

# HUNTER COLLEGE

INSTITUTIONAL REVIEW BOARD (IRB) FOR THE PROTECTION OF HUMAN SUBJECTS

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## UNAFFILIATED INVESTIGATOR AGREEMENT

Name of Unaffiliated Investigator: \_\_\_\_\_

Name of Institution Providing IRB Oversight: Hunter College of the City University of New York.

Office for Human Research Protections ("OHRP") Assurance Number: FWA00003623

Applicable Protocol Number: \_\_\_\_\_

Research Covered Under this Agreement ("Research Project"):

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1. The above-named Unaffiliated Investigator has reviewed the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*; the U.S. Department of Health and Human Services ("DHHS") regulations for the protection of human subjects at 45 CFR 46; the Assurance referenced above; and the relevant institutional policies and procedures for the protection of human subjects.
  2. The Investigator understands and hereby accepts the responsibility to comply with 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, or local law 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 any training required by the IRB prior to initiating research covered under this Agreement.

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 eliminated 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 seek, document and maintain records of informed consent from each subject or the subject's legally authorized representative as required under HHS 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.
10. The Investigator will not enroll subjects in research under this Agreement prior to its review and approval by the IRB.
11. The Investigator acknowledges that failure to comply with the IRB's requirements, this Agreement, or any federal, state, or local laws or regulations may results in termination of the Investigator's role in the Research Project, notification to federal oversight agencies, and civil and criminal liability.
12. 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 the research.

**Signatures:**

Investigator \_\_\_\_\_ Date \_\_\_\_\_