**EXEMPT PROTOCOL APPLICATION FORM**

Complete and submit this form, including all study materials, to request an exemption determination from the Northeastern University Department of Human Research. Are you using the correct form? See [Protocol Application Flowchart: what form do I need to submit](https://dhr.research.northeastern.edu/wp-content/uploads/2024/08/Protocol-Form-Flowchart-what-form-do-I-need-to-submit.pdf) if unsure.

Before completing this application, please familiarize yourself with the [Investigator Manual](https://hsrp.research.northeastern.edu/institutional-review-board/investigator-manual-2/) to understand the responsibilities for which you are accountable as an investigator in conducting research with human participants. For more information on exemption determination, eligibility criteria, and regulatory requirements for exempt studies, visit the [DHR Guidance Page](https://hsrp.research.northeastern.edu/forms-guidance/guidance/).

**Application materials need to be submitted to** **IRBReview@northeastern.edu****.**

# PROTOCOL INFORMATION

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| **Principal Investigator:** Click or tap here to enter text. |
| **NU College/Department:** 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 Sources (list agency and grant ID/title):** Click or tap here to enter text. |

## 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**](https://hsrp.research.northeastern.edu/institutional-review-board/training/) **completion date:** Click or tap to enter a date. **Investigator is:** [ ]  NU Faculty [ ]  NU Staff [ ]  Other: **NU Email:**  Click or tap here to enter text.**Dual Appointments:** does the PI also have any non-NU appointments or positions at any other universities, hospitals, or other institutions that conduct research or may be related to this 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 [ ]  NoIf 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 this investigator also have any non-NU appointments or positions at any other universities, hospitals, or other institutions that conduct research or may be related to this 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 NU Investigators**Are there other NU-affiliated investigators working on the human subjects research project?[ ]  No. Only the PI and student (if listed) will be working on the project.[ ]  Yes. Submit a [**Research Team Form**](https://hsrp.research.northeastern.edu/forms-guidance/forms/)**.** |
| **Other non-NU Investigators**Are there any non-NU investigators working on the human subjects research project?[ ]  No. [ ]  Yes. Please outline their affiliations and roles in the project, outline any potential conflicts of interest the collaborators may have related to the project, and detail the training, oversight, and communication plan for collaborators outside of NU. If the collaborators will be obtaining exemption determinations from another IRB, outline that plan. Please note that the NU IRB does not typically provide oversight for non-NU investigators on Exempt research: Click or tap here to enter text. |

## CONFLICTS OF INTEREST

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| **Does the PI or student investigator have a financial interest or fiduciary relationship to the research or research sponsor?**[ ] Yes [ ] No Click or tap here to enter text. |

## RESEARCH SUMMARY

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| **In lay language, summarize the objective of the research.** Click or tap here to enter text. |

## RESEARCH LOCATIONS

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| 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.**Have you obtained all required approvals/permissions at each research location, or will you obtain them before project implementation?** [ ]  Yes. Please attach documentation of site approval or permission in your submission.  [ ]  In Progress. Please reference your IRB # and submit documentation of site approval or permission to IRBReview@northeastern.edu when granted. [ ]  N/A \*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 and/or their data will be subject to GDPR, PIPL, or another international privacy law?**[ ] Yes [ ] No If yes, complete the International Research Form. Please note that this process is to ensure that relevant laws, policies, and regulations are being applied such as: GDPR, PIPL, country specific regulations, and other relevant policies. Please see [globalsafety.northeastern.edu](https://northeastern.sharepoint.com/sites/IRBReview/IRB%20Administrative%20Documents/IRB%20Forms/Drafts/globalsafety.northeastern.edu) and [security.its.northeastern.edu](https://security.its.northeastern.edu) for support.  |

## PARTICIPANT INFORMATION

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| **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. |

## RECRUITMENT PROCEDURES

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| **Select all types of recruitment materials that will be used. Be sure to attach all recruitment material with your application.** [ ]  Student subject pool posts e.g., Psychology subject pool, *please specify*: Click or tap here to enter text.[ ]  Social Media posts (Facebook, Twitter, etc)[ ]  Emails[ ]  MTurk, Qualtrics Panel, or similar online population posts[ ]  Postal Mail[ ]  Flyers[ ]  Website ad, online announcement, internal or external to NU[ ]  Verbal announcement or scripts, *please specify where*: Click or tap here to enter text.[ ]  Other, *please specify*: Click or tap here to enter text. |
| **For each group of participants, describe the details of the recruitment process.** * **How will potential participants be identified?**
* **How will participants be recruited and using what materials?**
* **How will participants be screened?**
* **Who will recruit participants?**

Click or tap here to enter text. |

## STUDY PROCEDURES

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| **Select all research methods and/or data sources that apply.**[ ]  Surveys, questionnaires, or writing prompts [ ]  Interviews[ ]  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. Include the order in which they will be conducted, the duration of each procedure, and the total duration of participating in the study.** Click or tap here to enter text. |

