Policy Title: External Institutional Review Board (IRB) Reliance

Effective Date: 10/19/2022

LOCATION(S) Policy is Applicable to:

☒ Saint Francis Hospital and Medical Center
☒ Mount Sinai Rehabilitation Hospital
☒ Johnson Memorial Hospital, Inc.
☒ The Mercy Hospital, Inc.
☒ Saint Mary's Hospital, Inc.
☒ Trinity Health Of New England Medical Group

To be reviewed every three years by:
Trinity Health Of New England Institutional Review Board (IRB)

Review By: 10/19/2025

PURPOSE:

This process implements the requirements of the Trinity Health Of New England (THOfNE) Institutional Review Board (IRB) who may rely on an external IRB, institution, or organization, or an independent (commercial) IRB for oversight and approval of human research if the reliance is beneficial to THOfNE, its investigators, and its Research participants.

PROCEDURE:

I. Research that may use External IRB Review:

a. THOfNE IRB will rely on a qualifying external IRB for research studies that meet ALL the following criteria:

- Phase II, III, or IV
- Industry-initiated protocols
- Industry-funded
- Multi-site
- Already possess external IRB approval from an AAHRPP-accredited IRB located in the U.S.

b. THOfNE IRB considers operating the services of a qualifying external IRB for review of research studies that meet ANY of the following criteria:

- A federally funded or cooperative group study utilizing a review by an AAHRPP-accredited IRB in the U.S.
- THOfNE employees are engaged in multi-site research involving only minimal risk study activities
- Research in which THOfNE has an institution has a conflicting interest

II. Requirements for approving an External IRB:

- The external IRB must be registered and in good standing with OHRP/FDA.
- Commercial IRB is AAHRPP-accredited
- For non-commercial IRBs: the IRB is AAHRPP-accredited or meets the standards of THOfNE IRB
- The external IRB is located within the U.S.

RESPONSIBILITIES:

III. THOfNE IRB Responsibilities:

- THOfNE will assign an IRB Chair or Vice Chair who will serve as the reviewer to perform an administrative review of the research protocol and the external IRB's decisions and determinations to ensure the research is consistent with THOfNE IRB policies.

IV. Responsibilities of the External IRB:

- The external IRB must ensure that in advance and by periodic review, those appropriate steps are taken to protect the rights and welfare of humans participating as subjects in the research.
- The external IRB is responsible for following the Code of Federal Regulations at 45 CFR 46 when providing equivalent protections.
- The external IRB will make available to THOfNE, upon request, relevant minutes of its meetings and any other documents related to the review, approval, and continuing oversight of the research study

V. Submission Responsibilities of the THOfNE Investigator/Study Team:

All submissions must be submitted through the THOfNE IRB electronic submission system iMedRIS

a. Initial Submission:

- The letter of approval from the external IRB.
- The final approved protocol and informed consent.
- The entire grant, if applicable, is exclusive of appendices.
- Relevant Investigator's Brochure(s) and package insert(s)
- Advertisements
- All surveys, questionnaires, phone scripts, and other participant materials
- Approved waivers of consent and HIPAA Authorization
- Any other documents considered by the external IRB in making its determination to support the study
- Financial Disclosure Forms
- IRB Authorization Agreement (IAA)
- Study Personnel must complete Research and Ethics Training

b. Annual Continuing review:

- The continuing review approval letter from the external IRB

- The final approved protocol and informed consent
- The continuing review form
- Research documents considered by the external IRB in making its determination to approve the study.
- Financial Disclosure Forms

c. Amendments:

- The proposed change or amendment
- Documentation from the external IRB of approval of the modification or amendment
- The external IRB-approved modified or amended protocol, consent form, or other study documents.

d. Unanticipated Problems or Serious Adverse Events Involving Risks:

- Any unanticipated events or serious adverse events involving risks to subjects or others must be reported according to THOfNE IRB policy in addition to the guidelines of the external IRB.

e. Closure of the study:

- When research is completed, the THOfNE investigator must submit a closure form to the THOfNE IRB.

RESPONSIBLE DEPARTMENT:

Additional information regarding the External IRB Reliance may be obtained from THOfNE IRB.

RELATED PROCEDURES AND OTHER MATERIALS:

https://www.aahrpp.org/resources/for-accreditation/tipsheets/single-irb-or-ec-review

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/using-centralized-irb-review-process-multicenter-clinical-trials

https://grants.nih.gov/policy/humansubjects/single-irb-policy-multi-site-research.htm

APPROVALS:

Initial Approval: 10/19/2022

Subsequent Review/Revision(s):