**Human Subject Research Determination Form**

**Instructions:**  Researchers can self-determine whether their activities are human research. If you are unable to determine whether your activities meet the regulatory definition of “research” with “human subjects,” OR if you would like/need the IRB to evaluate your study to provide an official determination with documentation that your activity is not human subjects research, complete this form in its entirety and send to **IRBReview@northeastern.edu**. Additional information may be requested as needed. If it is determined that the study is Human Subjects Research, an application will need to be submitted to HSRP for review. **NOTE**: The IRB can only make this determination **PRIOR** to the beginning of the activity. The IRB will not make a determination after the activity has already begun. **Please attach the grant application and, if available, notice of award**

**Principal Investigator:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Project Title:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Funding Agency**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Is the activity “Research”?** Research is defined as a systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalized knowledge.
2. Is the planned activity a systematic investigation? [ ] Yes [ ] No
3. Is the activity designed to develop or contribute to generalizable knowledge? [ ] Yes [ ] No

\*If **Yes** to both of the questions above, the activity meets the definition of **research** in the Common Rule.

1. **Does the activity involve “Human Subjects”?** Human subject means a living individual about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.
2. Will you obtain data through **intervention** or interaction with living individuals? [ ] Yes [ ] No
3. 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”.) [ ] Yes [ ] No

\*If **Yes** to both of the questions above, the activity involves human subjects.

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)

1. Are you gathering personally identifiable information? [ ] Yes [ ] No
2. Does the study collect or use Protected Health Information (PHI) [ ] Yes [ ] No

 c. Are you using private information that has been coded/have an identity key? [ ] Yes [ ] No

d. If yes to 3c, will researchers be granted access to the identity key? [ ] Yes [ ] No

\*If **Yes** to a, b or c above, the activity involves human subjects. If **No** to 3d, provide documentation of the agreement prohibiting the release of the key to the investigator.

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4. Human **Biospecimens:**

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

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**Study Activity**

1. **Describe the purpose or objectives of this activity/project.** *This should be a succinct and accurate description of your proposed work*

Click or tap here to enter text.

1. **Provide a description of the procedures**

Click or tap here to enter text.

1. **Explain where the data/specimens were collected/obtained** (i.e., identify the source of data/specimens. Does the activity involve the use of **publicly available data** that contains sensitive or identifiable data? Please confirm that the information you have provided here does not include private identifiable information (PHI)

Click or tap here to enter text.

1. **Explain how the data/specimens will be provided to the investigator** e.g. the investigator will be provided an already existing, de-identified data set, etc.). Indicate who will de-identify the data and/or specimens, and how the data and/or specimens will be de-identified.

Click or tap here to enter text.

**5. Funding:** Will the activities be supported by Federal Funding (e.g., NIH, NSF, DoE, DoD) awarded directly to the institution (i.e. Northeastern University is the primary awardee)?

[ ] Yes [ ] No

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| Note about Funding: If the Northeastern University is the primary recipient of a federal award (e.g., NIH, NSF, DoE, DoD), and one or more external entities will engage in human subject research, then the human research determination form is NOT appropriate because the Institution is also engaged in human subjects research.If Northeastern University is the primary awardee and the grant application designates this as being human subject research, the human research determination form is NOT appropriate. |

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| --- | --- | --- | --- |
| **Signature:** |  | **Date:** |  |
| *Principal Investigator /Researcher/Student* |  |  |