**PROTOCOL NON-EXEMPT APPLICATION FORM**

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

|  |
| --- |
| **Note: This is a revised protocol application form. Beginning September 11, 2023, all prior versions of the application form will not be accepted.** |

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

**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/) **[Note: this is a separate form and can be found on the Forms page of the IRB website.]**
* Informed consent materials including: consent forms or verbal scripts
* All data collection instruments to be used in the study including: survey questions, interview guides, and/or other data collection sheets.
* Letters of support from any physical non-NU locations where research or recruitment will occur.
* 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**

|  |
| --- |
| **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**

|  |
| --- |
| **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 |  |  |
| 3 |  |  |
| 4 |  | (Add additional lines as needed) |

1. **INVESTIGATOR INFORMATION**

|  |
| --- |
| **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**

|  |
| --- |
| **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 LOCATIONS**

|  |
| --- |
| A ***research location*** is a location or place where the NU researchers will conduct the research procedures. Examples: lab space, schools, community centers, public venues  **Where will study activities occur? Outline each location, describe what activities will occur at each.**  Click or tap here to enter text.  Research teams are responsible for obtaining letters of approval, permission, or support from each research location before any research activities begin. Please keep in mind that if you plan to do research in K-12 schools, some school systems require an additional research review process. |
| **Will any study activities (data collection, recruitment, or other) occur internationally or is it likely that participants will be international participants? If you plan to conduct research using online activities, explain whether you anticipate your participants may reside outside the United States.**  Yes No  **If yes, complete the International Research Form.**  NOTE: If you plan to collect data **from individuals located in the European Economic Area**, you must consider the General Data Protection Regulations (GDPR), other laws such as the China PIPL may apply, plan accordingly based on your study population. |

1. **RESEARCH SUMMARY**

|  |
| --- |
| **In lay language, summarize the objective and significance of the research.**  Click or tap here to enter text. |
| **Background and Lit Review.** 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. Where relevant, include citations. Use lay language whenever possible. Length should be commensurate with risk and study size. Exempt research can be ~1-2 sentences.  Click or tap here to enter text. |

1. **PARTICIPANT INFORMATION**

|  |
| --- |
| **List the estimated total number of participants**  Click or tap here to enter text. |
| **Describe all inclusion and exclusion criteria/the population being recruited**  Click or tap here to enter text.  **Select all participant populations that will be recruited, either intentionally or are likely to be included.**  **Age & Enrollment goal**  Adults (18+ years old), specify age range: Click or tap here to enter text.  Minors (≤17 years old), specify age range: Click or tap here to enter text.  Click or tap here to enter text.  **Other populations targeted or discernable:**  Individuals with low literacy levels  Individuals who are cognitively impaired or legally unable to consent.  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 |
| **If the study will enroll limited or non-English fluent individuals or uses translated materials, submit a completed** [**Certificate of Translation form**](https://research.northeastern.edu/hsrp/forms/)**.** Translated materials may be submitted at a later date after initial approval.  Click or tap here to enter text. |

1. **RECRUITMENT PROCEDURES**

|  |
| --- |
| **Select all recruitment procedures that will be used.**  Student subject pool e.g., Psychology subject pool, *please specify*: Click or tap here to enter text.  Social Media (Facebook, Twitter, etc)  Email distribution  MTurk, Qualtrics Panel, or similar online population  US Mail  Flyers  Website ad, online announcement, internal or external to NU  Verbal announcement  Other, *please specify*: Click or tap here to enter text.  Not applicable (secondary data only)  **Attach all recruitment material with your application.** |
| **For each group of participants, describe the details of the recruitment process. Include how potential participants will be identified, who will recruit participants and what type of recruitment material will be used..**  Click or tap here to enter text. |
| **Select all that apply.**  Eligibility is assumed due to the population being recruited or by virtue of responding to  recruitment materials.  Eligibility is confirmed via a screening tool or process(screening questions, survey, interview, etc).  Eligibility will be confirmed via secondary data (chart review, student records, etc).  **Narratively describe any screening processes selected above.** Be sure to also upload any questions/materials you might use to screen.  Click or tap here to enter text. |

