OFFICE OF RESEARCH INTEGRITY & COMPLIANCE UNT

Unaffiliated Investigator Agreement

With the University of North Texas Institutional Review Board FWA00007479

Name of Principal Investigator:
Department of Principal Investigator:
Principal Investigator Phone Number:

Name of Unaffiliated Investigator:
Title of Research Proposal Covered by this Agreement:

(1) The above-named unaffiliated investigator has reviewed the relevant institutional policies and procedures for the protection of human subjects including: 1) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (or other internationally recognized equivalent; see B1 of FWA Terms for institutions outside the United States); 2) the U.S. Department of Health and Human Services (DHHS) regulations for the protection of human subjects at 45 CFR 46 (or other internationally recognized equivalent, see B3 of FWA Terms for institutions outside the United States); 3) the Federalwide Assurance (FWA) referenced above; and 4) the relevant institutional policies and procedures for the protection of human subjects.

(2) The unaffiliated 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.

(3) The unaffiliated investigator will comply with all other Federal, State, or local laws or regulations that may provide additional protection for human subjects.

(4) The unaffiliated investigator will abide by all determinations of the UNT IRB, designated under the above Federalwide 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.

(5) The unaffiliated investigator will complete any training required by the Institution prior to initiating research covered under this Agreement.

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

(7) The unaffiliated investigator will report immediately to the IRB any unanticipated problems in research covered under this Agreement that involve risks to subjects or others.

(8) The unaffiliated investigator will seek, document, and maintain records of informed consent from each subject or the subject's legally authorized representative as required under regulations (or other international or national equivalent) and stipulated by the UNT IRB.

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

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

(11) 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.

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

(13) The unaffiliated 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.

Unaffiliated Investigator

I understand my responsibilities and agree to comply with all applicable local, state and federal regulations as well as all applicable research policies of the University of North Texas as they pertain to the protection of human subjects' research activities.

Unaffiliated Investigator Signature: _____ Date: _____

Name: _____ Degree(s): _____

Address: _____ Phone: _____

_____

(City) (State) (Zip/Country)

Principal Investigator

I understand my responsibilities and agree to direct and appropriately supervise all of the collaborative research activities to be performed by the above collaborating unaffiliated related to this research study. I have verified this individual meets the minimum training, experience, and credential requirements set by the IRB to conduct his/her assigned research duties.

UNT Principal Investigator Signature: _____ Date: _____

Institutional Review Board Designee

I have reviewed this request to add an unaffiliated investigator to this research study and agree to this addition.

IRB Designee Signature: _____ Date: _____