**SECONDARY & SPECIMEN PROTOCOL APPLICATION FORM**

**Protocol Version Date[[1]](#footnote-2):** Click or tap here to enter text.

Before completing this application, please familiarize yourself with the [*Policies and Procedures for Human Research Protections*](https://research.northeastern.edu/hsrp/hsrp-manual/) to understand the responsibilities for which you are accountable as an investigator in conducting research with human participants

This application form is intended for research projects where the procedures **exclusively** consist of the analysis of identifiable secondary data and/or specimens, with no involvement of the research team in direct contact with individuals associated with the data or specimens AND no other study procedures. If your project falls outside of this scope, please do not submit using this form.

**It is the policy of Northeastern University [NU] that no activity involving human subjects be undertaken until those activities have been reviewed and approved by the University's Institutional Review Board (IRB).**

**Application material need to be submitted to** [**IRBReview@northeastern.edu**](mailto:IRBReview@northeastern.edu)**.**

Only complete applications will proceed for review. A complete application includes:

* A signed [PI Assurance Form](https://research.northeastern.edu/hsrp/forms/)
* Letters of support from any physical non-NU locations where research will occur as applicable
* CITI training completion dates for study team members. Information about how to access and complete required training can be found on our [website](https://research.northeastern.edu/hsrp/training/)**.**

**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. |

**Revision History (for changes submitted to the IRB after approval):**

|  |  |  |
| --- | --- | --- |
| Revision number | Submission Date | Reason for change |
| 1 |  |  |
| 2 |  |  |
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| 4 |  | (Add additional lines as needed) |

1. **INVESTIGATOR INFORMATION**

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| **Principal Investigator *(PI cannot be a student)* ­­­­­­­­­­­­­­** Click or tap here to enter text.  **CITI Human Subjects Research course completion date:** Click or tap to enter a date.  **Investigator is:**  NU Faculty  NU Staff  Other:  **College:** Click or tap here to enter text.  **Email:**  Click or tap here to enter text.  **Dual Appointments:** does the PI also have any non-NU appointments at any other universities, hospitals, or other institutions that conduct research?  No other appointments or positions  Has one or more other appointment(s) or position(s). Please explain the position and how the position might or might not relate to this research project: Click or tap here to enter text. |
| **Is this student/postdoc/trainee research?**   Yes  No  If yes, please provide the following information:  **Student/Postdoc/Trainee Name:** Click or tap here to enter text.  **CITI Human Subjects Research course completion date:** Click or tap to enter a date.  Undergrad  Grad Student  Postdoc  Other: Click or tap here to enter text.  **College:** Click or tap here to enter text.  **NU** **Email:**  Click or tap here to enter text.  **Dual Appointments:** does the student/postdoc/trainee also have any non-NU appointments at any other universities, hospitals, or other institutions that conduct research?  No other appointments or positions  Has one or more other appointment(s) or position(s). Please explain the position and how the position might or might not relate to this research project: Click or tap here to enter text.  **Oversight Plan:** How will communication occur between the PI and student/postdoc/trainee researcher to ensure appropriate oversight of study conduct, unexpected problems, project modifications, and interim results?: Click or tap here to enter text. |
| **Other Investigators**  Are there other investigators working on the project:  No. Only the PI and student (if listed) will be working on the project.  Yes. Submit a **Research Team Form.** |
| **Multisite or Collaborative Research**  Will the study involve any collaborators outside Northeastern?  No. Only the PI, student (if listed) and other named NU personnel will be working on the project.  Yes. Submit a **Reliance Plan Form.** |
| **Investigator Qualifications.**  Please identify any special qualifications or experience the research team has conducting the procedures and/or working with the population.  Click or tap here to enter text. |

1. **CONFLICTS OF INTEREST**

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| **Does the PI or student investigator (or any of their immediate family members) have a financial interest or fiduciary relationship with the research sponsor?**  Yes No  Click or tap here to enter text. |
| **Does the PI or student investigator (or any of their immediate family members) have a financial interest or fiduciary relationship that is related to the research?**  Yes No  Click or tap here to enter text. |
| **Are two or more members of the same family acting as research team members on this protocol?**  Yes No  Click or tap here to enter text. |

1. **RESEARCH SUMMARY**

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| **In lay language, describe the objective, specific aims and state the hypotheses to be tested.** How is the study intended to be generalizable beyond the specific context in which the data/specimens were collected?  Click or tap here to enter text.  **If you are developing an algorithm/clinical decision tool/artificial intelligence/machine learning tool** describe whether the Algorithm/Product/Software is intended to become proprietary, and if it will be commercialized outside of NU.  Click or tap here to enter text. |
| **Background.** Describe the study’s background via a short summary. Outline what is currently known from the existing literature/scholarship and explain the gap in the literature that this research aims to address. Use lay language whenever possible. Length should be commensurate with risk and study size.  Click or tap here to enter text. |