1. **STUDY PROCEDURES**

|  |
| --- |
| **Select all research methods and/or data sources that apply.**  Surveys, Questionnaires, Interviews, or writing prompts  Focus groups  Observations  Cognitive or aptitude tests  Physiological measurements, e.g., EEG, MRI  Mobile applications or devices (fit bits, etc.)  Intervention (behavioral or biomedical)  Using custom devices or custom software developed by the study team  Recording audio and/or video and/or taking photographs  Data that have already been collected or already exist,  Other, *please specify*: Click or tap here to enter text.  **Describe each research procedure checked above, the order in which they will be conducted and the duration of each procedure and the total duration of participating in the study.**  Click or tap here to enter text. |
| **List all research instruments, surveys, interview guides, etc. that will be used in this research along with how long each instrument is expected to take. Attach all instruments, surveys, interview questions, data collection forms, intervention materials, etc.**  Click or tap here to enter text. |
| **Who will conduct the research procedures; collect data; administer surveys, etc.**  Click or tap here to enter text. |
| **Describe where research activities will take place and which activities will take place at each locations (e.g. a NU lab, via Zoom, an online survey platform like Qualtrics, etc).**  Click or tap here to enter text. |
| **How many times will participants engage in research activities, what is the timing between sessions, and what is the duration of each activity?**  Click or tap here to enter text. |
| **If the study will audio or video record participants, describe who will be recorded, describe if it is optional (and how/when participants will be informed of this), and the analysis/dissemination plan for the recordings.**  Click or tap here to enter text. |

1. **CONSENT, ASSENT, AND PARENTAL PERMISSION**

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Describe how, when and where the consent forms will be presented and distributed to potential participants.**  Click or tap here to enter text.  **Describe how the consent materials will be distributed to participants.**  Click or tap here to enter text.  **Will a 1:1 consent discussion occur between a study team member and each prospective participant?**  Yes, *please outline what will be discussed*: Click or tap here to enter text.  No, *please explain why a discussion is not practicable*: Click or tap here to enter text.  **How will consent be documented?**  Physical signature  Digital or e-signature, *please specify platform*: Click or tap here to enter text.  Providing an exempt participant information sheet (for exempt research)  Requesting a waiver of documentation of consent (for verbal, ‘implied’, or online consent), *please explain why*: Click or tap here to enter text.  Requesting an alteration of consent (in cases of deception or incomplete disclosure), *please explain*: Click or tap here to enter text.  Requesting a waiver of consent or waiver of parental permission (if you will not be obtaining consent or parental permission, explain below. Waiver criteria must be met.  **To request a complete waiver of consent OR an alteration of consent, explain for each criteria:**  i) The study is no more than minimal risk to the participants Click or tap here to enter text.  ii) You could not practicably carry out the research without the requested waiver or alteration Click or tap here to enter text.  iii) If the research involves using identifiable private information or identifiable biospecimens, you could not practicably carry out the research without using such information or biospecimens in an identifiable format; Click or tap here to enter text.  iv) The waiver or alteration will not adversely affect the rights and welfare of the participants Click or tap here to enter text.  v) Whether you will provide participants with additional pertinent information after participation (i.e, whether you will debrief participants). Click or tap here to enter text.  **For studies using multiple consent/assent documents, please describe the consent process for each.**  \*Please note that you must obtain parental permission and child assent for children's participation in research unless the IRB grants a waiver of parental permission. The IRB expects you to use and document the assent process with children ages 7 years to 17 years old, unless special circumstances justify a waiver of assent. You must tailor the assent process to the reading and comprehension levels of the children you plan to enroll in your study.  **Will the consent form disclose all study activities and research purposes or will the study involve incomplete disclosure?**  Click or tap here to enter text.  **Additional Considerations for the Consent Process and Forms:**  \*If you plan to use incomplete disclosure (withholding information about the study purpose during the consent process) or deception (purposely misleading participants by providing them with overt misdirection or false information about some aspect of the research during the consent process), provide a rationale explaining why it is necessary to the research.  \*If you plan to obtain approval to access identifiable student educational records protected by the FERPA law, FERPA requires that the consent to access FERPA-protected information be signed and dated by the student (or the student's parent, depending on what level of school the student is enrolled in).  \*If you plan to access **HIPAA Protected Health Information (PHI) from medical records** for recruitment and eligibility screening purposes and/or to analyze as research data, **you must explain what PHI data you plan to access, from what source, and under which HIPAA pathway you plan to access that data.**  **List all consent documents used and provide all copies of consent/assent forms and scripts, including online consents. Add additional lines as needed. Click** [**here**](https://research.northeastern.edu/hsrp/forms/) **for consent form templates.**   |  |  |  | | --- | --- | --- | | Document Name | Type (verbal script, signed consent, etc. | Population and purpose | | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | |

