**Multi-site Review Plan**

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

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| **When to use this form:** Please list all non-NU institutions where agents of the institution will be helping facilitate research and Northeastern (NU) will be a reviewing IRB. Include all institutions where agents of that institution will be involved in: 1) project oversight and/or implementation, 2) recruitment, 3) obtaining informed consent, or 4) data collection, analysis of identifiable data, and/or follow-up. **Please copy and paste text fields to add additional non-NU sites.** Note: * NU typically does not enter into reliance agreements for Exempt research. For exempt research, the site investigators should consult with their institution’s IRB to ensure they are following their site’s requirements for exempt research or research teams should develop a training and oversight plan for non-NU collaborators.
* Submit this form (with a modified study protocol form): IRBReview@northeastern.edu
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**Definitions:**

**Site or Institution** means any public or private entity, or department or agency (including federal, state, and other agencies). 45 CFR 46.102 (f)

For purposes of this document, an institution’s employees or agents refers to individuals who: (1) act on behalf of the institution; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities. “Employees and agents” can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.

**Engagement**. In general, an institution is considered engaged in a particular human subjects research project when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research. However, OHRP engagement guidance should be consulted when exploring whether an institution is or is not engaged. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html>

**Federalwide Assurance (FWA)** is an assurance of compliance with the U.S. federal regulations for the protection of human subjects in research. An FWA is submitted and approved by OHRP under DHHS. It is usually required whenever an Institution conducts federally funded non-exempt human subjects research.
More information can be found here: <https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/forms/fwa-instructions/index.html>
You can search for and find details about individual FWAs here: <https://ohrp.cit.nih.gov/search/>

**PROTOCOL INFORMATION (NU)**

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| **Principal Investigator (NU):** Click or tap here to enter text. |
| **Student Investigator (NU) [if applicable]:** Click or tap here to enter text. |
| **IRB Number [if available]:** 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:** 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.**Lead Institution on Grant:** Click or tap here to enter text. |

**NON-NU SITES** (copy for each site)

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| **Site Name:** Click or tap here to enter text. |
| **Site Location (state or country):** Click or tap here to enter text. |
| **Site PI Name:** Click or tap here to enter text.  |
| **Site PI Email:** Click or tap here to enter text. |
| **Provide a summary of the institution's or site's role in the research and what study activities they will be performing.** Please note that the protocol document will need to be updated to explicitly describe the specific procedures carried out by site investigators. Click or tap here to enter text.**Check each type of research activity that will be conducted by investigators at or from the site:**[ ] Project design [ ]  Recruitment [ ] Obtaining informed consent[ ] Data collection (including secondary data from medical records)[ ]  Data analysis[ ] Access to identifiable or coded data |
| **Does the site have an IRB or other Ethics Review Processes for Human Subjects Research?** Please explain and provide the site’s IRB/HRPP contact information:Click or tap here to enter text. |
| **Review Path:**[ ]  **Site Not Engaged. IRB Review Not Required.** *Explain why the site is not engaged/site investigators are not conducting human subjects research activities and provide any official determination provided by the site:* Click or tap here to enter text.[ ]  **Site is Engaged, has a FWA, and Requests to Rely on NU IRB Review.**[ ]  Reliance Agreement is pending and site will not begin working until the agreement is finalized.[ ]  Reliance Agreement is finalized. *Date of agreement and NU reference number:* Click or tap here to enter text.[ ]  **Site is Engaged and Site IRB Will Conduct Own IRB Review: Study is not federally funded.** [ ]  Site has already approved and approval is attached.[ ]  Site review is pending. *Describe the plan for obtaining approval:* Click or tap here to enter text.[ ]  **Site is Engaged and Will Conduct Own IRB Review: Study is federally funded, an exemption to the single IRB mandate was obtained, and the site has FWA.** *Describe why an exemption to single IRB is requested and provide a copy of the grant or exception request. Please also explain when the site will conduct review or submit a copy of their approval:* Click or tap here to enter text.[ ]  **Site is Engaged but has no FWA OR is an International Site.** *Please explain the situation and how IRB oversight or coverage will be handled. Outline any oversight plans or training that will be implemented. Note that NU generally does not enter into reliance agreements with international sites*: Click or tap here to enter text.[ ]  **Other.** *Please explain the situation and how IRB oversight or coverage will be handled. Outline any oversight plans or training that will be implemented*: Click or tap here to enter text. |
| **Describe how communication will occur between the NU study team and the site study team for discussion of study conduct, unexpected problems, modifications, and interim results.** *Consider:** *how frequently communication will occur between sites*
* *how are sites instructed to report unanticipated problems, adverse events, or noncompliance*
* *how sites can communicate needed revisions to study procedures*
* *who will disseminate IRB decisions*
* *who will notify the IRB of potential problems and changes to the protocol*

Click or tap here to enter text. |
| **Has a Conflict of Interest been identified for any investigators at this local site?** [ ] No [ ] Yes. Describe the Conflict of Interest: Click or tap here to enter text.  |
| **Describe any local laws, regulations, community consideration, or other context might impact the conduct of this study as it relates to this site:**Click or tap here to enter text. |