**Human Subjects Research Engagement Worksheet**

 **When to use this form:** This worksheet is designed to help Northeastern University researcher teams determine if Northeastern University is engaged in human subjects research. This can apply when Northeastern is collaborating on projects with outside universities or when Northeastern University researchers have a dual appointment/affiliation and may be working on a project in one or more of those roles. The guidance is based on OHPR’s [Engagement of Institutions in Human Subjects Research (2008)](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html.).

If Northeastern University is engaged in human subjects research, the activity must be approved by the Northeastern University IRB or a reliance agreement must be established to allow an external IRB to serve as the reviewing IRB.

**Key definition:**

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| **Employees or agents** refers to individuals who meet one or more of the following criteria: * act on behalf of the institution while conducting the research activity(s);
* exercise institutional authority or responsibility while conducting the research activity(s);
* or perform institutionally designated activities while conducting the research activity(s).

“Employees and agents” can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation. Please note that being an NU affiliate and conducting research does not necessarily mean you are acting as an employee or agent of NU while conducting the research.  |

**Criteria 1: Northeastern University is always engaged, without exception, if:**

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| [ ]  | Northeastern receives an award through a grant, contract, or cooperative agreement directly from a federal agency for human subjects research, even if all activities involving human subjects are carried out by employees or agents of another institution. Please note that exempt research will require an independent exemption determination from the NU IRB.  |
| [ ]  | Northeastern University employees or agents obtain the informed consent of human subjects for the research. |
| **STOP: If one of the above apply, Northeastern University is Engaged in human subjects research without further criteria. If none of the above apply, please continue to Criteria 2.**  |

**Criteria 2: Northeastern University may be engaged if one or more of the following are met:**

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| [ ]  | Northeastern University employees or agents intervene for research purposes with any human subjects of the research by performing invasive or noninvasive procedures. |
| [ ]  | Northeastern University employees or agents intervene for research purposes with any human subject of the research by manipulating the environment. |
| [ ]  | Northeastern University employees or agents interact for research purposes with any human subject of the research. |
| [ ]  | Northeastern University employees or agents obtain for research purposes identifiable private information or identifiable biological specimens from any source for the research. |
| **STOP: If none of the conditions in Criteria 1 or 2 are met, Northeastern University is *not* engaged in human subjects research. If one or more of Criteria 2 are met, please continue to Criteria 3 and Criteria 4 for possible exceptions.**  |

**Criteria 3: Conditions in which Northeastern University is not engaged even if one or more conditions under Criteria 2 are met:**

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| [ ]  | Northeastern University employees or agents perform commercial or other services for investigators provided that all of the following conditions also are met:* the services performed do not merit professional recognition or publication privileges;
* the services performed are typically performed by those institutions for non-research purposes; and
* the institution’s employees or agents do not administer any study intervention being tested or evaluated under the protocol.
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| [ ]  | Northeastern University employees or agents:* inform prospective subjects about the availability of the research;
* provide prospective subjects with information about the research (which may include a copy of the relevant informed consent document and other IRB approved materials) but do not obtain subjects’ consent for the research or act as representatives of the investigators;
* provide prospective subjects with information about contacting investigators for information or enrollment; and/or
* seek or obtain the prospective subjects’ permission for investigators to contact them.
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| [ ]  | Northeastern University employees or agents release to investigators at another institution identifiable private information or identifiable biological specimens pertaining to the subjects of the research. Note that, if the identifiable private information or identifiable biological specimens to be released were collected for another research study covered by 45 CFR part 46, then the institution releasing such information or specimens should:* ensure that the release would not violate the informed consent provided by the subjects to whom the information or biological specimens pertain (under 45 CFR 46.116), or
* if informed consent was waived by the IRB, ensure that the release would be consistent with the IRB’s determinations that permitted a waiver of informed consent under 45 CFR 46.116 (c) or (d).
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| [ ]  | Northeastern University employees or agents:* obtain *coded* private information or human biological specimens from another institution involved in the research that retains a link to individually identifying information (such as name or social security number); and
* are unable to readily ascertain the identity of the subjects to whom the coded information or specimens pertain because:
	+ the institution’s employees or agents and the holder of the key enter into an agreement prohibiting the release of the key to the those employees or agents under any circumstances;
	+ the releasing institution has IRB-approved written policies and operating procedures applicable to the research project that prohibit the release of the key to the institution’s employees or agents under any circumstances; or
	+ there are other legal requirements prohibiting the release of the key to the institution’s employees or agents.

*coded* means that:* identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, and/or combination thereof (i.e., the code); and
* a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.
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| [ ]  | Northeastern University employees or agents access or utilize individually identifiable private information only while visiting an institution that is engaged in the research, provided their research activities are overseen by the IRB of the institution that is engaged in the research. |
| **STOP: If none of the conditions under Criteria 1 apply and all activities fully meet the conditions under Criteria 3 above, Northeastern University is not considered to be engaged in human subjects research. If Criteria does not apply, you can review Criteria 4 below.**  |

**Criteria 4: Unlikely and uncommon conditions in which Northeastern University is not engaged even if one or more of Criteria 2 are met.**

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| *Note that these additional criteria are very unlikely to apply to NU given the type of institution we are. They are listed below for the sake of completeness and the unlikely event they may apply.*  |
| [ ]  | Northeastern University is not selected as a research site whose employees or agents provide clinical trial-related medical services that are dictated by the protocol and would typically be performed as part of routine clinical monitoring and/or follow-up of subjects enrolled at a study site by clinical trial investigators (e.g., medical history, physical examination, assessment of adverse events, blood test, chest X-ray, or CT scan) provided that all of the following conditions also are met:* the institution’s employees or agents do not administer the study interventions being tested or evaluated under the protocol;
* the clinical trial-related medical services are typically provided by the institution for clinical purposes;
* the institution’s employees or agents do not enroll subjects or obtain the informed consent of any subject for participation in the research; and
* when appropriate, investigators from an institution engaged in the research retain responsibility for:
	+ overseeing protocol-related activities; and
	+ ensuring appropriate arrangements are made for reporting protocol-related data to investigators at an engaged institution, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol.
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| [ ]  | Northeastern University is not initially selected as a research site whose employees or agents administer the study interventions being tested or evaluated under the protocol limited to a one-time or short-term basis, provided that all of the following conditions also are met:an investigator from an institution engaged in the research determines that it would be in the subject’s best interest to receive the study interventions being tested or evaluated under the protocol;* the institution’s employees or agents do not enroll subjects or obtain the informed consent of any subject for participation in the research;
* investigators from the institution engaged in the research retain responsibility for:
	+ overseeing protocol-related activities;
	+ ensuring the study interventions are administered in accordance with the IRB-approved protocol; and
	+ ensuring appropriate arrangements are made for reporting protocol-related data to investigators at the engaged institution, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol; and
* an IRB designated on the engaged institution’s FWA is informed that study interventions being tested or evaluated under the protocol have been administered at an institution not selected as a research site.
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| **STOP: If none of the conditions under Criteria 1 apply and all activities fully meet the conditions under Criteria 4 above, Northeastern University is not considered to be engaged in human subjects research.**  |

**Note that if you require documentation from the Northeastern IRB that Northeastern is not engaged in human subjects research, please submit the following to** **IRBReview@northeastern.edu****:**

* **This completed checklist that is signed and dated.**
* **A detailed description of why the listed criteria applies.**
* **Copies of any supporting documents (for example, Data Use Agreements, etc) which support the determination along with a clear description of why the document supports the determination.**
* **A description of why a determination is required. For example, copies of the program officers request for an official determination can be supplied.**