This template MUST be used for new Social Behavioral studies submitted in eIRB+ on or after February 4, 2022.

This protocol must be completed for human participant research studies **unless your study will ONLY involve secondary data and/or specimen analysis** (use **HRP-1704** for secondary data analysis/specimen analysis studies). Use this protocol template whether your study will be determined to be exempt or approved via other IRB review procedures (investigators do not make their own determination as to whether a research study qualifies for an exemption -- the IRB issues exemption determinations). **If you are unsure whether your project is human research requiring IRB review**, complete and submit **HRP-503** instead of this document.

It will be helpful to your submission to understand the type of review you are requesting. Further resources can be found on the Northwestern IRB website: **Types of Review** OR **Department of Health and Human Services (DHHS) Decision Trees.** DHHS has provided numerous decision trees regarding whether an activity meets the definition of human subjects research; whether research is eligible for a Claim of Exemption, and whether research can be reviewed via expedited review.

NOTE: Your consent documents, data collection instruments (surveys, questionnaires, interview guides, etc.), and recruitment materials need to be uploaded in eIRB+ in the consent, recruitment, and supporting documents sections of the application and should NOT be attached or incorporated into this protocol document. For any supporting documents you upload, please use filenames for the documents that make clear what type of document you are uploading. If your study will include multiple phases, please make sure the filename is clear as to which phase of the study the document is related to.

TIPS ON COMPLETING THE PROTOCOL FORM:

- If any sections are not applicable to your research, mark that section as N/A (for not applicable)
- Keep an electronic copy of your protocol. If you submit modifications to your study at a later time, you will need to include tracked changes to all affected study documents, including the protocol.
- As you write this protocol, remove the text boxes and all instructional text contained inside the text boxes in each section. There should be no text boxes or instructional text (including these instructions) in the final version of your protocol.
- 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 fill out and upload **Appendix B (HRP-1724)** in addition to this protocol document.

STUDY TITLE:

Include the full study title

PRINCIPAL INVESTIGATOR:

Name:
Department:

NOTE: Per Northwestern University policy, undergraduate and graduate students are not allowed to be the Principal Investigator on a research study. Visiting faculty, visiting scholars, postdoctoral fellows, and medical residents are not eligible to serve as Principal Investigator on a research study unless they obtain special permission. For further information on who is eligible to serve as a Principal Investigator, see https://irb.northwestern.edu/submitting-to-the-irb/initial-studies/principal-investigator-eligibility-and-permissions.html

CO-INVESTIGATORS:

Name:
Department:

NOTE: students should **not** be listed as co-investigators

STUDENT INVESTIGATOR (complete this section only if the project is student-initiated):

Name:
Department:

Are you an:
☐ Undergraduate Student
☐ Graduate Student or Medical Student

VERSION DATE:

Include the version date of this protocol (today's date)

RELATED STUDIES:

If any related NU IRB applications provide context for the activities covered by this IRB submission, please explain and provide the IRB study numbers for those related applications. (For example, if you plan to use samples or data collected by another study, recruit participants from a registry established by a colleague's research activity, or conduct a continuation of a prior study.)

Check any **applicable** boxes in the table below – you will be asked for further detail on these topics later in the protocol form:

Indicate Vulnerable Populations to be enrolled: ☐ Children ☐ Cognitively Impaired Adults ☐ Pregnant Women (IF the research activities will affect the pregnancy or the fetus) ☐ Prisoners (or other detained/paroled individuals)
☐ International Research (check this box if you will collect data from individuals located outside the United States)
☐ Research involving external collaborators (some research activities will be carried out by individuals not employed by Northwestern or NU affiliates will carry out some research activities)
☐ Research has U.S. Federal government funding via one or more direct awards or a sub-award (e.g., NIH, NSF, other federal agencies or departments)

1.0 Purpose and rationale of the study:

State the purpose of your study. Please also describe specific aims or objectives, or research questions that will guide your study. Explain briefly how the data you plan to collect ties in with your research questions – toward what ends are you collecting the data, and how those data connect to the research questions you seek to answer. Provide the scientific or scholarly background, rationale, and significance of the proposed research based on the existing literature and how it will add to existing knowledge. If your study will have multiple phases or sequential aims, please describe the purpose of each phase and whether you are only seeking IRB approval for certain phases of the study at this time. For example, if the initial phase of your study will involve preliminary activities such as literature review, please make that clear.

