectrum Health complies with the Terms of Assurance. If HHS receives an allegation or indication of noncompliance related to research to which the FWA applies and that is conducted or supported solely by a U.S. federal department or agency other than HHS, HHS will refer the matter to the other U.S. federal department or agency for review and action as appropriate.

A.5. Statement on Written Procedures

Spectrum Health has established written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, the head of any U.S. federal department or agency conducting or supporting the research (or designee), and OHRP of any:

- unanticipated problems involving risks to subjects or others;
- serious or continuing noncompliance with the applicable U.S. federal regulations or the requirements or determinations of the IRB(s); and
- suspension or termination of IRB approval.

Spectrum Health will also ensure that the IRB(s) that reviews research to which the FWA applies has established written procedures for:

- conducting IRB initial and continuing review (not less than once per year, when applicable), of research, and reporting IRB findings to the investigator and the Institution;

- determining which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since the previous IRB review; and
- ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to the subjects.

Upon request, the Institution will provide a copy of these written procedures to OHRP or any U.S. federal department or agency conducting or supporting research to which the FWA applies. The Office of IRB is also responsible for mechanisms for communicating and ensuring policies and procedures are available to the Spectrum Health Human Research Protections Program.

A.6. Components

All components included under the Spectrum Health FWA are responsible for the ethical conduct of human subjects research. The Spectrum Health IRB provides oversight to the identified components below and each component is responsible to follow the determinations set forth by the Spectrum Health IRB and its policies and procedures.

- Helen Devos Children's Hospital
- Reed City Hospital
- Cancer Research Consortium of West Michigan (CRCWM)

A.7. Entering into Reliance Agreements

Any designation under this Assurance of another Institution's IRB or an independent IRB for review of federally-supported research will be documented by a written agreement between Spectrum Health and the IRB organization outlining their relationship and will include a commitment that the designated IRB will adhere to the requirements of this Assurance. The Authorization Agreement will be kept on file and made available to OHRP upon request.

- Verification of Outside Performance Sites' FWA

  Spectrum Health will ensure that all institutions and investigators engaged in its U.S. federally-supported human subject research operate under an appropriate OHRP or other federally-approved Assurance for the protection of human subjects. When Spectrum Health enters into an IRB Authorization Agreement or Cooperative Review Agreement with another Performance Site, verification via the OHRP's website that the Performance Site entering into the agreement with Spectrum Health has an approved FWA will occur. When Spectrum Health is relying on the other Performance Site's IRB, staff will also verify the IRB being relied upon has a current IRB registration.

A.8. Extension of the FWA to Individual Investigators

Spectrum Health will ensure that engagement in human research activities of each independent investigator who is not an employee or agent of Spectrum Health may be covered under the FWA only in accordance with a formal, written agreement of commitment to relevant human subject protection policies and IRB oversight. Spectrum Health will maintain commitment agreements on file and provide copies to OHRP upon request.

A.9. Institutional Support for the IRB(s)

Spectrum Health will ensure that each IRB upon which it relies for review of research to which the FWA applies has meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

A.10. Assurance Training

Spectrum Health will ensure that the Institutional Signatory Official, key Human Protection Program Administrators, and the IRB chairs are familiar with the contents of the OHRP Assurance Training Modules. Spectrum Health has established education opportunities and oversight mechanisms to ensure that research investigators on federally-sponsored research, IRB members and staff, and other appropriate personnel maintain continuing knowledge of the relevant ethical principles, relevant Federal Regulations, OHRP guidelines and other applicable guidance, state and local laws, and institutional policies for the protection of human subjects.

B. Institutional Official

The Senior Vice President and Spectrum Health West Michigan Chief Medical Officer is designated as the Institutional Official (IO) for the Spectrum Health Human Research Protection Program. The IO is delegated the legal authority to represent Spectrum Health and all components listed on the Spectrum Health FWA on matters related to human subject research. Where the IO is presented with a conflict of interest due to a role as an investigator of human subject research, the Vice President, OME/Research will preside over all issues concerning the HRPP.

