



## **Trinity Health Of New England Institutional Review Board**

### **STATEMENT OF COMPLIANCE**

Trinity Health Of New England (THOfNE) has submitted a Federalwide Assurance (FWA) to confirm compliance with the Office of Human Research Protections under FWA00020300. The organization is dedicated to conducting human subjects research in accordance with the principles outlined in the Belmont Report, regardless of the funding source. THOfNE's FWA is specific to a single registered internal Institutional Review Board (IRB), Saint Francis Hospital and Medical Center Hartford, CT, under IORG# IORG000021 and IRB00000357.

THOfNE IRB has documented procedures for the initial and ongoing review of human subjects research. The THOfNE IRB keeps written records of IRB meetings and uses an electronic research application system to ensure compliance with record retention requirements. All documented processes adhere to relevant FDA regulations 21 CFR Parts 50 and 56, HHS regulations 45 CFR 46, and International Conference on Harmonization (ICH) E6, Good Clinical Practice (GCP) as adopted by the FDA, as applicable. THOfNE IRB ensures compliance with other applicable federal and state laws and regulations governing IRBs and human subjects research.

The complete set of IRB policies and procedures is accessible on the THOfNE IRB website at <https://www.trinityhealthofne.org/clinical-education-and-research/clinical-trials-and-research/institutional-review-board/>. Furthermore, THOfNE IRB has obtained full accreditation from the esteemed Association for the Accreditation of Human Research Protection Programs (AAHRPP).