2.0 Enrollment Criteria (who can be in your study and who would not be eligible to participate in your study):

Briefly describe the inclusion/exclusion criteria (age range, gender, language, etc.) that define the participants you plan to include in your study population.

Indicate whether you will include any vulnerable populations. You may not include these populations as participants in your research unless you indicate this in your inclusion criteria:

- Adults unable to consent/Cognitively Impaired
- Individuals who are not yet adults (**specify the exact age range of children you plan to enroll**)
- Pregnant women (where the activities of the research may affect the pregnancy or the fetus)
- Prisoners or other detained individuals

* **Undergraduate Student Researchers Only**: It is unlikely that the IRB office would approve undergraduate researchers doing an independent project that plans to enroll prisoners, pregnant women (if the research activities may affect the pregnancy or the fetus), children, or cognitively impaired individuals as target populations.

3.0 Sample Size:

Briefly describe the anticipated total number of participants. If there will be multiple study sub-groups, describe how many participants you plan to enroll in each sub-group.

Justify the sample size – explain why this number of participants is needed to answer your research questions.

4.0 Recruitment and Screening Methods:

Be specific and spell out for the IRB how the recruitment process and any eligibility screening procedures will occur. Your recruitment plan should incorporate methods that specifically address, and detail how potential participants from particular racial and ethnic groups/under-represented populations (with respect to the study) will be recruited. This is to ensure that the recruitment plan is inclusive and representative of the eligible population within the location at which the research is being conducted, and considers the impact of the research on all such populations.

Explain step-by-step:

1) **how you will locate individuals who might be eligible to participate in your study;**
2) **how, where, and when you will contact people who might be eligible to participate in your study; and**
3) **how you will access/collect information to determine which people are eligible to participate in your study**

If you plan to use **online websites/platforms** (e.g., Facebook or Craigslist) for recruitment, specify which online venues you will use to post recruitment information and whether prior approval is required to post recruitment materials. If you will use a registry or subject pool, specify which one (for example, the Psychology 110 subject pool).

If you plan to collect data during the **Psychology 110 mass testing**, you must explain which data collection instruments you will use during the mass testing and for what purposes (eligibility screening or other purposes).

Some **crowdsourcing platforms and survey panels** include participants from outside the United States. If you plan to use a crowdsourcing platform/survey panel that could include individuals who reside outside the U.S., you must specify whether you will set the study qualifications only to include U.S. residents or not.

If you plan to send recruitment materials using a listserv, please check with the listserv administrator whether this is allowed.

If you plan to contact potential participants directly (by email, letter, phone, etc.), explain how you will obtain their contact information. In addition, explain whether other organizations or individuals beyond the NU research team will be involved in recruitment activities.

Note: For additional guidance on the recruitment process and documents, see: https://irb.northwestern.edu/resources-guidance/recruitment-materials-guidelines.html

Eligibility screening activities:

"Screening" is the term used to describe activities performed to ensure participants are qualified for the study. Screening activities may involve interaction or intervention with potential study participants (e.g., an online screening survey, a telephone interview) or accessing information about potential study participants from records (e.g., medical records, educational records). Researchers must protect the privacy of the potential participant and the confidentiality of information collected about him/her during the screening process.

Explain how the screening process will occur (e.g., telephone interview, online questionnaire, etc.) and what you will do with the data for people who are eligible and do participate in your study and for people who turn out not to be eligible for your study or are eligible and decide not to participate. Attach a copy of the screening questions/criteria to your eIRB+ application in the "Supporting Documents" section (not in this protocol document).