The IO:

- Understands Spectrum Health's responsibilities under the FWA;
- Has the authority to ensure that:
    - The safety, rights, and welfare of human research subjects are protected,
    - Members of the designated IRBs are knowledgeable about the local research context and comply with the terms of the FWA,
    - All components are functioning satisfactorily,
    - The Spectrum Health FWA is updated as necessary with OHRP, and has ensured OHRP's approval of any updates; and
- Supports the independent authority of the Spectrum Health IRB as required under federal regulations.

The IO is responsible for:

- Demonstrating a commitment to the protection of human subjects and sets the tone for a culture of respect for human subjects and adherence to foundational ethical principles;
- Overseeing compliance with all applicable federal regulations and guidance, state law and institutional policies;
- Being a signatory authority for the FWA submitted by Spectrum Health;
- Serve as a knowledgeable point of contact for OHRP, FDA, and other governmental and non-governmental agencies regarding human research protections, or delegating this responsibility to another appropriate individual;
- Ensuring effective institution-wide communication and guidance on human subjects protections issues;
- Ensuring that investigators fulfill their responsibilities under applicable regulations by overseeing processes related to human subjects protections;
- Investigating allegations of potential undue influence and taking corrective actions as appropriate;
- Encouraging that all staff engaged in the conduct or oversight of human subject research participate in education activities;
- Designating one or more IRBs that will review research covered by the Spectrum Health FWA;

- Reviewing and allocating sufficient resources, space, and staff to support the IRB's review and record keeping duties;
- Appointing, either directly or through a designee, the IRB Chair; and
- Reviewing the annual review of the Human Research Protection Program.

C. Jurisdiction of the Spectrum Health IRB

The Spectrum Health IRB is established and empowered under the authority of the Board of Trustees for Spectrum Health. The Spectrum Health IRB is responsible for reviewing all research projects determined to involve the use of *human subjects* being conducted at any Spectrum Health entity or utilizing patient tissue/data owned by Spectrum Health, unless Spectrum Health is determined not to be engaged in the research per the policy *Qualifying Engagement in HSR.*

Regardless of the sponsorship, the Spectrum Health IRB, or another appropriate IRB designated by the Spectrum Health FWA, is responsible for the review of all activities determined to be human subjects research when:

- The human subjects research is conducted by Spectrum Health or any of the components covered by the Spectrum Health FWA.
- The human subjects research is conducted by or under the direction or supervision of Spectrum Health or of any employee, faculty member, staff member, student, or agent of Spectrum Health, or of any of the components covered under the Spectrum Health FWA, in connection with their institutional responsibilities or program of education;
- The human subjects research is conducted by or under the direction or supervision of Spectrum Health or of any employee, faculty member, staff member, student, or agent of Spectrum Health, or of any of the components covered under the Spectrum Health FWA, using Spectrum Health property, facilities, or services of Spectrum Health for research purposes;
- The human subjects research involves the use of non-public individually identifiable private information or Protected Health Information (PHI) for research purposes that is held by Spectrum Health, or any of the components covered under the Spectrum Health FWA, to identify human subjects;
- Spectrum Health receives a direct HHS award to conduct human subjects research, even where all activities involving human subjects are carried out by a subcontractor or collaborator;
- The research is sponsored by Spectrum Health;
- The research is sponsored by Spectrum Health or any employee, faculty member, staff member, student, or agent of Spectrum Health, or any of the components covered under the Spectrum Health FWA, in connection with their institutional responsibilities;
- The human subjects research is conducted by a person who, or entity that, has entered into an agreement with Spectrum Health per which Spectrum Health IRB is designated under the Spectrum Health FWA as the reviewing IRB for the human subjects research.

The Spectrum Health IRB shall also provide review when research projects utilize Spectrum Health services for research purposes. When research projects utilize Spectrum Health services for human subjects research, Spectrum Health will ensure adequate protections for subjects are in place and may require the research project adhere to Spectrum Health IRB's policies and procedures.