1. **SUBJECT COMPENSATION**

|  |
| --- |
| **Will subjects receive compensation or rewards before, during, or after participation?**  Yes No  **If yes, provide a brief description of compensation or rewards, including amount, payment frequency/schedule (including pro-rating), payment method (e.g., gift card, cash), and any odds of winning a raffle/etc.**  Click or tap here to enter text. |

1. **DATA ANALYSIS**

**Does the study include secondary analysis of identifiable data that was or will be collected for a different purpose?**

Yes  No

***If you answered yes, please complete the following sections.***

**What is the original source of data? (Check all that apply):**

Survey/Questionnaire  Department Data

Medical Records/Charts  Student Data

Previous IRB Approved Study  Institutional Research & Assessment

Interview transcripts Other, *please specify*: Click or tap here to enter text.

**Describe the elements, characteristics, and variables of the dataset(s) or provide a code book containing only the data elements you will be analyzing:**

Click or tap here to enter text.

**What permission(s) do you have to access and analyze the dataset?**

Describe the investigator, agency or institution granting access and permission for secondary analysis of the data for research purposes. Note that having access to the data for non-research purposes is not equivalent to having permission to use it for research purposes.

Click or tap here to enter text.

1. **RISKS AND BENEFITS**

|  |
| --- |
| **Select all potential risks that may result from taking part in the study**  Emotional (e.g. discussing sensitive topics, reliving troubling experiences)  Physical discomfort (including temporary pain, soreness, or discomfort by being touched by research staff)  Health or physical injury risks  Privacy and Confidentiality Risks  Social or financial risks  Professional risks  Population specific risks  Risks to individuals who are not the research participant (e.g. family members, research staff)  Potential for perception of coercion due to existing relationships (student/professor, employee/employer, etc)  Other risks not covered |
| **Narratively describe each potential risk including their magnitude and likelihood**  Click or tap here to enter text. |
| **Describe what safeguards will be implemented to minimize each 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. |
| **Indicate if this study will have a Data Safety Monitoring Board (DSMB) or a Data Safety Monitoring Plan (DSMP): [Required for all greater than minimal risk studies]**  No  Yes (please also submit a copy of your plan as a document) |
| **Describe any potential direct benefits to participants in this study. If there are no direct benefits,**  **please explain.**  Click or tap here to enter text.  **Explain why, in your opinion, the benefits of the study outweigh the possible risks.**  Click or tap here to enter text. |
| **Describe any potential for direct community impacts in this study (beyond the scientific knowledge created).**  Click or tap here to enter text. |