If you plan to obtain screening information from secondary sources (i.e.,

records/data not obtained directly from potential study participants), such as the Northwestern Medicine Enterprise Data Warehouse (NM EDW), or from other records (e.g., electronic medical records, student educational records), explain from which records/datasets you will obtain eligibility screening information.

If you plan to access medical record data for recruitment and eligibility screening purposes, you must fill out and upload Appendix B.

5.0 Research Locations:

A ***research location*** is a location or place where the NU researchers will conduct the research procedures. Examples: lab space at Northwestern, schools, community centers, public venues, online, etc.

If your research takes place in multiple states within the United States, please explain.

Indicate that you have obtained all required approvals/permissions, or that you will obtain approval/permission, at each research location before project implementation. Please keep in mind that if you plan to do research in K-12 schools, some school systems require an additional research review process (including Chicago Public Schools, Evanston/Skokie District 65, and Evanston Township High School.)

If you plan to collect data through or from online/internet sources, please describe which survey platforms or websites you plan to use for data collection (e.g., Qualtrics survey panels, Amazon Mechanical Turk, internet chat rooms and support groups, etc.). If you plan to conduct research using online activities, explain whether you anticipate your participants may reside outside the United States.

6.0 Multi-Site or Collaborative Research:

Reliance agreements are formal arrangements between institutions allowing an IRB, institution, or individual to rely on the IRB of another institution for the review of human research. The NU IRB will not serve as IRB of record for another IRB, institution, or individual unless they have agreed to this arrangement. Please see our website for further information: https://irb.northwestern.edu/reliance/index.html

Multi-site and collaborative research occurs when researchers from NU and external institutions, or individual external investigators, carry out the research. Provide the following information:

- Which institutions or individuals are participating in the research?
- What activities will institutions or individuals participate in?
- Will each institution or individual's IRB review their activities, or will one IRB

serve as the IRB of Record?

Regardless, if you are unsure how to pursue IRB review and oversight for your multi-site or collaborative research, please indicate your compliance with the following statements:

- No activities will occur at external sites until they obtain approval from their local IRB, or the NU IRB and external sites fully execute (complete and sign) a reliance agreement.
- External study teams will obtain sign-offs or permissions per their local policies.
- You will provide IRB approval letters from external sites, documentation that IRB review at external sites is unnecessary, or fully executed reliance agreements when available with accompanying protocol updates via modification requests in eIRB+.
- You will report non-compliance with the study protocol or applicable requirements per local policy.

If one IRB serves as the IRB of Record for all institutions or individuals engaged in the study, also known as reliance, please provide a detailed reliance plan:

- Is reliance mandated per federal guidelines or sponsor requirements?
- If this research is federally funded, who is the prime awardee?
- Who is the proposed IRB of Record for all participating sites?
- What type of reliance agreement will be used?
- When will institutions or individuals be onboarded? When NU is the proposed IRB of Record, we prefer to review the NU site and overall study scope first, and onboard institutions or individuals in subsequent modifications via fully executed reliance agreements. Onboarding during the initial review process may delay initial approval.
- How will you communicate IRB approval of modifications to study procedures to relying institutions or individuals, and ensure approval before implementation? How will you keep participating institutions or individuals abreast of any problems, interim results, or the eventual closure of the study? See WORKSHEET: Communication and Responsibilities (HRP-830).
- How will you manage information to protect participants? All institutions and individuals must safeguard data, including the secure transmission of data, as required by applicable local information security policies, state laws, and federal regulations.

If your research involves non-exempt, federally funded, human research happening at multiple research sites, you may be required to establish a Single IRB via reliance agreement(s). When NU serves as the Single IRB, fees may be applicable. Please see our website for further information: https://irb.northwestern.edu/reliance/single-irb-planning.html

The NU IRB serves as the IRB of record and HIPAA Privacy Board for

Northwestern Memorial Healthcare (NMHC), Northwestern Medicine affiliated institutions, and the Shirley Ryan AbilityLab. Therefore, if your research involves collaborations with these institutions and you are a Northwestern faculty member, you do **NOT** need to fill out this section of the protocol.

