

State University of New York at Delhi

**Unaffiliated Investigator Agreement**

*Adopted with permission from the University at Albany*

**Unaffiliated Investigator's Name:**

**Research Covered by this Agreement:**

**Protocol Number: #**

**Project Title:**

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**SUNY Delhi Sponsor (College affiliate sponsoring the unaffiliated principle investigator):**

**SUNY Delhi sponsor Role in Research Study Covered by this Agreement:**

**SUNY Delhi sponsor email:**

**SUNY Delhi sponsor phone:**

1. The above-named unaffiliated investigator has reviewed: (1) 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 participants at 45 CFR 46; and (4) SUNY Delhi's Policies and Procedures for the protection of human participants.

Belmont Report: <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>

45 CFR 46: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>

FWA:

College Policies:

2. The unaffiliated 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 participants involved in research conducted under this Agreement.
3. The unaffiliated investigator will comply with all other National, State, or local laws or regulations that may provide additional protection for human participants.

4. The unaffiliated investigator will abide by all determinations of SUNY Delhi's Institutional Review Board (IRB) and will accept the final authority and decisions of the IRB, including but not limited to directives to terminate participation in designed research activities.
5. The unaffiliated investigator will complete the training and education requirement mandated by SUNY Delhi, prior to initiating the research covered under this Agreement.
6. The unaffiliated investigator will report promptly to the IRB, through the principal investigator, any proposed changes 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 participants.
7. The unaffiliated investigator will report immediately to the IRB any unanticipated problems involving risks to participants or others in research covered under this Agreement.
8. The unaffiliated investigator will obtain, document, and maintain records of informed consent from each participant or the participant's legally authorized representative as stipulated by the IRB.
9. The unaffiliated investigator acknowledges and agrees to cooperate in the IRBs 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. The unaffiliated investigator will not enroll participants 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. However, data and information obtained as a result of emergency medical care may not be included as part of the research.
12. This Agreement does not preclude the unaffiliated investigator from taking part in research not covered by this Agreement.
13. The unaffiliated investigator acknowledges that he/she is primarily responsible for safeguarding the rights and welfare of each participant, and that the participant's rights and welfare must take precedence over the goals and requirements of the research.
14. The unaffiliated investigator agrees to comply with all provisions of the Health Insurance Portability and Accountability Act of 1996 and regulations promulgated there under, as such law and regulations may be amended from time to time.
  - a. The unaffiliated investigator agrees to not use or further disclose Protected Health Information other than as permitted or required by an Underlying Agreement or as Required by Law.

- b. The unaffiliated investigator agrees to use appropriate safeguards to prevent use or disclosure of the Protected Health Information other than as provided for by this Agreement.

**Individual Investigator Signature**

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**Print Unaffiliated Investigator  
Name**

**Investigator Signature**

**Date**

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**Business Address**

**City, State Province, Country**

**Phone Number**

**Email address**

**SUNY Delhi Sponsor Assurance:**

By signing this form you are acknowledging the responsibility to maintain communications between the Unaffiliated Investigator and the College with regards to the role that you have identified with the primary unaffiliated investigator.

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**Print SUNY Delhi Investigator  
Name**

**Investigator Signature**

**Date**