Individual Investigator Agreement

Name of Institution with the Federalwide Assurance (FWA): Trustees of Boston University (BU)

Applicable FWA #: 00002457

**Individual Investigator’s Name and Degrees:**  Click or tap here to enter text.

Specify Research Covered by this Agreement:

* **BU Protocol #:** Click or tap here to enter text.
* **BU Protocol Title:** Click or tap here to enter text.
* **BU Principal Investigator:** Click or tap here to enter text.
* **Individual Investigator Research Activities:**  Click or tap here to enter text.

**Mark if true**:

The Individual Investigator has a financial interest and/or personal relationship (including as an employee) with a company, foundation, organization, etc. (“entity”) that is associated with this research (e.g., sponsor, licensee, donor, provider of reagents/equipment/services, etc.) or with the technology to be studied. If yes:

1. Describe the relationship: Click or tap here to enter text.
2. Describe how the financial interests and/or relationships might have the potential to affect, or be affected by, this proposed research: Click or tap here to enter text.

The research is Public Health Service (PHS)-sponsored **or** the individual investigator is responsible for the

design, conduct or reporting of the research. If true, a FIND1 form (and FIND2 if appropriate) must be submitted to Boston University’s [Conflict of Interest (COI) office](mailto:Conflict%20of%20Interest%20(COI)%20Office). Contact the [COI](mailto:coi@bu.edu) office to obtain a copy of the FIND1 and/or FIND2 forms.

1. The above-named Individual Investigator has reviewed materials based on the [Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html) and will complete Boston University’s human subjects training curriculum, available through the [BU IRB website](https://www.bu.edu/researchsupport/compliance/human-subjects/human-subjects-training/) prior to initiating research covered under this Agreement.
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 Institutional Review Board (IRB) designated under the above FWA 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 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 IRB.
9. The Investigator acknowledges and agrees to cooperate in the 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 or conduct any research activities 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.
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.

**Individual Investigator:**

An electronic signature is acceptable; however, please refrain from typing your name.

**Signature:** Click or tap here to enter text. **Date:** Click or tap to enter a date.

**Address:** Click or tap here to enter text. **Phone #:** Click or tap here to enter text.

**Email:** Click or tap here to enter text.

**Trustees of Boston University Institutional Official:**

Signature: Date: Click or tap to enter a date.

*Designee:* LaNeia Thomas, MSW, Assistant IRB Director, Phone: 617-358-6346; Email: laneia@bu.edu

*Signing on behalf of* Kathryn Mellouk, Institutional Official & Associate Vice-President Research Compliance.