7.0 International Research (where data collection will occur outside the United States and U.S. territories, including online activities)

For guidance on IRB review of research that will take place outside the United States, see https://irb.northwestern.edu/resources-guidance/policies-guidance/irb-review-of-international-research.html

The HHS Office of Human Research Protections annually updates a compilation of international laws and regulations governing human research, available at: https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html

If you plan for your research to take place outside the United States, please explain:

Will you obtain a review by an IRB/research ethics committee located in the country where you will be doing research? Some countries do not have IRBs/research ethics committees. For example, in some countries, the IRBs only review biomedical research – we understand that IRB review in another country is not always possible, but expect that review by an IRB/research ethics committee be obtained whenever possible in the country where research will take place – it is your responsibility to determine whether there is an IRB/research ethics committee that can review your research in the countries where you plan to collect data.

Where there is no equivalent board or group, investigators are expected to consult with local experts or community leaders about the project and to secure their support for the conduct of the research. The IRB does require that there be good faith effort applied to secure local cooperation for the research and to provide documentation as part of the application.

What sociocultural factors could affect the consent process in the countries/regions where you will do research? For example, are there low literacy rates, cultural customs requiring consent from a community or family leader, etc.?

Are there any mandatory reporting laws that apply to your research (e.g., mandatory reporting of child abuse and neglect?)

NOTE: If you plan to collect data **from individuals located in the European Economic Area**, you must consider the General Data Protection Regulations

(GDPR) (see https://irb.northwestern.edu/resources-guidance/policies-guidance/index.html). This includes fielding surveys/questionnaires with individuals in the European Economic Area. Some crowdsourcing platforms and survey panels include participants from the EEA countries. If you plan to use a crowdsourcing platform/survey panel that could include individuals in EEA countries, you must specify whether you will set the study qualifications to only include U.S. residents or not.

NOTE: If you plan to collect sensitive data, you must use good **data security practices** to collect, store, and transport your data. Keep in mind that officials in other countries and U.S. Customs and Border Protection could potentially try to access data stored on a phone, laptop, or other devices. For more information on good data security practices when traveling, see https://www.it.northwestern.edu/security/travel.html

8.0 Procedures Involved:

Please check the boxes for all applicable data collection procedures you plan to use:

☐One-on-one interviews

☐Focus Groups

☐Questionnaires/surveys

☐Secondary Data Analysis (medical record data, educational records, government or private sector datasets, etc.)

☐Ethnographic observation

☐Physiological measurements (e.g., EEG, EKG, MRI)

☐Biospecimen collection (saliva samples, blood draws, hair samples, etc.)

☐Mobile applications/data collection devices (e.g., Fitbits, actigraphs, etc.)

☐Behavioral decision making tasks (e.g., puzzles, interactive games, etc.)

☐Physical activities such as walking and other forms of exercise

☐Other procedures (briefly list types of procedures here if not covered by the check-boxes above): _____

For each of the procedures you checked off above, please describe the procedure and data collection timeline. We need to know how you will collect all of your study data and in what order data collection will occur. If the study involves **multiple conditions** where each condition involves different procedures, please provide a table or diagram that breaks down the procedures by condition and in chronological order.

Describe the **duration** of an individual's participation in the study ***for each study activity*** and the estimated total time for each participant to complete all study activities.

If you plan to access medical record data that are Protected Health Information (PHI) under HIPAA, you must fill out and upload Appendix B.

If you plan to **analyze secondary data** as part of your study that are NOT HIPAA protected PHI, specify in this section what datasets/records you plan to access, from which institutions (student education records from a particular school district, a dataset from a government agency or other data provider such as ICPSR, etc.), and which variables they will include in the dataset. If the data you will be receiving will contain identifiers, explain why it is necessary for the information to include identifiers and whether you will retain the data with identifiers or strip the identifiers from the data. **You must list the specific variables you plan to analyze in any data you access – you can upload a list of the variables to the electronic IRB application as a supporting document if easier.**

If you plan to use **mobile apps** for data collection, please see guidance on the IRB website: https://irb.northwestern.edu/resources-guidance/policies-guidance/index.html

If you plan to use any **attention check measures or performance bonuses/incentives**, you must describe them and explain what happens if a participant fails the attention checks or does not qualify for a bonus/incentive.