1. **CONFIDENTIALITY AND PRIVACY**

|  |
| --- |
| **Describe all identifiers collected or used at all stages of the project (including recruitment, data collection, and transmission). Identifiers include, but are not limited to, name, date of birth, email address, street address, phone number, audio or video recordings…**  Click or tap here to enter text. |
| **Describe if data will be coded or anonymized.**  Click or tap here to enter text.  **If the study will code (i.e. de-identify) the research data by replacing subjects’ names and/or other identifiers with assigned subject IDs, explain the following aspects of the coding process:**  - The process for how subject IDs will be generated/assigned (e.g. random, sequential)  - Whether there will be a key that links the subject ID with direct identifiers. If there will be no linkage key, state that.  - When identifiers will be replaced in each dataset/source of data.  Click or tap here to enter text.  **If a key will be created, describe:**  - The place where the key will be stored  - The role(s) of all individuals who will have access to the key  - When the key will be destroyed  Click or tap here to enter text. |
| **Select all methods used to safeguard research records during storage (select any that apply):**  **Data Management Practices**  Signed consent, assent, or parental permission forms are stored in a separate location from all data.  Direct identifiers are removed from collected data as soon as possible  Direct identifiers (including the key/master list) are destroyed as soon as possible  Direct identifiers are removed and data is coded as soon as possible. The master list or key linking codes to identifiers is stored separately from the data  **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. |
| **How long will identifiable data be kept? For interview and group recordings, when will these be destroyed following transcription?**  Click or tap here to enter text. |
| **Check provisions to protect the privacy interests of subjects.**  **In-person interactions or interventions:** All interactions or interventions will occur in a private setting where others cannot see or overhear activities. The study team will ask participants if they are comfortable answering questions in that location and setting Using generic signs on research rooms and spaces, particularly for research on stigmatizing or sensitive topics Other, *please specify*: Click or tap here to enter text.  **Remote interactions or interventions (Zoom, Teams, phone, etc):** Conducting activities in a private location by limiting people around to only study staff, closing doors, and wearing headphones.  Asking participants if they feel their own setting is appropriate for the discussion or intervention and that others won’t be able to overhear/oversee.  Ensuring that non-participants/individuals who did not consent are not captured in any video or audio recordings.  Offering a way to stop and resume later to the online activity if privacy is compromised Other, *please specify*: Click or tap here to enter text.  **In-person or remote group interactions or interventions (e.g. focus groups, group surveys, or family interactions):** Discussing the importance of not talking outside the group about what other people say during the group activities. Encouraging participants to use a pseudonym or limit the use of names or other details during the group activity Asking everyone in a public group setting (e.g. classrooms, workshops) to turn something in (blank or filled) so participants do not have to self-identify when turning in materials Documents will be collected in a box, envelope, etc to ensure others cannot see responses.  Other, *please specify*: Click or tap here to enter text.  **Communicating with participants via phone, email, text, or mail (including for scheduling, follow-up, etc):** Leaving/sending generic messages, emails, or letters that avoid using study and participant identifiers, such as names, clinics, study topics, etc. Obtaining permission prior to leaving voicemails or sending letters, emails, or text messages. Using generic return addresses, labels, or document headers that don’t suggest a research topic, lab, or department. Removing participant identifiers and study topics from voicemails, letters, emails, or text messages. Other, *please specify*: Click or tap here to enter text.  **Analyzing and disseminating data (Required for all studies)** Only publishing or presenting aggregate data or results (i.e. no individual-level information published or shared outside the research team). Analyzing data in a private space by limiting people around to only study staff, closing doors, and wearing headphones. Permanently blurring, hiding, or redacting any identifiable features (faces, tattoos, birthmarks, etc) before analyzing data. Removing any direct and indirect identifiers from any transcripts or open ended responses before analysis begins. Other, *please specify*: Click or tap here to enter text. |

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

|  |
| --- |
| **Check all that apply**  Data 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 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  If yes, the consent form should provide the opportunity for the participant to opt-out of this, or explicitly inform participants that it is required in order to participate in the study. |
| **Will the individual or aggregate results be returned to participants?**  Yes No  If yes, explain the plan to return results. Please specify what information will be returned, how results will be contextualized, how participants might use the results, and how you will ensure participant privacy and confidentiality in any communication attempts : Click or tap here to enter text. |

1. **DOCUMENTS AND ATTACHMENTS**

List all documents to be used in this research study and provide a version date for each. Documents may be added, modified, or removed any time after initial approval is granted. The version date should be updated to reflect this change. Add additional rows, as needed. Documents to include: protocol application (this form); consents and assent documents; consent/assent scripts; online consents; participant information sheet; all data collection documents to include: interview instruments; survey instruments (or a link to the actual survey); focus group instruments; and any other standardized tools used to collect data; recruitment material (both written and text for online recruitment). Add additional lines, as needed.

|  |  |  |
| --- | --- | --- |
| Document Name | Description of document use | Version Date |
|  |  |  |
|  |  |  |
|  |  |  |

**Please submit a signed** [**PI assurance form**](https://research.northeastern.edu/hsrp/forms/)

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