1. **DATA/SPECIMEN INFORMATION**

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| **List the estimated total individuals about whom the data and or specimens will be from/about**  Click or tap here to enter text. |
| **Inclusion/Exclusion Criteria: Describe the population characteristics that will determine which data/specimens you analyze for this study** (e.g., diagnosis with certain medical conditions/diseases, specific age range, gender, location…)  Click or tap here to enter text.  **Age & Enrollment goal**  Data/specimens from/about Adults (18+ years old), specify age range: Click or tap here to enter text.  Data/specimens from/about Minors (≤17 years old), specify age range: Click or tap here to enter text.  Click or tap here to enter text.  Age of the individuals unknown. Please explain: Click or tap here to enter text.  **Populations discernable in the data:**  Parolees or incarcerated individuals  Members of a recognized American Indian or Alaskan Native tribe  (provide details related to tribal approval if so)  Wards of the state or Emancipated Minors  Pregnant women or fetuses  Undocumented individuals |

1. **DATA/SPECIMEN DETAILS**

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| **Describe all the data elements and/or specimens you will be accessing and using.** List specific data elements you will have direct access to and, if you won’t be using all the data you will have access to, describe the data elements you plan to document and/or analyze. If available, please include web links to dataset descriptions or submit copies of any data dictionaries or data collection sheets/codebook that offer contextual information.  Click or tap here to enter text. |
| **Describe why the data or specimens were originally collected.** Explain if the data/specimens were collected in a previous research study, collected as part of a government program or as part of an organization’s standard operations, or for other purposes.  Click or tap here to enter text. |
| **Detail whether any of the following are brought to a Northeastern research laboratory for further experimentation:** microorganisms or infectious materials; nanomaterials; genetically modified primary cells or cell lines; genetically modified live or live-attenuated microbes (e.g., bacteria, fungi, virus, etc.); toxins; environmental samples; human cells, cell lines, stool samples, or other human source materials; and human blood, blood products or tissue**. (Note: If yes, then IBC or other ancillary review may be required.)**  Click or tap here to enter text. |

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| **Describe if any codes, subject IDs, participant numbers, or other unique identifiers are recorded with the data**. If yes, describe:   1. Whether or not the data provider can link the code back to identifiers   And   1. Describe weather or not anyone on the NU research team can link the code back to identifiers. If the NU research team will have access to the key, where will the key linking the codes to identifiers be stored?   Click or tap here to enter text. |

1. **WAIVER OF INFORMED CONSENT**

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| **In this section, the term “participant” refers to individuals from whom the data or specimens were gathered and/or are about.** |
| **Describe if participants gave permission for future uses of the data or specimens when they were originally collected.** Outline what they agreed to and submit copies of any agreements, consent forms, etc that might be available.  Click or tap here to enter text. |
| **Describe why the research cannot practicably be carried out without the waiver or alteration**. Highlight the specific reason why are you are unable to contact participants or why contacting participants to obtain consent from participants would render the study impractical or unviable.  Click or tap here to enter text. |
| **Describe why this study can only be carried out using identifiable or de-identified information/biospecimens.** Why would it be impossible to conduct the study using only anonymous information/biospecimens? Studies with Department of Justice funding may state “Not applicable.”  Click or tap here to enter text. |
| **Describe why the waiver or alteration will not adversely affect the rights or welfare of the participants.** Why would this consent waiver will not violate any of the participant’s rights, expectations, or adversely affect their welfare?  Click or tap here to enter text. |
| **Describe whether or not participants will be provided with additional pertinent information after participation and, if not, explain why:**  Click or tap here to enter text. |
| Note that secondary data or specimen studies are still required to meet the regulatory requirements for a waiver of informed consent (even if participants agreed to have their data used for future research studies). You will need to respond to each prompt with a direct and clear answer to document why a waiver applies. |