* **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.

9.0 Research with Vulnerable Populations

If the research will involve individuals who are vulnerable or susceptible to coercion or undue influence, describe any applicable additional safeguards included to protect their rights and welfare. Vulnerable populations include **children, prisoners, cognitively impaired adults, and pregnant women,** where the research activities are expected to affect the pregnancy. The above list is not an exclusive listing of vulnerable populations.

Additional safeguards include (but are not limited to) considerations involving:
i) Recruitment: Where/how precisely does recruitment to the study take place? For example, do you plan to recruit participants separately or in the presence of a Parent/LAR/Advocate?

ii) Assent/Permission Process: Does this take place separately or in the

presence of a Parent/LAR? How will you tailor the assent process to the developmental stages and capacity of the children you seek to enroll? Describe this process in detail and how you are documenting it. A formal assent process with documents uploaded for 7-17-year-old participants is the expectation. If any participants are under 7 years old, describe how you will verbally explain the study to them, as appropriate.

iii) Data Collection: Explain how the method of data collection is appropriate for this population. Describe whether it is appropriate forinteractions/interventions to occur alone with the participant.

Reference the IRB **Guidance on Children as Research Participants, Parental Permission, and Child Assent** for details on the additional ethical and regulatory considerations that you need to address when you plan to include children. https://irb.northwestern.edu/resources-guidance/policies-guidance/index.html

If members of the research team have roles that can give rise to concerns about undue influence with participants (such as physician-patient, teacher-student), please explain the steps you will take to minimize the possibility of undue influence/coercion.

Reference the IRB has checklists for vulnerable populations at https://irb.northwestern.edu/resources-guidance/checklists-worksheets/index.html to help you ensure you have provided sufficient information (NOTE—the IRB office completes these checklists, refer to them only as a source of guidance).

10.0 Incomplete Disclosure or Deception:

If you plan to use incomplete disclosure (withholding information about the study purpose during the consent process because disclosing the study purpose in detail could significantly impact the validity of your study results) or deception (purposely misleading participants by providing them with overt misdirection or false information about some aspect of the research during the consent process), see the Deception and Incomplete Disclosure Guidance on the IRB website: https://irb.northwestern.edu/resources-guidance/policies-guidance/index.html

If you plan to use incomplete disclosure or deception, describe the incomplete disclosure or deception and provide a rationale explaining why it is necessary to the research.

Because deception and incomplete disclosure alter the information presented during the consent process, the debriefing process serves as the remedy by completing the consent process. If debriefing is appropriate, explain how you

will conduct the debriefing process. (The IRB Office provides sample debriefing text in the Deception and Incomplete Disclosure Guidance on the IRB website.)

NOTE: If you plan to alter the consent process because you are using deception/incomplete disclosure as a research technique, you must complete Protocol Section 13 to request an alteration of the consent process.

11.0 Consent Process:

You can find all templates for consent forms and scripts on the IRB website at:
https://irb.northwestern.edu/resources-guidance/protocol-templates-forms/index.html

Describe the process you will use to obtain informed consent (written, verbal, online, etc.) from participants, including where and when the consent process will occur. If you will obtain consent in different ways for different participant groups or study phases, describe the consent process that you will be use for each participant group or study phase.

Consent is not merely a document – it is a process in which the participant gains an understanding of the research procedures and the potential study benefits and risks to make an informed, voluntary decision on whether to participate in a research study.

The **standard** is that you should document consent by having the participant sign a consent form after explaining the study to them, answering their questions, and providing them time to think about whether to agree to participate.

