



HUMAN SUBJECT RESEARCH DETERMINATION FORM

Instructions: Only certain activities require review and approval by the Institutional Review Board (IRB). Because of funding, publication or other legal requirements a written determination that an activity is not “Human Subject Research” may be needed. The Human Subject Research Protection Office makes the determination as to whether an activity is Human Subject Research requiring IRB review and approval.

Please attach the grant application and, if available, notice of award. Please complete and sign this form and return it to: n.regina@northeastern.edu.

Principal Investigator: _____

Funding Agency: _____

1. **Research:** Research is defined as a systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalized knowledge.

- a. Is the planned activity a systematic investigation? No Yes
- b. Is the activity designed to develop or contribute to generalizable knowledge? No Yes

2. **Human Subjects:** Human subject means a living individual about whom an investigator conducting research.

- a. Are living individuals participating in the study? No Yes
- b. Does the activity gather data about the individuals participating in the study?
(**Note:** if any information about the individual, for example, the individual’s opinions, personal information, physical characteristics, etc., is obtained as part of the study select “Yes”.) No Yes
- c. The information about the individual is obtained through intervention or interaction with the individual? No Yes

3. **Private, Personally Identifiable Information (Data):** is information or data about an individual that an individual would reasonably expect to remain private or not be made public (e.g. sensitive information)

- a. Are you gathering personally identifiable information? No Yes
- b. If 3.a. is “yes”, does the study collect or use Protected Health Information (PHI)? No Yes

3.1. **De-Identified Data**

- a. Are you using PHI data that has been de-identified? No Yes

4. **Human Biospecimens:**

- a. Does the study involve the use of human materials (tissues, blood, cells, etc.)? No Yes
- b. If 4.a. is “yes”, are the biomaterials human stem cells? No Yes
- c. If 4.a. is “yes”, are the biospecimens from a commercial provider? No Yes

Principal Investigator

Date