**INSTRUCTIONS:**

Use “TEMPLATE PROTOCOL (HRP-583)” to prepare a document for social and behavioral research with the information from the following sections.

Depending on the nature of what you are doing, some sections may not be applicable to your research. If so mark as “NA”. For example, research involving a retrospective chart review may have many sections with NA. For subsections you can delete it if it’s not applicable.

When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes.

As you are writing the protocol, remove all instructions so that they are not contained in the final version of your protocol.

Note: If your project is a Training, Development or Umbrella Grant Application (waiting for funding with no human participant research yet) you should complete the protocol template but you are not required to submit any of the other participant facing documents.

**PROTOCOL TITLE:**

Include the full protocol title.

**PRINCIPAL INVESTIGATOR:**

Name

Department

Telephone Number

Email Address

**VERSION DATE:**

Include the version date. This is the date this protocol version was finalized.

**1.0 Purpose of the Study:**

1. Describe the purpose, specific aims, or objectives. State the hypotheses to be tested or the research questions that will guide the study.

**2.0 Background / Literature Review / Rationale for the study:**

1. Briefly (500 words or fewer):
   1. Describe the relevant current context of the study and gaps in current knowledge.
   2. Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.
   3. Add relevant references at the end of the protocol (not at the end of this section).

**3.0 Inclusion and exclusion criteria:**

1. Briefly describe the total number of participants and the criteria (such as age, gender, language, etc.) that define who will be included or excluded in your study sample.
2. Indicate specifically whether you will include or exclude any special populations: (You may not include members of these populations as participants in your research unless you indicate this in your inclusion criteria.)
   1. Adults unable to consent
   2. Individuals who are not yet adults (minors): infants, children, teenagers
   3. Pregnant women (where the activities of the research may affect the pregnancy or the fetus.)
   4. Prisoners or other detained individuals.

**4.0 Procedures Involved:**

1. Describe the setting of the study, including all locations where research procedures will be performed.
2. Describe the study design including the rationale.
3. Provide a description of all research procedures and activities.
4. Include when they are performed, and any procedures being used to monitor participants for safety or minimize risks.
5. Describe the study timelines including: the duration of an individual participant’s participation in the study and the overall anticipated duration of the project.
6. Describe the actual source records or measures that will be used to collect data about participants. (All surveys, interview scripts, and data collection forms will be attached elsewhere in the application. Do not add other documents to the protocol.) Describe what data will be collected and how it will be collected at all measurement/data collection time-points.
7. If doing online research, include the URL where the data collection will occur.
8. If your research is conducted outside of Northwestern University, please identify any site-specific regulations or customs affecting your project, including any local scientific and ethical review structure.
9. Describe any approvals that will be obtained prior to commencing the research. (e.g., school, external site. funding agency.)
10. If the research involves individuals who are vulnerable or susceptible to coercion or undue influence[[1]](#footnote-1), describe additional safeguards included to protect their rights and welfare:
    1. If the research involves pregnant women where the research activities are expected to affect the pregnancy, review “CHECKLIST: Pregnant Women (HRP-412)” to ensure that you have provided sufficient information.
    2. If the research involves neonates of uncertain viability or nonviable neonates where the research activities are expected to affect the neonates, review “CHECKLIST: Neonates (HRP-413)” or “HRP-414 – CHECKLIST: Neonates of Uncertain Viability (HRP-414)” to ensure that you have provided sufficient information.
    3. If the research involves prisoners, review “CHECKLIST: Prisoners (HRP-415)” to ensure that you have provided sufficient information.
    4. If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research (“children”), review the “CHECKLIST: Children (HRP-416)” to ensure that you have provided sufficient information.
    5. If the research involves cognitively impaired adults, review “CHECKLIST: Cognitively Impaired Adults (HRP-417)” to ensure that you have provided sufficient information.

**5.0 Multiple sites:**

1. If this research involves multiple sites, specify which is the lead site and describe the roles of each site in the study.
2. Indicate that all required approvals are already obtained or will be obtained at each site prior to project implementation. In addition:
3. Describe the processes you have in place to ensure successful coordination of activities among sites. For example, do all sites have the most current version of the protocol, consent document, and HIPAA authorization? How will modifications be communicated to sites and approved prior to implementation? How will participating sites be kept abreast of any problems, interim results, or the eventual closure of the study?
4. Describe the processes you have in place to ensure successful coordination of activities among sites. For example, do all sites have the most current version of the protocol, consent document, and HIPAA authorization? How will modifications be communicated to sites and approved prior to implementation? How will participating sites be kept abreast of any problems, interim results, or the eventual closure of the study?
5. Describe the mechanisms you have in place to ensure that all local site investigators conduct the study appropriately and that engaged participating sites safeguard data as required by local information security policies. Please confirm that all non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.