There are many **exceptions** where obtaining a participant's signature on the consent document is not feasible (e.g., research collecting data online or via telephone), or where obtaining consent is not feasible (primarily for studies that are only analyzing secondary data).

If you do not plan to obtain the participant's signature on the consent document, you must complete Protocol Section 12. If you are requesting a complete waiver of the consent process, or plan to alter the consent process because you are using deception/incomplete disclosure as a research technique, you must complete Protocol Section 13.

SPECIAL CONSIDERATIONS:

ENROLLING CHILDREN: 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. If any participants are under 7 years old, describe how you will verbally explain the study to them, as appropriate.

Reference the IRB **Guidance on Children as Research Participants, Parental Permission and Child Assent** for applicable definitions and applicable regulatory criteria:
https://irb.northwestern.edu/resources-guidance/policies-guidance/index.html

STUDENT EDUCATIONAL RECORDS (FERPA): 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). For more information on FERPA, see https://studentprivacy.ed.gov/?src=fpco

If you do NOT plan to obtain consent to access student education records, you must check with the custodian of the student records whether it is acceptable to access the records without student or parent consent.

For Northwestern University, if you seek to access **identifiable NU student education records for research**, and you do not plan to seek student consent to access those records, you must complete a FERPA Studies Exception Agreement (available from the NU Registrar's Office), submit that agreement to the NU FERPA officer, and upload the approved Studies Exception Agreement to your IRB application in the "Supporting Documents" section.

NON-ENGLISH SPEAKING PARTICIPANTS: Explain which language(s) the person(s) obtaining consent will use and which language(s) you anticipate the potential participants understand/speak.

Describe your plan to ensure that the oral and written information you provide to participants who are not fluent in English (whether in the United States or other countries) will be in the language they are most comfortable with.

Explain how you will identify an appropriate translator, If you plan to use a translator.

If you plan to translate your recruitment, consent, or data collection materials into other languages, we recommend you first obtain IRB approval of the English-language versions of those materials and then submit the translated materials as a modification to your study. Upload the translated documents with a Certificate of Translation - Template for Non-English Documents found here: https://irb.northwestern.edu/resources-guidance/consent-templates-hipaa-requirements/short-forms/index.html

INDIVIDUALS WHO LACK THE CAPACITY TO CONSENT: If you plan to include individuals who may lack the capacity to consent, describe how you will assess their capacity to consent.

If you plan to have more than one interaction with the participants, you must re-check capacity to consent at each interaction with the participant. This is because some participants may lack the capacity to consent at one time point and have the capacity to consent at other time points.

When research involves adults unable to consent, you must obtain permission for the individual to participate in the research from a Legally Authorized Representative (unless the IRB has granted a waiver of consent). For assistance in determining who can serve as a Legally Authorized Representative, review SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013): https://irb.northwestern.edu/resources-guidance/sops.html

12.0 Waiver of Participant Signature on Consent Form:

There are various reasons why a research study might not find it feasible to obtain the participant's signature on the consent form. For example, if consent and data collection will occur via telephone, Skype, or through an online survey, obtaining the participant's signature on the consent is cumbersome and can render obtaining consent infeasible. In other studies (e.g., studies of illegal or socially stigmatized activities), the participant's signature on the consent could create additional risks for the participant. If doing research in other countries, it may not be the norm for members of a distinct cultural group or community to sign a consent form.

If you will not obtain the participant's signature on the consent, explain why.

13.0 Waivers and Alterations of Consent Information:

For some studies, not obtaining consent is appropriate (for example, studies that only involve secondary data analysis). For some studies, omitting certain information in the consent process may be necessary to render the research feasible and produce valid data (research using deception as a technique).

If you want to request **a complete waiver of consent OR an alteration of consent**, please explain why:

i) the study is no more than minimal risk to the participants;
ii) you could not practicably carry out the research without the requested waiver or alteration
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;
iv) the waiver or alteration will not adversely affect the rights and welfare of the participants; and
v) whether you will provide participants with additional pertinent information after participation (i.e, whether you will debrief participants).

