Investigator Qualifications and Responsibilities

I. Policy Statement:

The protection of the rights and welfare of human subjects who participate in research does not end with the IRB review. Researchers are ultimately responsible for the conduct of their research. Though research responsibility may be delegated to research staff, researchers must maintain oversight and retain ultimate responsibility for the conduct of those to whom they delegate responsibility.

Providers who are employees of a Trinity Health West Region (THWR) site or have a paid faculty appointment at Saint Agnes Medical Center and/or Saint Alphonsus Regional Medical Center may serve as a principal investigator for human research. Providers must also meet the eligibility criteria defined within this policy.

This policy applies to all providers who meet the defined principal investigator criteria and are employed by a THWR site. The purpose of this policy is to define the eligibility requirements for Principal Investigators who aim to conduct human research at a THWR site. Additionally, this policy will outline the responsibilities of a principal investigator.

Definitions:

Investigator: an individual who conducts a clinical investigation (i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject) or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.
Principal Investigator: the lead investigator conducting a clinical investigation where there is more than one investigator (i.e., "Sub-investigator(s)).
Trinity Health West Region: any clinical site (inpatient, outpatient, or clinic) that is a part of the Saint Agnes Medical Center or Saint Alphonsus Health System. Also referred to as THWR.

II. Equipment: None

III. Procedure:

A. Investigator Qualifications:

Principal investigators and supporting investigators must ensure the ethical and responsible conduct of research involving human subjects. They must possess the education, training, experience, and commitment to upholding all ethical principles and regulatory requirements.

Providers who intend to be an investigator or principal investigator of a human research study conducted at a THWR site must meet the following criteria:

1. Documentation of completion of training in human subjects research as defined by Trinity Health. Training requirements are defined within *Trinity Health West Region IRB Policy: Education and Training on Human Subjects Research Protections*. Training must be current within timeframes established in the policy and not in an expired status.

2. Affiliation with a THWR site. Investigators who are not employed by or possess a faculty appointment at a THWR site may not serve as a Principal Investigator. Collaboration with External Investigators is described in Research Collaborations with External Investigators The Institutional Official for Research must approve external collaborations.
3. Identification of faculty advisor for those investigators who are identified as an undergraduate student, graduate student, medical student, medical resident or visiting scholar.
4. Be in good standing within either organization with no active Performance Improvement Plan.
5. Adherence to any applicable specialty training, rostering, and credentialing requirements and assurance that none reaches an expired status.
6. Compliance with annual and trial specific conflict of interest disclosure requirements as defined in POLICY.
7. Disclosure of actual and potential conflicts of interest, inclusive of financial conflicts and conflicts of commitment, with trial sponsors or other stakeholders.
8. Disclosure of all financial interests, in a timely manner, that exceed the threshold established within the *Trinity Health West Region Leadership Policy*: *Promoting Objectivity in Research – Financial Conflict of Interest.*

B. Investigator Responsibilities

A PI is responsible for the overall conduct of a study and the protection of the rights, safety and welfare of those individuals who are participating in the research. Some of these responsibilities include, but are not limited to, the following:

1. Conducting the research in compliance with relevant regulations (e.g., 45 CFR 46/the Common Rule, FDA, other federal agencies, state law) as well as ethical principles described in the Belmont Report.
2. Complying with all institutional requirements related to human subjects research, including conflict of interest.
3. Completing required human subjects research training as defined in *Trinity Health West Region IRB Policy: Education and Training on Human Subjects Research Protections*.
4. Obtaining IRB approval, or an IRB exemption determination, before conducting research involving human subjects.
5. Obtaining all other required institutional approvals (Research Review Committee), including approvals of departments or divisions for the additional resources that may be necessary to conduct the research (pharmacy, radiology, laboratory, etc.)
6. Ensuring there are adequate resources to conduct the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.
7. Ensuring that Research Staff are qualified (e.g., including but not limited to training, education, expertise, credentials, protocol requirements and, when relevant, privileges) to perform procedures and duties assigned to them during the study.
8. Providing adequate training to and oversight of study personnel.
9. Ensuring the protocol complies with applicable Good Clinical Practice requirements.
10. Compliance with the protocol as approved by the IRB.
11. When required by the IRB, ensuring consent or permission is obtained as required by the protocol and as described in your IRB submission.
12. Obtaining permission for the use and disclosure of protected health information in compliance with the HIPAA Privacy Rule, as applicable

13. Assurance that the approved protocol will not be modified (inclusive of a planned deviation) without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subject(s).
14. Submitting follow-up applications and notifications, as required, for approved or exempt studies, including amendments, continuing reviews, and reportable events.
15. Submitting a closure report when a study is completed.
16. Submission of an updated disclosure of financial interests for you and your key research staff within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest.
17. Refusal or offer of payments to professionals in exchange for referrals of potential subjects ("finder's fees").
18. Refusal of payments designed to accelerate recruitment that were tied to the rate or timing of enrollment ("bonus payments").
19. Follow applicable federal department or agency requirements when conducting human subject research funded or supported by that department or agency.

IV. Ministry Specific Related Addendums, Procedures, and/or Policies:

A. Saint Agnes Medical Center: None

B. Saint Alphonsus Health System: None

V. Additional Approval: Not applicable.