**6.0 Incomplete Disclosure or Deception:**

If the study will use incomplete disclosure or deception, please provide a rationale. Please also provide a description of the debriefing process that will be used to make participants aware of the deception and their right to withdraw any record of their participation. Include here if reconsent will occur (see the Deception Guidance on the IRB website).

**7.0 Recruitment:**

1. Describe when, where, and how potential participants will be recruited.
2. Describe the types of strategies and materials that will be used to recruit participants.

Note: Do not attach recruitment documents to the protocol but for additional guidance on the recruitment process and documents see: <http://irb.northwestern.edu/process/new-study/requirements/recruitment-materials-guidelines>.

**8.0 Consent Process** (see also the [Process of Obtaining Consent](http://www.irb.northwestern.edu/process/new-study/informed-consent) guidance on the web site.

1. If obtaining consent using a written consent document, describe:

1. Where the consent process will take place.
2. Any process to ensure ongoing consent if appropriate. This may include reconsent for longitudinal studies or if there are multiple stages to a project over time.
3. The details of the consent process including:
   * 1. The role of the individuals listed in the application as being involved in the consent process.
     2. The amount of time that will be devoted to the consent discussion.
     3. Steps that will be taken to minimize the possibility of coercion or undue influence.
     4. Steps that will be taken to ensure the participants’ understanding.
4. If there are Non-English speaking participants who will be enrolled, describe the process to ensure that the oral and written information provided to those participants will be in the language with which they are most comfortable speaking or writing. Indicate the language that will be used by those obtaining consent. If you will be using a translator during recruitment, consent, data collection, or data analysis specify how you will identify an appropriate translator and what the provisions will be for protecting the confidentiality of participants.
5. Participants who are not yet adults (infants, children, teenagers):
6. Describe whether parental permission will be obtained from:
   1. Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
   2. One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.
   3. Individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals’ authority to consent to each child’s participation.
7. Describe the process for assent of the participants. Indicate whether:
   1. Assent will be required of all, some, or none of the participants. If some, indicated, which participants will be required to assent and which will not.
   2. If assent will not be obtained from some or all participants, an explanation of why not.
   3. Describe whether assent of the participants will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require participants to sign assent documents.
8. For research conducted outside of the state, provide information that describes which persons have not attained the legal age for consent procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of “children” in “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013).”

4. Cognitively Impaired Adults:

Describe the process to determine whether an individual is capable of consent. The IRB allows the person obtaining assent to document assent on the consent document and does not require separate assent documents, although that is an option.

5. Adults Unable to Consent:

1. List the individuals from whom permission will be obtained in order of priority. (E.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child.)
   1. For research conducted in the state, review “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)” to be aware of which individuals in the state meet the definition of “legally authorized representative.”
   2. For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective participant to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of “legally authorized representative” in “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013).”

**9.0 Process to Document Consent:**

1. Describe whether and how consent of the participant will be documented in writing.
2. If you will document consent in writing, you will attach a consent document. You must use [SOCIAL BEHAVIORAL TEMPLATE CONSENT DOCUMENT (HRP-583)” to create the consent document or script.]
3. If you will obtain consent, but not document consent in writing, you must attach a consent script. Review “CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)” to ensure that you have provided sufficient information.
4. Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception): Review the “CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)” to ensure you have provided sufficient information for the IRB to make these determinations.

**10.0 Risks to Participants:**

1. List the reasonably foreseeable risks, discomforts, hazards, or inconveniences related the participants’ participation in the research. Describe the probability, magnitude, duration, and reversibility of the risks.
2. Consider physical, psychological, social, legal, and economic risks as well as community or group harms.
3. If applicable, describe risks to others who are not participants.
4. Withdrawal of Participants:
   1. Describe anticipated circumstances under which participants will be withdrawn from the research without their consent.
   2. Describe procedures that will be followed when participants withdraw from the research, including withdrawal from some but not procedures with continued data collection.
   3. Describe the use of data after withdrawal.

**11.0 Potential Benefits to Participants:**

Note: participation in the research itself and compensation from participating in the research are not benefits.