Debriefing primarily applies to studies that use deception/incomplete disclosure. If you will not debrief participants, write "debriefing does not apply to this study."

14.0 Financial Compensation:

There is no requirement to compensate research participants.

If you plan to compensate participants, describe any financial or other compensation you plan to provide to participants.

Describe the payment method, including how much money or other compensation you plan to provide for which activities, as well as when you will provide compensation (the timing). Please describe how many participants will receive compensation if you plan to use a lottery/raffle process to provide compensation, and the process to provide the compensation.

Describe whether you will provide prorated compensation if there are multiple research activities or if a participant withdraws from the study before finishing. If you plan for your study to involve multiple visits/interactions, the IRB recommends that you provide compensation at regular intervals and not be contingent upon completing the entire study.

If you plan to enroll children, specify whether you will give the payment to the parent or directly to the child.

Describe any costs that participants may be responsible for because of participation in the research, such as parking, cellphone-related costs, etc.

If the research involves more than Minimal Risk to participants, describe the available compensation in the event of research-related injury.

For further discussion of compensation in the research context, see the NU IRB Guidance on Research Participant Payments: https://irb.northwestern.edu/resources-guidance/policies-guidance/index.html

Northwestern University's policy on paying human research participants is available at: https://www.northwestern.edu/financial-operations/policies-procedures/policies/HumanSubjectPayments.pdf

15.0 Audio/Video Recording/Photography

Describe the type of recording you plan to use, why the type of recording is necessary to the research, and whether the recording is mandatory or optional to participate in the research.

Describe how you plan to use the recording(s) in the research (e.g., data analysis only or data analysis and presentations). If you intend to use recordings or images for public presentation or publication, you must obtain the participants' consent to those uses of the data.

Describe how and where you will store the recordings, who will have access to them, and if/when you will destroy them.
If audio/video recording is mandatory for participation, you must provide a rationale, and you must include that the recording is mandatory in the consent form.

16.0 Potential Benefits of this Research:

Explain the potential benefits that could result from your research -- indicate if there is no direct benefit to participants. Include a discussion of potential benefits to society or others.

Note: participation in the research itself and **payment** for participating in the research are not benefits, and you **cannot describe them as research benefits in the consent process**.

17.0 Potential Risks to Participants:

Describe the reasonably foreseeable risks, discomforts, hazards, or inconveniences related to the participant's participation in the research. Describe the probability, magnitude, duration, and reversibility of the risks.

Consider physical, psychological, social, legal, and economic risks as well as community or group harms. Note: a breach of confidentiality is a common risk in social and behavioral research.

18.0 Provisions to Protect Participant Privacy and Data Confidentiality:

Participant Privacy:
Describe the steps that you will take to protect participants' privacy interests. "Privacy" refers to a person's desire to place limits on with whom they interact or to whom they provide personal information. For example, will you conduct interviews that ask sensitive questions in areas where others cannot overhear the interview?

Confidentiality of data/biospecimens:
Describe how you will maintain confidentiality for data/specimens throughout the life-cycle of your study, including initial collection, data management (including data transfers), and storage. We need to know the procedures you will implement to maintain good data security (e.g., authorization of access, password protection, encryption, physical controls, and separation of identifiers and data) during collection, transmission, and storage.

NOTE: Per Feinberg School of Medicine (FSM) policy, research studies that will collect health information must fill out data security information as part of the **Research Supplemental Submission** (RSS) if you, the PI, are affiliated with FSM OR if NMHC (or one of its affiliates) is a study site. Feinberg requires you to complete the RSS when you submit a new study located in the RSS section of the eIRB+ application. Feinberg IT Security reviews the information you provide in the RSS, which is independent of the IRB approval process.
The IRB reviewers do NOT view the information you provide via the RSS – you must also provide detailed data security information in this section of the protocol.

