Albert Einstein College of Medicine, Inc. (FWA #00023382)

Individual Investigator Agreement

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of Individual Investigator (External Collaborator)** **(Last, First, Middle Initial):** | Click here to enter text. | **Degrees:** | Click here to enter text. |
| **Street Address:** | Click here to enter text. | **Phone:** | Click here to enter text. |
| **City:** | Click here to enter text. | **State:** | Click here to enter text. | **Zip/Country:** | Click here to enter text. |

**Einstein IRB Signature:**

|  |  |
| --- | --- |
|  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Director/Associate Director or Designee Signature | \_\_\_\_\_\_\_\_\_Date\_\_\_\_\_\_\_\_ |

 Print Full Name:

**Research Covered by this Agreement:**

Einstein/Montefiore PI: Click here to enter text.

Study Title: Click here to enter text.

iRIS ID #: Click here to enter text.

1. The above-named Individual Investigator has reviewed: 1) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>); 2) the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46 (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>); and 3) the relevant institutional policies and procedures for the protection of human subjects (<http://www.einstein.yu.edu/administration/institutional-review-board/policies.aspx>).
2. The Individual 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 Individual 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 Individual 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 Individual Investigator will complete any educational training required by the Institution and/or the IRB prior to initiating research covered under this Agreement.
6. The Individual Investigator will report promptly to the IRB any proposed changes in the research conducted under this Agreement. The Individual 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 Individual Investigator will report immediately to the IRB any unanticipated problems involving risks to subjects or others in research covered under this Agreement.
8. The Individual 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 Individual 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 Individual Investigator will provide all information requested by the IRB in a timely fashion.
10. The Individual Investigator will not enroll subjects 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.
12. This Agreement does not preclude the Individual Investigator from taking part in research not covered by this Agreement.
13. The Individual 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.

|  |  |  |  |
| --- | --- | --- | --- |
| **External Collaborator’s Signature** |  | **Date:** |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **FWA Institutional Official (or Designee):** | Burns, Edward R. | **Institutional Title:** | Executive Dean |
| **Address:** | Belfer Bldg, Room 307; 1300 Morris Park Avenue; Bronx, NY 10461 (718-430-2337) |
| **Signature:** |  | **Date:** |  |