Spectrum Health defines human subject research as any activity that represents research that involves human subjects as defined by OHRP Regulations, or any activity that represents research/clinical investigations that involve human subjects as defined by the FDA.

C.2. Collaboration

Spectrum Health recognizes that collaborative research may originate, be conducted at, or include multiple institutions, organizations, and/or companies, that are public, not-for-profit, or private entities. The Office of the Spectrum Health IRB is available to offer assistance to investigators regarding these collaborations. Investigators are encouraged to consult with the Spectrum Health IRB when:

- It is necessary to determine whether review by the Spectrum Health IRB is required in accordance with federal regulations;
- Whether Spectrum Health is engaged in the human subjects research activity;
- Whether review by multiple institutions may be necessary and if reliance agreements between institutions may be considered; and
- Whether a collaborating institution requires an assurance of compliance when they are engaged in the human subjects research activity and the collaborating institution receives federal funding.

The Spectrum Health IRB follows the definition of "collaboration" employed by NIH Office of Human Research Subjects, which states that collaboration exists if a researcher expects "something in return" as a result of having participated in a research activity. Collaborative activities may include the collection of specimens, visits to institutions to perform research activities or clinical work, exchange of information containing personal identifiers, preliminary data collection activities involving human subjects, substantive intellectual contributions to research techniques, protocol design, or interpretation of data, and under some circumstances, supplying important reagents, performing tests or analyzing data.

C.3. Spectrum Health Employees or Agents Acting as Consultant

Spectrum Health IRB review is required for any human subject research activity undertaken by a Spectrum Health employee, student, resident, or agent unless the employee, resident, or agent functions strictly as a consultant to the research team (i.e., does not interact or intervene with human subjects for research purposes), holds no rights to the work (such as study design, data analysis, publication, co-authorship, etc.), and does not obtain, receive, or possess identifiable and private information about any research subject.

C.4. Spectrum Health IRB's Authority as the Privacy Board for Research

The HIPAA Privacy Rule establishes the conditions under which Protected Health Information (PHI) may be used or disclosed by covered entities for research purposes. Spectrum Health, as a covered entity, must abide by the HIPAA Rules for the use and disclosure of PHI under its jurisdiction for related purposes (45 CFR §160 and 45 CFR §164). The Spectrum Health Board of Trustees has charged the Spectrum Health IRB to act as Privacy Boards on behalf of the Covered Entity.

C.5. IRB Registration

Spectrum Health renews its IRB registration every three years, even if no changes have occurred, to maintain an active registration. Spectrum Health will update its IRB registration within 90 days after changes occur to the contact person who provided the IRB registration information, the IRB chairperson, or a change in the membership and will update the registration within 30 days after permanent cessation of an IRB's review of HHS-conducted or –supported research.

D. Governing Ethical Principles and Regulations for the Protection of Human Subjects

D.1. The Belmont Report

The Spectrum Health 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.* The Belmont Report identifies the basic ethical principles underlying the acceptable conduct of research involving human subjects. Those principles, respect for persons, beneficence, and justice, are now accepted as the three fundamental requirements for the ethical conduct of human subjects research and serve as the basis for regulations and guidelines pertaining to the protection of human subjects. Spectrum Health requires investigators, research staff, IRB members, IRB staff, employees and students to follow the ethical principles of the Belmont Report when participating in, or conducting, human subjects research.

