Unaffiliated Investigator Statement of Assurance and Commitment
To Federal and Institutional Human Subject Protection Policies and
East Tennessee State University IRB Oversight

Unaffiliated Investigator Agreement
Complete and submit one completed agreement for each unaffiliated investigator

Name of Unaffiliated Investigator:

Name of Institution Providing IRB Oversight:

☐ MEDICAL CAMPUS
   East Tennessee State University / James H. Quillen Veterans Affairs IRB
☐ ETSU CAMPUS Institutional Review Board
☐ External IRB

OHRP Federalwide Assurance Number:
   FWA #00002703 (ETSU)
   FWA #00002117 (VAMC)
   FWA #00001815 (MSHA)

Research Covered Under This Agreement:

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

(2) 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.

(3) The Investigator will comply with all other National, State, or local laws or regulations that may provide additional protection for human subjects.
(4) 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.

(5) The Investigator will complete the CITI training required by the IRB prior to submitting research covered under this Agreement. Similar training or sessions received from other institutions (or meetings) may be acceptable. In this instance, the Director and the IRB Chair will make the final determination for education compliance.

(6) 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.

(7) The 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 Investigator will obtain, document, and maintain records of informed consent from each subject or the subject's legally authorized representative as required under DHHS and FDA regulations (or other international or national equivalent) and stipulated by the IRB.

(9) 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. (Note: failure to meet reporting deadlines will result in the immediate suspension of research and possible withdrawal of IRB approval)

(10) 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.

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

(12) The investigator will allow the IRB [or its authorized designee(s)] appropriate access to research sites and study related records upon request to support administration audits as required by §46.109(e) including the authority of the IRB to observe or have a third party observe the consent process.
(13) Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable Federal regulations and State law (e.g., Emergency or Compassionate Use guidelines). However, data and information obtained as a result of emergency medical care may not be included as part of Federally-supported or –conducted research.

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

(15) 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 society and the research.

Signatures:

Investigator Signature: ____________________________ Date ______________

Printed Name: ____________________________________________ Degree(s):

  (Last)   (First)   (Middle Initial)

Address: ____________________________________________ Phone #:

  (City)   (State/Province)   (Zip/Country)

Do not write below this line

________________________________________________________

FWA Institutional Official (or Designee): __________________________ Date __________

Name: ____________________________________________ Institutional Title: ________________

  (Last)   (First)   (Middle Initial)

Address: ____________________________ phone #: __________________________

  (City)   (State/Province)   (Zip/Country)

IRB Chairman responsible for review: __________________________ Date _________

A copy of this fully executed agreement will be returned to the principal investigator, the ETSU Institutional Official and the VA R&D administration (if the protocol is reviewed/approved by the ETSU/VA IRB). The original will be added to the study file maintained by the IRB administration.