**RESEARCH WITH HUMAN SUBJECTS DETERMINATION FORM**

*Instructions: Please complete and submit this form via email to IRB@bu.edu along with any supporting documentation, such as a grant or contract supporting the project, data collection forms and other materials (e.g. assessments, questionnaires) to be used in the project.*

 **Date:** date

**Project Title:** Click or tap here to enter text.

**Principal Investigator:** Click or tap here to enter text.

**PI Email:** Click or tap here to enter text. **PI Phone #:** phone #

**Department/School:** Click or tap here to enter text.

**Project Funding Source:** Click or tap here to enter text.

* + - 1. **Please provide a brief description of the project**: *Please be sure to include how you will be collecting data, how many participants you will enroll, and the location of the research.*

Click or tap here to enter text.

* + - 1. **The project is a systematic investigation** [ ] **Yes** [ ] **No**

Check if ‘Yes’

|  |  |
| --- | --- |
| [ ]  | The project will attempt to answer research questions (e.g. includes a hypothesis, research methods such as randomization, comparison of techniques/groups) |
| [ ]  | The project is methodologically driven (information collected is organized/consistent, guided by data, actual experiences or clinical results)  |
| [ ]  | Conclusions will be drawn from the results |

* + - 1. **The project is designed to contribute to generalizable knowledge** [ ] **Yes** [ ] **No**

Check if ‘Yes’

|  |  |
| --- | --- |
| [ ]  | Results will contribute to a theoretical framework of established knowledge |
| [ ]  | Results are expected to be generalized to a larger population beyond the site of data collection and in some circumstances, the population being studied |
| [ ]  | Results are intended to be replicated in other settings |

* + - 1. **The project involves ‘human subjects’** [ ] **Yes** [ ] **No**

Check if ‘Yes’

|  |  |
| --- | --- |
| [ ]  | The subjects of the research are currently alive |
| [ ]  | The information to be collected is about the subjects (e.g. personal information about the individuals, not about products, organizations, systems, etc.) |
| [ ]  | Information/biospecimens will be collected by an intervention or interaction with the subjects AND the Investigator will use, study or analyze the info/biospecimens |
| [ ]  | The Investigator obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens.  |

**If you have answered ‘Yes’ to all of the questions in 2, 3 & 4, you likely need IRB review/approval.**

**Principal Investigator Certification / Signatures**

By signing below, you certify that the information contained in this Application is true, complete, and accurate.

**Principal Investigator Signature:**  **Date:**

**Submission:** This form can be completed, signed, scanned and submitted to the IRB at irb@bu.edu.

**-------------------------------------------------------------------------------------------------------------------------------**

**IRB USE ONLY:**

[ ]  **Does not meet the definition of ‘research’ under 45 CFR 46.102(l)**

[ ]  **Does not meet the definition of ‘human subjects’ under 45 CFR 46.102(e)**

[ ]  **Requires more information to make a determination.**

 **If yes, describe here:** Click or tap here to enter text.

[ ]  **Requires IRB Review. Investigator should complete the following IRB Application:**

[ ]  **Exemption Application** [ ]  **Expedited and Full Board Review Application**

**Analyst/Reviewer Signature:  Date of Determination:**

**45 CFR 45.102(l)\***

(l) *Research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed **not** to be research:

(1) Scholarly and journalistic activities (*e.g.,* oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

**45 CFR 46.102(e)\*\***

(e)(1) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research:

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

(2)  *Intervention* includes both physical procedures by which information or biospecimens are gathered (*e.g.,* venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

(3)   *Interaction* includes communication or interpersonal contact between investigator and subject.

(4)  *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (*e.g.,* a medical record).

(5)  *Identifiable private information* is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

(6)  *An identifiable biospecimen* is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.