Discuss the following elements, as applicable to your study:

• Will you include participant identifiers (e.g., name, residential address, phone number, email address, etc.) with the data/specimens? Will you strip identifiers at some point? Keep in mind that some participants may be identifiable from video or audio recordings.

• If you will not collect direct participant identifiers, will you use a coding system with a key? Where will you store the key to the coding system, and who will

have access to the key?

• Do you plan to transcribe audio recordings, and if so, will you delete the audio recordings when you have completed the transcription?

• How will you transport data from the point of collection to the point of storage?

• Where and how will you store data/specimens? How long will you store the data or specimens? What will happen to the data/specimens at the end of your study? (Note: Under NU policy, you must keep research data a minimum of 3 years after the completion of the study. However, there are circumstances when other time periods may apply. You must retain consent forms that contain HIPAA authorizations must be retained for at least 6 years after completion of the study.)

For detailed guidance on good research data security practices, please see NU IT's website at https://www.it.northwestern.edu/security/research.html.

If you will be collecting research data while outside the United States, please see NU IT's tips on data security when traveling: https://www.it.northwestern.edu/security/travel.html

19.0 Data Monitoring Plan to Ensure the Safety of Participants:

You must fill out this section if your study is:

- a **clinical trial**

or

- you will be collecting data that **could indicate potential harm to participants (e.g., participants expressing intent to harm self or others, OR data indicating child, spousal, elder, or other forms of abuse or neglect)**.

Describe your plan to monitor and evaluate the information you collect regarding risks or harms to determine whether participants and others remain safe. The frequency of monitoring should be appropriate to the sensitivity of the data and level of risk. For example, if participant responses could suggest the likelihood of an intent to harm self or others, what is your plan for monitoring severity, and how will you respond if a participant indicates intent to harm? If directly assessing this data, you must have someone on the team appropriately qualified to perform the assessment.

Illinois state law and Northwestern University policy require all NU employees, students, volunteers, and third-party contractors to report suspected cases of **child abuse or neglect**. See: https://www.northwestern.edu/hr/careers/new-employees/reporting-suspected-child-abuse.html.

Note regarding studies that may involve the disclosure of information regarding sexual misconduct:
If there is a reasonable expectation that the target population of your research study will disclose information about sexual misconduct that involves members of the Northwestern community, you must plan for this circumstance in your protocol and the consent form. Sexual harassment and sexual violence are forms of sex discrimination prohibited by a federal law called Title IX. If you are an employee of NU, you are required to report to the NU Office of Equity any instances of sexual misconduct of which you become aware during the scope of your employment, if at least one of the individuals involved in the sexual misconduct was a member of the Northwestern community. Sexual misconduct includes sexual assault, sexual exploitation, stalking, dating and domestic violence, and sexual harassment. The requirement to consult with the Office of Equity is specific to NU employees. Student researchers who learn of reportable information should discuss this with the Principal Investigator (PI) on the study -- it is then the responsibility of the PI to contact the Office of Equity. For further information, see https://www.northwestern.edu/sexual-misconduct/docs/sexual_misconduct_policy.pdf andhttps://www.northwestern.edu/sexual-misconduct/title-IX/faqs.html

20.0 Long-term Data and Specimen Storage and Sharing:

If you plan to store data/specimens and share them long-term for future research, explain your plan for storing and sharing the data. If you plan to place your data in a data repository, explain which repository/database and why.

Explain whether you will include identifiers with the data/specimens when you share them.

21.0 Qualifications of Research Team to Conduct the Research:

Describe the qualifications of the research team to conduct this research. The IRB is looking for information such as area(s) of expertise, past research experience, relevant certifications, etc.

For international research or research with vulnerable populations, describe your qualifications (e.g., training, experience, oversight) to conduct the research and your knowledge of the local study sites, culture, and society.

Note: If you specify a person by name, a change to that person will require prior approval by the IRB. If you specify people by role (e.g., coordinator, research

assistant, co-investigator, or pharmacist), a change to that person will not require prior approval by the IRB, provided that person meets the qualifications described above to fulfill their roles.