



Delaware Department of Health & Social Services (DHSS)
Human Subjects Review Board (HSRB)
Investigator Agreement

Name of Institution with the Federalwide Assurance (FWA): Delaware Health & Social Services

Applicable FWA #: 00005447

Individual Investigator's Name:

Research Covered by this Agreement: _____

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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; (4) the privacy regulations at 45 CFR 160 and 164, and (5) the relevant institutional policies and procedures for the protection of human subjects and their privacy.
 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, privacy, 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.

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4. The Investigator will abide by all determinations of the DHSS HSRB and will accept the final authority and decisions of this Board, including but not limited to directives to terminate participation in designated research activities.
5. The Investigator will complete any educational training required by the HSRB prior to initiating research covered under this Agreement.
6. The Investigator will report promptly to the HSRB any proposed changes in the research conducted under this Agreement. The Investigator will not initiate changes in the research without prior HSRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.
7. The Investigator will report immediately to the HSRB 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 (or any other international or national procedural standards selected on the FWA for the institution referenced above) and stipulated by the HSRB.
9. The Investigator acknowledges and agrees to cooperate in the HSRB'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 HSRB 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 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 HSRB.
12. Emergency medical care may be delivered without HSRB review and approval to the extent permitted under applicable Federal regulations and State law.
13. This Agreement does not preclude the Investigator from taking part in research not covered under the Agreement.
14. The Investigator acknowledges that her/his primary responsibility is to safeguard the rights, privacy, and welfare of each research subject, and that the subject's

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rights, privacy, and welfare must take precedence over the goals and requirements of the research.

Signatures:

Investigator: _____ Date _____
(signature)

Name: _____ Degree(s): _____
(Last) (First) (Middle Initial)

Address: _____ phone #: _____

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

FWA Institutional Official (or Designee):

_____ Date _____
(signature)

Name: _____ Institutional Title: _____
(Last) (First) (Middle Initial)

Address: _____ phone #: _____

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