Florida International University (FWA 00000060) - Individual Investigator Agreement

External Individual Investigator Information:

Full Name: _____ Institution (if any): _____

Address: _____

Phone: _____ E-mail: _____

Project Title**:** _____

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1. The above-named Individual Investigator has reviewed: (i) T*he Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*; (ii) the U.S. Department of Health and Human Services (DHHS) regulations for the protection of human subjects at 45 CFR 46; (iii) the Federalwide Assurance (FWA) referenced above; and (iv) the relevant Florida International University 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 federal, 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 institutional review board (IRB) designated above 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 any 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 from each subject or the subject's legally authorized representative as required under DHHS and FDA regulations 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.
10. In conducting research involving FDA-regulated products, the Investigator will comply with all applicable FDA regulations and fulfill all investigator responsibilities (or all sponsor-investigator responsibilities, as applicable), including without limitation those described at 21 CFR parts 312 and 812.
11. The Investigator will not enroll subjects in research under this Agreement prior to review and approval of the research by the IRB.
12. Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable federal regulations and state law. However, data and information obtained as a result of emergency medical care may not be included as part of the research that is the subject of this Agreement.
13. This Agreement does not preclude the Investigator from taking part in research not covered by the Agreement; nor does it obligate Florida International University or any of its IRBs to review any such research.
14. The Investigator acknowledges that he or she is primarily responsible for safeguarding the rights and welfare of each research subject, and that the subject's rights and welfare must at all times take precedence over the goals and requirements of the research.
15. The Investigator will promptly report to the IRB and the Institutional Official noncompliance with any of the standards or requirements referenced in this Agreement, whether by the Investigator, any co-investigators, research staff, or others, regardless of fault or intent.

External Investigator

Signature: _____

Date: _____

Institutional Official or Designee

Signature: _____

Date: _____