Commitment Statement of an Individual Investigator, Not Covered by an Institutional Federalwide Assurance, to UCF Institutional Human Subject Protection Policies and IRB Oversight

UCF IRB Individual Investigator Agreement

Name of Institution with the Federalwide Assurance (FWA): University of Central Florida

Applicable FWA #: 00000351

Individual Investigator’s Name (Non-UCF): ____________________________

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 [or other internationally recognized equivalent; see section B.1. of the Terms of the Federalwide Assurance (FWA) for International (Non-U.S.) Institutions]; 2) the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46 [or other procedural standards; see section B.3. of the Terms of the FWA for International (Non-U.S.) Institutions]; 3) the FWA and applicable Terms of the FWA for the institution 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 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 University of Central Florida Institutional Review Board (UCF IRB) designated under the above FWA and will accept the final authority and decisions of the UCF IRB, including but not limited to directives to terminate participation in designated research activities.

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

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

(9) The Investigator acknowledges and agrees to cooperate in the UCF 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 UCF IRB.

(11) Emergency medical care may be delivered without UCF IRB review and approval to the extent permitted under applicable federal regulations and state law, but the Investigator shall notify the UCF IRB within 5 working days of the administration of such care.

(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 Signature: ___________________________ Date ____________

Name: ___________________________________________ Degree(s): ____________

(Last) (First) (Middle Initial)

Company: __________________________________________

Address: ___________________________________________ phone #: ____________

_________________________________________________________________________

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

UCF FWA Official (or Designee) Signature: _________________ Date __________

Name: Debra Reinhart, Ph.D. Institutional Title: Associate Vice President for Research & Scholarship (First) (Last)

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