Commitment Statement of an Individual Investigator to Institutional Human Subject Protection Policies and IRB Oversight

Individual Investigator Agreement

Name of Institution with the Federalwide Assurance (FWA)	**New York State Department of Health**
Applicable FWA #	**FWA 00003700**
Individual Investigator's Name	
Specify Research Covered by this Agreement	

(1) The above-named Individual Investigator has reviewed: 1) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research;* 2) the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46; 3) the FWA and applicable Terms of the FWA for the institution referenced above; and 4) the relevant policies and procedures for the protection of human subjects for the institution referenced above.

(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 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.

(4) The Investigator will abide by all determinations of the New York State Department of Health Institutional Review Board (IRB) designated under the above FWA 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 all educational training required by the Institution and/or the IRB prior to initiating research covered under this Agreement.

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

(8) The Investigator, when responsible for enrolling subjects, will obtain, document, and maintain records of informed consent for each such subject or each subject's legally authorized representative as required under HHS regulations at 45 CFR part 46 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 for the research referenced above. The Investigator will provide all information requested by the IRB in a timely fashion.

(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.

(12) This Agreement does not preclude the Investigator from taking part in research not covered by this Agreement.

(13) The Investigator acknowledges that he/she is primarily responsible for safeguarding 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.

Investigator's Signature: _____ Date: _____

Name: _____ Degree(s): _____
(*Last*) (*First*) *(Middle Initial)*
Address: _____ phone #: _____

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

FWA Institutional Official (or Designee) Signature: _____ Date: _____

Name: _____
(*Last*) (*First*) (*Middle Initial*)

Institutional Title: _____

Address: _____ phone #: _____

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

Note: *For international research additional procedural standards and policies may apply. Please contact the IRB office at (518) 474-8539 for information on investigator agreement for international research*