Trinity Health
Of New England

Unaffiliated Investigator Agreement

Name of Unaffiliated Investigator: _____

Name of Principal Investigator of the study: _____

Name of Institution Providing IRB Oversight: Trinity Health Of New England

OHRP Federalwide Assurance Number: 00020300

Research Protocol Covered Under This Agreement:

Study Title: _____

IRB #:_____

The above-named Unaffiliated Investigator has reviewed *the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*; the U.S. Department of Health and Human Services (DHHS) regulations for the protection of human subjects at 45 CFR 46, the Assurance referenced above, and the relevant institutional policies and procedures for the protection of human subjects.

(1) The Investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this Agreement.

(2) The Investigator will comply with all other applicable federal, international, state and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this agreement.

(3) The Investigator will abide by all determinations of the IRB designated under the above Assurance and will accept the final authority and decisions of the IRB, including but not limited to directives to terminate participation in designated research activities.

(4) The Investigator will complete any training required by the IRB prior to initiating research covered under this Agreement.

(5) The Investigator will report promptly to the IRB proposed changes in the research conducted under this Agreement. The investigator will not initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.

(6) The Investigator will report immediately to the IRB any unanticipated problems involving risks to subjects or others in research covered under this Agreement.

(7) The Investigator, when responsible for enrolling subjects, will obtain, document, and maintain records of informed consent for each subject or each subject's legally authorized representative as required under HHS regulations at 45 CFR part 46 (or any other

international or national procedural standards selected on the FWA for the institution referenced above) and stipulated by the IRB.

(8) The Investigator acknowledges and agrees to cooperate in the IRB's responsibility for initial and continuing review, record keeping, reporting, and certification. The Investigator will provide all information requested by the IRB in a timely fashion.

(9) In conducting research involving FDA-regulated products, the investigator will comply with all applicable FDA regulations and fulfill all investigator responsibilities (or investigator-sponsor responsibilities, where appropriate), including those described at 21 CFR 312 and 812.

(10) The investigator will not enroll subjects in research under this Agreement prior to its review and approval by the IRB.

(11) Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable Federal regulations and State law. However, such medical care may not be included as part of Federally-supported research.

(12) This Agreement does not preclude the investigator from taking part in research not covered under the Agreement.

(13) The investigator acknowledges that her/his primary responsibility is to safeguard the rights and welfare of each research subject, and that the subject's rights and welfare must take precedence over the goals and requirements of the research.

Signatures:

Investigator Signature: _____ Date: _____

Investigator Name: _____ Degrees: _____

Address: _____ Phone #: _____

_____

(City) (State) (Zip)

FWA Signatory Official Signature: _____ Date: _____

FWA Signatory Official Name: Carlos Brown
Regional Vice President, Integrity & Compliance
Trinity Health Of New England
1000 Asylum Avenue, 5th Floor
Hartford, CT 06105 860-714-9847