## PARTICIPANT INFORMATION SHEET (or “Exempt Information Sheet”)

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| **If a study is granted exemption from IRB review, a signed consent is typically not required, but the study will still require that that participants receive information about the study and indicate affirmative agreement to take part in the study. This is achieved via a participant information sheet in place of an informed consent form.** **Describe how the participant information sheet will be distributed to participants and how the research team will ensure participants agree to take part in the study.**Click or tap here to enter text.**Will the participant information sheet describe all research activities?** ☐ All study activities will be disclosed in the information sheet☐ The study involves deception or incomplete disclosure but the information sheet describes this. Please note that, to remain eligible for exemption, the subject must authorize the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.  |

## SUBJECT COMPENSATION

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| **Will subjects receive compensation or rewards for 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. |

## SECONDARY DATA ANALYSIS

**Does the study include secondary analysis of data that was or will be collected for a different purpose? Please note that this is for research studies that both collect prospective data AND use secondary data or data collected for non-research purposes. *(If you will not be able to access any identifiers, consider whether this project meets the*** [***definition of Human Subjects research***](https://hsrp.research.northeastern.edu/getstarted/)***.)***

[ ]  Yes [ ]  No

**If yes, what is the original source of the data?**

Click or tap here to enter text.

**Describe the 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.

## RISKS AND BENEFITS

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| **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 |
| **For any potential risks checked above, describe what safeguards will be implemented to minimize each risk.**Click or tap here to enter text. |

## CONFIDENTIALITY AND PRIVACY

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| **Select all identifiers collected or used at any stages of the project (including recruitment, data collection, and transmission):**[ ]  Names[ ]  Dates (date of birth or other dates)[ ]  Emails, phone numbers, or usernames[ ]  Street address or other location data[ ]  Audio recording[ ]  Video recording or photographs[ ]  Detailed demographic data[ ]  Other identifiers[ ]  No identifiers used or collected**Briefly describe the identifiers checked above:**Click or tap here to enter text. |
| **If data will be coded or anonymized, describe:*** When data will be coded or anonymized in each dataset.
* When and how identifiers will be destroyed (if data will not be coded)
* What identifiers will be removed from the data set
* How data might be processed to remove identifiers in data without clear identifiers (video footage, etc.).

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 subject ID with direct identifiers. If there will be no linkage key, state that.Click or tap here to enter text.**If a key will be created linking identifiers to subject IDs, describe:**- How the key will be stored separate from research data- The role(s) of all individuals who will have access to the key- When the key will be destroyedClick or tap here to enter text. |
| **Please describe how all data will be collected and stored.** **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:*  [ ]  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:* [ ]  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:*  [ ]  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:* [ ]  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*:* [ ]  No physical materials will be collected or stored. **Other methods to secure data not described above:**Click or tap here to enter text.**Please check to indicate that you have read and agree to comply with NU’s document management guidelines, which outline how research data can be collected, stored, and analyzed.** [ ]  I agree to comply with NU’s document management guidelines. All data will be collected and stored using platforms consistent with this policy/using services approved by OIS and any approvals required by OIS will be obtained before the research begins. Please note that all research data is considered Lock 4 data per NU policy. Please find guidance here: <https://uds.northeastern.edu/wp-content/uploads/New-Document-Management-Guidelines.pdf>. |
| **Check provisions that will be used 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 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 do not 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. |

## DISSEMINATION AND FUTURE USES OF DATA

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| **Will any identifiers (including audio or video recordings and photographs) be published, shared, or otherwise disseminated?** [ ] Yes [ ] No If yes, the participant information sheet 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. |

## DOCUMENTS AND ATTACHMENTS

**Make sure to submit all study materials including:**

[ ]  A complete protocol application (this form) with all relevant questions answered.

[ ]  A signed PI Assurance Form [Note: this is a separate form and can be found on the [Forms page](https://hsrp.research.northeastern.edu/forms-guidance/forms/) of the IRB website].

[ ]  All recruitment material, including but not limited to emails, scripts for verbal announcements, flyers, social media posts, etc.

[ ]  Participant information materials including exempt information sheet or verbal scripts, debriefing materials.

[ ]  All data collection instruments to be used in the study, including but not limited to survey questions, interview guides, and/or other data collection sheets.

☐ Any other participant-facing materials such as a video (or script of a video), still images, etc. If the research includes participant-facing materials you are unsure how to include, please reach out to the IRB team at IRBReview@northeastern.edu

☐ Letters of support from any physical, non-NU locations where research or recruitment will occur.

☐ Research Team Form (if the research team has NU personnel beyond the PI and student listed on this application) [Note: this is a separate form and can be found on the [Forms page](https://hsrp.research.northeastern.edu/forms-guidance/forms/) of the IRB website.]

☐ International Research Form (if conducting research internationally)

**Please submit a signed PI assurance form**