SPECTRUM HEALTH

Research –Qualifying "Engagement" in Human Subjects Research at Spectrum Health

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

This policy is applicable to activities that have been determined to be research involving human subjects. For further clarification on determination of human subjects research or engagement determination reference the Spectrum Health Institutional Review Board (IRB) "Research Determination" form HRP-411 and "Engagement Determination" form HRP-410 located at http://www.spectrumhealth.org/irbforms.

II. Purpose

The purpose of this policy is to provide guidance to the organization and its investigators on when individuals are considered an agent of Spectrum Health in relation to research and when the institution is considered engaged in human subjects research.

III. Definitions

Spectrum Health defines engagement in research when anyone employed by, a student of, or contracted with Spectrum Health interacts with living individuals for research purposes or obtains individually identifiable private information for research purposes.

For purposes of this policy, Spectrum Health's "agents" refers to individuals who act on behalf of the institution, exercise institutional authority or responsibility or perform institutionally designated activities as it relates to research. This includes, but is not limited to: employees, medical staff, students, residents and anyone who interacts with Spectrum Health patients, tissue, and/or patient data

IV. Policy Content

A. When Spectrum Health is engaged in research:

Spectrum Health considers itself to be engaged in a particular project when its agents for the purposes of the research project obtain:

- Data about the subjects of the research through intervention or interaction with them;
- Identifiable private information about the subjects of the research; or
- The informed consent of human subjects for the research.

If the above three items are met, you are *engaged in human subjects research* at Spectrum Health and you must submit your research in accordance to and in adherence with all Spectrum Health Research and Spectrum Health IRB policy.

B. When Spectrum Health is not engaged:
Spectrum Health considers itself **not** to be engaged in a *human subjects research* project when its agents for the purposes of the research fit the below circumstances:

1. Provision of services, when:

- Services performed do not merit professional recognition or publication privileges;
- The services performed are typically performed by the institution for non-research purposes; **and**
- The institution's agents do not administer any study intervention being tested or evaluated under the protocol (the reference to "the protocol" is the IRB approved protocol at the engaged institution).

Note: If there are any questions as to the applicability of provision of services, contact the Office of the IRB for guidance.

2. Provision of Routine Medical Services Dictated by the Protocol, when:

- The institution's agents do not administer the study interventions being tested or evaluated under the protocol;
- The clinical trial-related medical services are typically provided by the institution for clinical purposes;
- The institution's agents do not enroll subjects or obtain the informed consent of any subject for participation in the research; **and**
- When appropriate, investigators from an institution engaged in the research retain responsibility for:
  - overseeing protocol related activities; and

  - ensuring appropriate arrangements are made for reporting protocol-related data to investigators at an engaged institution, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol.

Note: If there are any questions as to applicability of the circumstances of this provision, contact the Office of the Spectrum Health IRB for guidance.

3. One-time or Short-Term Administration or Study Intervention when:

- An investigator from an institution engaged in the research determines that it would be in the subject's best interest to receive the study interventions being tested or evaluated under the protocol;
- The institution's agents do not enroll subjects or obtain the informed consent of any subject for participation in the research;
- Investigators from the institution engaged in the research retain responsibility for:
  - overseeing protocol-related activities;
  - ensuring the study interventions are administered in accordance with the IRB-approved protocol; and

- ensuring appropriate arrangements are made for reporting protocol-related data to investigators at the engaged institution, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol; **and**

- An IRB designated on the engaged institution's FWA is informed that study interventions being tested or evaluated under the protocol have been administered at an institution not selected as a research site.

Note: If the purpose of the research fits any of these circumstances, consultation with the Office of the Spectrum Health IRB and applicable departments is required (i.e. pharmacy) before implementation.

***4. Recruitment or Referral*:**

- Inform prospective subjects about the availability of the research;
- Provide prospective subjects with information about the research (which may include a copy of the relevant informed consent document and other IRB approved materials) but do not obtain subjects' consent for the research or act as representatives of the investigators;
- Provide prospective subjects with information about contacting investigators for information or enrollment; **and/or**
- Seek or obtain the prospective subjects' permission for investigators to contact them.

Note: If activity relates to recruitment or referral, submission to the Office of the Spectrum Health IRB for administrative review and acknowledgement of material is required.

5. Release of Identifiable Information to another Institution (the receiving Institution must have current IRB approval and have met the informed consent requirements as determined by that IRB):

- Ensure that the release would not violate the informed consent provided by the subjects to whom the information or biological specimens pertain (under 45 CFR 46.116); **or**
- If informed consent was waived by the IRB, ensure that the release would be consistent with the IRB's determinations that permitted a waiver of informed consent under 45 CFR 46.116 (c) or (d).

Note: If the activity will entail release of identifiable information to another institution, notification must be submitted to the Office of the Spectrum Health IRB, acting as the Privacy Board for Spectrum Health, for review and acknowledgement of regulatory compliance.

6. Obtain Coded Private Information without Access to the Link:

- Obtain coded private information or human biological specimens from another institution involved in the research that retains a link to individually identifying information (such as name or social security number); **and**
- Are unable to readily ascertain the identity of the subjects to whom the coded information or specimens pertain because, for example:
  - The institution's employees or agents and the holder of the key enter into an agreement prohibiting the release of the key to the those employees or agents under any circumstances;

  - The releasing institution has IRB-approved written policies and operating procedures applicable to the research project that prohibit the release of the key to the institution's employees or agents under any circumstances; or

- There are other legal requirements prohibiting the release of the key to the institution's employees or agents.

Note: If the activity fits any of these circumstances, contact the Office of the IRB for questions related to applicability.

V. Revisions

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

VI. Policy Development and Approval

Document Owner:
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Not Assigned

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Not Assigned

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VII. Keywords

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