1. **DATA/SPECIMEN ACCESS**

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| **Describe who will provide the study team with the data or specimens you plan to use.** If you already have access to the data or specimens, describe the role, job position, or capacity that grants you access.  Click or tap here to enter text. |
| **What permission(s) or requirements are needed to access and analyze the data or specimens?**  Note that having access to the data for non-research purposes is not equivalent to having permission to use it for research purposes. Please provide copies of any determination or requirement agreements (can be incomplete).  Click or tap here to enter text.  *NOTE: If you wish to access* ***Northeastern University******student education records*** *for analysis and are unsure whether you must obtain student consent to access those records for research purposes, please contact the NU Registrar’s Office. See the university policy at:* [*https://registrar.northeastern.edu/article/student-data-policies-for-employees/*](https://registrar.northeastern.edu/article/student-data-policies-for-employees/)*.*  *For research projects that wish to access* ***student education records held by other institutions*** *(including other universities, and K-12 schools), you will need to verify with the institution holding the data that appropriate steps are in place to ensure FERPA compliance.* |
| *NOTE: Data providers often require that the researcher enter into a data sharing agreement or other type of agreement setting forth data security requirements and associated non-disclosure agreements. In all of these cases,* ***principal investigators must determine if they have the capability to meet the data security requirements*** *– if you need assistance with compliance with data security requirements, please contact Northeastern University privacy office.*  ***Researchers cannot sign a DUA, DTA, or MTA on behalf of the University*** *– the agreement must be submitted to the NU-RES for review and signature. Direct all requests to* [NU-RES@northeastern*.edu*](mailto:NU-RES@northeastern.edu)*.* |
| *NOTE: For studies that involve* ***medical record data,*** *if the data are protected health information (PHI) under HIPAA, the HIPAA Privacy Board review and approval will be required.* |

1. **ANALYSIS AND SECURITY PLAN**

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| **Describe the data or specimen analysis plan, including any statistical procedures and/or analysis.**  Click or tap here to enter text. |
| **Select all methods used to safeguard research records during storage (select any that apply):**  **Data Management Practices**  Direct identifiers are removed from collected data or specimens as soon as possible  Direct identifiers (including the key/master list) are destroyed as soon as possible  Direct identifiers are removed and data or specimens is coded as soon as possible. The master list or key linking codes to identifiers is stored separately from the data or specimens  **Offline Digital Data Collection and Storage (tablet, laptop, thumb drive, etc):**  Offline digital data is collected and stored only using NU secured and owned devices, *please specify:* Click or tap here to enter text.  Offline digital data is collected and stored using personal or other non-NU owned devices, *please specify and outline how these devices will be secured:* Click or tap here to enter text.  Data will not be collected or stored using an offline device.  **Online or Cloud Digital Data Collection and Storage (Discovery Cluster, Google Drive, Qualtrics, etc)**  Online or cloud digital data is collected and/or stored using NU-approved platforms using only NU-official account login credentials, *please specify:* Click or tap here to enter text.  Online or cloud digital data is collected and/or stored using personal or other non-NU owned devices, *please specify and outline how these devices will be secured:* Click or tap here to enter text.  Data will not be collected or stored using an online or cloud platform.  **Physical Material Storage (paper consent forms/surveys/notes, flash drives, physical specimens, etc)**  Yes: describe where physical materials will be collected or stored*:* Click or tap here to enter text.  No physical materials will be collected or stored.  **Other methods to secure data not described above:**  Click or tap here to enter text. |
| **Describe if the data provider places any restrictions on how the data can be accessed or where the data can be stored.**  Click or tap here to enter text. |

1. **RISKS AND BENEFITS**

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| **Discuss possible risks (both the probability of the risk and the magnitude of the risk) that could occur if there were a breach of confidentiality (social, economic, legal, reputational, or other possible harms to individuals or a community/group).**  Click or tap here to enter text. |
| **Describe any safeguards that will be implemented to minimize risk.**  Click or tap here to enter text. |
| ⁎ **Student Researchers Only**: If your study may involve risks to participants, explain how you will check in with your PI and receive appropriate supervision while carrying out the study.  Click or tap here to enter text. |
| **Discuss any potential benefits of this project to society** Click or tap here to enter text. |

1. **DISSEMINATION AND FUTURE USES OF DATA**

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| **Check all that apply:**  Data or specimens will only be used for this research study to accomplish the aims/goals outlined in this Project and **will not** be reused in the future for any purpose.  Anonymized data or specimens will be stored and might be used for future research and may be shared with other researchers for their own studies. If yes, explain how data will be anonymized including how any code/master list will be destroyed: Click or tap here to enter text.  Coded or directly identifiable data might be used for future research and may be shared with other  researchers for their own studies or added to a registry. If yes, explain how this data will be used in the future and the privacy and confidentiality measures you will implement for these uses: Click or tap here to enter text. |
| **Will any identifiers (including audio or video recordings and photographs) be published, shared, or otherwise disseminated?**  Yes No |
| **Describe if the data provider places any restrictions on how the data can be retained or used in the future.**  Click or tap here to enter text. |

**DOCUMENTS AND ATTACHMENTS**

List all documents relevant to this research study and provide a version date for each. Documents may be added, modified, or removed any time after initial approval is granted by submitting a modification to the IRB. The version date should be updated to reflect this change. Add additional rows, as needed.

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| Document Name | Description of document use | Version Date |
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**Please submit a signed PI assurance form**

1. This date is to be updated whenever modifications are made to an approved IRB protocol application [↑](#footnote-ref-2)