- **Beneficence** – the sum of benefits to the subject and the importance of the knowledge to be gained outweigh the risks to the subjects as to warrant a decision to allow the subject to accept these risks. It is in consideration of this ethical principle that the IRB is required to conduct a systematic assessment of risks and benefits associated with research. Adhering to the ethical principle of beneficence, the IRB may review the scientific merits of a research study to determine that the potential benefits and the likelihood of their occurrence outweigh the potential risks and the likelihood of their occurrence.
- **Autonomy and Respect for Persons –** recognition of the personal dignity and autonomy of individuals necessitates special protection for persons with diminished autonomy. This principle requires that IRBs ensure that researchers disclose complete information about the nature of research to prospective subjects and obtain their informed consent prior to engaging them in research-related activities. In addition, it justifies additional protections for individuals who are vulnerable or of diminished capacity.
- **Justice –** the selection of subjects is equitable and is representative of the group that will benefit from the research. This ethical principle requires that the benefits and burdens of research be distributed fairly among individuals and different classes of people. The IRB is to carefully consider the selection of research subjects. The IRB must judge whether some classes are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied. The IRB reviews research to ensure equal selection standards to all potential subjects and subject selection should not be limited to certain population or groups - such as racial minorities, the socio-economically disadvantaged, the very sick, or the institutionalized, when conducting research with increased risks.

D.2. Additional Governing Ethical Principles

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.

D.3. DHHS Regulations (Title 45 Code of Federal Regulations)

The DHHS regulations for the protection of human subjects in research were codified at the Code of Federal Regulations (CFR) Title 45 §46 (45 CFR §46). All research involving human subjects, which receives federal funding, must comply with the DHHS regulations. OHRP is the federal oversight entity within DHHS responsible for the administration of 45 CFR §46.

The DHHS regulations contain four Subparts that provide the foundation for the review and approval of all research conducted at Spectrum Health regardless of funding.

- Subpart A, Federal Policy for the Protection of Human Subjects (DHHS Policy for Protection of Human Research Subjects), has been adopted by seventeen federal agencies that conduct, support, or otherwise regulate human subjects research in order to ensure

uniformity of the human subjects protection system. Subpart A is also referred to as the "Common Rule."

- Subpart B of 45 CFR §46 regulates research involving pregnant women, human fetuses, and neonates.
- Subpart C of 45 CFR §46 outlines additional protections for prisoners involved as subjects in research.
- Subpart D of 45 CFR §46 describes additional regulations for children involved as subjects in research.

D.4. FDA Regulations (Title 21 Code of Federal Regulations)

The provisions of the Food, Drug, and Cosmetic Act of 1938 provide authority to the Food and Drug Administration (FDA) to regulate clinical investigations, development, and approval of drugs, biologics, and devices. The FDA regulations for the protection of human subjects are contained in (21 CFR §50) and the FDA regulations governing IRBs are contained 21 CFR §56. All research activities involving food, investigational new drugs, biologics, or medical devices, and approved drugs, biologics, or medical devices which are used off-label in a clinical investigation must comply with all applicable FDA regulations and Good Clinical Practice (GCP) standards for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials.

Spectrum Health participates in clinical investigations under the jurisdiction of the FDA, and complies with the regulations:

- 21 CFR §50, (General Provisions, Informed Consent); 21 CFR §56 (IRB Regulations);
- 21 CFR §50 Subpart D (Additional Safeguards for Children in Clinical Investigations);
- 21 CFR §312 (Investigational New Drug Applications);
- 21 CFR §612, (Biological Products); and
- 21 CFR §812 (Investigational Device Exemptions).

D.5. Other Federal Funding Agencies

If funded by other federal agencies that have specifications, their requirements will be applied. Examples include but are not limited to:

- Department of Education: 34 CFR §97
- Department of Defense: 32 CFR §219
- National Science Foundation: 45 CFR §690
- Department of Energy: 10 CFR part §745
- Department of Justice: 28 CFR §46

D.6. International Research

Any transnational research activities that are conducted under the auspices of Spectrum Health must be conducted consistent with the ethical principles set forth in this policy and must meet equivalent levels of participant protection as research conducted at Spectrum Health.

Both investigators and the IRB must take into consideration local laws and cultural context and make sure the research complies with the local regulations. When research is conducted internationally the Spectrum Health IRB will require IRB/Ethics Committee review at the local site for consideration of the local research context and regulations. Documentation of this review will be required.

