**Human Subject Research [HSR] Determination Form**

**Submission Date:** Click or tap here to enter text.

**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 need the IRB to provide an official determination that your activity is not human subjects research, complete this form in its entirety and send to **IRBReview@northeastern.edu**.

***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.*

For guidance on human subject research terms and definitions, please refer to [HSR Guidance page](https://research.northeastern.edu/hsrp/guidance/).

**PROTOCOL INFORMATION**

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| **Principal Investigator:** Click or tap here to enter text. |
| **Student Investigator [if applicable]:** Click or tap here to enter text. |
| **Protocol Title:** Click or tap here to enter text. |

**FUNDING INFORMATION**

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| --- |
| **Funding agency/source [NU if no external funding source]:** Click or tap here to enter text. |
| **Grant Title:** Click or tap here to enter text. |
| **Grant ID:** Click or tap here to enter text. |

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

*Insert text here.*

If **No** to either,

 explain why:

\*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? [ ] Yes [ ] No

(**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”.)

*Insert text here.*

If **No** to either,

 explain why:

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

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

*Insert text here.*

If **No** to any,

 explain why:

\*If **Yes** to a, b or c above, the activity may involve human subjects. **SUBMIT the appropriate application**.

\*If **No** **to 3d**, provide documentation of the agreement prohibiting the release of the key to the investigator.

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

*Insert text here.*

If **No** to any,

 explain why:

\*If **Yes** to a, b or c above, IBC review may be needed. SUBMIT the Data and Specimen Analysist application.

\*De-identified or coded specimens where investigators have no access to private information and no subject contact usually qualifies as not human subjects, confirm with your provider.

**STUDY ACTIVITY INFORMATION**

**Complete the following section ONLY if you need formal IRB determination that it is NOT human research.**If while reviewing the questions above you determine that it is Human Research, please submit the appropriate application. Additional information may be requested as needed. Please attach the grant application and, if available, notice of award.

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

*Insert text here.*

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

*Insert text here.*

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 Protected Health Information(PHI)

*Insert text here.*

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.

*Insert text here.*

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

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| Note: This determination is not appropriate when:* Northeastern University is the primary recipient of a federal award (e.g., NIH, NSF, DoE, DoD), the grant applications designates this as HSR and one or more external entities will engage in HSR
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