1. Describe the potential benefits that individual participants may experience from taking part in the research. Describe also the probability, magnitude, and duration of the potential benefits.
2. Indicate if there is no direct benefit to participants. Do not include benefits to society or others.

**12.0 Financial Compensation:**

1. Describe any financial compensation that will be provided to participants. Include how much money or what gifts will be provided and for what activities.
2. Include whether compensation will be prorated if there are multiple research activities or if a participant withdraws from the study before finishing.
3. Describe any costs that participants may be responsible for because of participation in the research.

**13.0 Provisions to Protect the Privacy Interests of Participants:**

1. Describe the steps that will be taken to protect participants’ privacy interests throughout the research activities.
2. Indicate who on the research team and how the research team is permitted to access any sources of information about the participants.

**14.0 Confidentiality and Data Management:**

1. Describe how data (and if applicable, biological specimens) will be handled study-wide including:
   1. What information will be included as data (or associated with the specimens)? “Data” includes all information collected in the conduct of the research, such as but not limited to: consents, surveys, interview notes, audio or video recordings, photographs, notes of observations, field notes, etc.
   2. Where and how will data (or specimens) be stored? How will data be transported from the point of collection to where they will be stored? Note: electronic storage of data in both domestic and international research must be secured using adequate protections.
   3. How long will the data or specimens be stored? (Note: IRB policy is 7 years after the completion of the study. However, there are circumstance when other time frames may apply.)
   4. Who will have access to the stored data or specimens?
   5. Who is responsible for receipt or transmission of the data or specimens?
2. Describe the steps that will be taken secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission.
3. Describe any procedures that will be used for quality control of collected data. If conducting online research, specify if you will be using any attention check measures. If yes, you need to indicate what you will be doing and what happens if a participant fails the attention checks.
4. Describe the data analysis plan, including any statistical procedures is applicable.

**15.0 Data Monitoring Plan to Ensure the Safety of Participants:**

1. Describe the plan to periodically evaluate the information collected regarding risks or harms to determine whether participants remain safe. For example, if you are collecting depression or suicidality data, what is your plan for monitoring severity? Note: the plan might include establishing a data monitoring committee and a plan for reporting their findings to the IRB and the sponsor. It also could include referral to an appropriate resource. Include the following:
   1. What information / data are reviewed, including safety data, untoward events, and efficacy data.
   2. How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).
   3. The frequency of data collection, including when safety data collection starts.
   4. Who will review the data.
   5. The frequency or periodicity of review of cumulative data.
   6. The statistical tests for analyzing the safety data to determine whether harm is occurring.
   7. Describe any conditions where the research team may intervene and what the plan is for intervening. (For example, if a participant identifies harm to self or others.)
   8. Describe any conditions that might trigger an immediate suspension of the research.

**16.0 Data and if applicable, Specimen Banking:**

1. If data or specimens will be banked for future use, describe where the data or specimens will be stored, how long they will be stored, how the data or specimens will be accessed, and who will have access to the specimens.
2. If storing data electronically, include a plan for managing the long term storage of the data if appropriate.
3. If storing data in a data repository outside of Northwestern, include the agreement with the entity where the data will be stored.
4. List the data to be stored or, in the case of specimens what information will be associated with each specimen.
5. Describe the procedures to release data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.

**17.0 Qualifications to Conduct Research and Resources Available:**

1. For international research or research with vulnerable populations, describe the qualifications (e.g., training, experience, oversight) of you and your staff as required to conduct the research. When applicable describe the knowledge of the local study sites, culture, and society. Provide enough information so the IRB knows that you have qualified staff for the proposed research.

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.

1. Describe other resources available to conduct the research: For example, as appropriate:
   * 1. Describe your facilities or other physical resources needed for the conduct of the research.
     2. Describe the availability of social, emotional or psychological resources that participants might need as a result of an anticipated consequences of the human research.
     3. Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.

R: 8/1/2015

1. Coercion occurs when an overt or implicit threat of harm is intentionally presented to obtain compliance. Undue influence, by contrast, often occurs through an offer of an excessive or inappropriate reward or other overture in order to obtain compliance (<http://www.hhs.gov/ohrp/policy/faq/informed-consent/what-does-coercion-or-undue-influence-mean.html>). For example, the threat of the loss of reputation, good standing in class or of a bad grade if a student does not participate in a study would be an example of coercion. The offer of excessive money or special treatment or rewards for participation could be an example of undue influence. [↑](#footnote-ref-1)