Additionally, the Spectrum Health IRB may request the use of local consultants or rely on one of its members with personal knowledge of local context. The OHRP website provides links to key regulatory and ethical guidance for countries outside the United States. This site may be found at http://www.hhs.gov/ohrp/internneational/index.html.

If the research is funded by a United States federal agency, the regulations of that agency apply, unless the applicable federal agency has made a determination to accept the equivalent protections in lieu of the required federal protections.

During negotiation of the legal contract/clinical trial agreement, the Principal Investigator and the Spectrum Health IRB will work with the international site to seek agreement to obtain local review by the IRB, Research Ethics Committee, or other comparable regulatory or ethical body, as appropriate to the country or region. To the greatest extent possible, the SH IRB will work with the IRB/Ethics Committee/other review body at the international site to seek agreement to the following core principles of subject protections:

- Confirming the qualifications of the researcher(s) and research staff to conduct the applicable study in that country;
- Conducting initial review, review of modifications, and appropriate ongoing review (preferably annually and based on level of risk);
- Conducting post-approval monitoring or other monitoring activity of the research activities;
- A plan for handling of complaints, non-compliance, and unanticipated problems involving risk to participants or others and for informing the SH Principal Investigator.
- Ensuring communication and coordination with other local IRBs or Research Ethics Committees, as applicable.

The SH IRB will require the investigator at the international site, or the investigator's institution, as appropriate, to function as the sponsor of the trial in that country (i.e., equivalent to the Spectrum Health investigator's role as "sponsor-investigator," for FDA regulatory purposes, etc.). The international site investigator and his/her institution is to ensure the process for obtaining and documenting consent will be appropriate given the local laws, customs and traditions.

E. Authority and Independence of the Spectrum Health IRB:

Spectrum Health grants, recognizes, and safeguards the independent authority of the Spectrum Health IRB as required by federal regulations. The Spectrum Health IRB's primary responsibility is the protection of the rights, safety, and welfare of human subjects participating in research under its jurisdiction. No individual or group of individuals may inappropriately try to influence the deliberations and decisions of the IRB.

In accordance with the FWA, the Spectrum Health IRB has the authority to perform the following tasks:

- Knowledgeably review human subjects research in accordance with federal, state, and local laws and regulations, and Spectrum Health research and/or Spectrum Health IRB policy(s).
- Approve, disapprove, or require modifications to secure approval, for all human subject research activities.
- 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.

- 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.
- When appropriate, observe or have a third party observe the consent process and the research.
- 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 (for federally funded research).
- Notify parties in writing of its decisions to approve, disapprove, or require modifications to approve research. If the Spectrum Health 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.
- Review of all unanticipated problems involving risk to study subjects or others or any allegations of serious or continuing non-compliance.
- Determine the period of time until the next continuing review of research at intervals appropriate to the degree of risk, but not less than once per year, when applicable.
- 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.

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

- It is understood that Spectrum Health officials and other committees may be required to review and approve human subject's research.
- While the Spectrum Health IRB may work collaboratively with officials and other committees, the IRB is obligated to function independently of these processes. Spectrum Health IRB Members and staff should report any concerns/issues of undue influence to the Spectrum Health Institutional Official (IO). The IO will work with the appropriate executive leadership and Human Resources to address/mitigate the situation.
- Although a Spectrum Health official or committee may disapprove research that has been approved by the Spectrum Health IRB, no official or committee may approve research that has been disapproved by the Spectrum Health IRB.

3. Revisions

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

4. Policies Superseded and Replaced: This policy supersedes and replaces the following policies as of the effective date of this policy: [policy name, # and entity]; [policy name, # and entity]; [policy name, # and entity] **[This section may be deleted for policies not replacing or superseding a policy previously in effect]**

5. References

This optional section can be used to provide links to related reference materials, such as other policies, procedures, or websites.

6. Policy Development and Approval

Document Owner:
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Not Assigned

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Not Assigned

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7. Keywords

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