**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 all of the guidance** (red text) before submitting.

**STUDY TITLE:**

Include the full study title

**PRINCIPAL INVESTIGATOR:**

Name:

Department:

**CO-INVESTIGATORS:**

Name:

**VERSION DATE:**

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

**RELATED STUDIES:**

If there any related MSI IRB applications that provide context for the activities covered by this IRB submission, please explain and provide the IRB study numbers for those related applications.

# Purpose and rationale of the study:

State the purpose of your study. Please also describe if there are 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 do those data connect to the research questions you seek to answer. Provide the scientific or scholarly background for, rationale for, and significance of the proposed research based on the existing literature and how it will add to existing knowledge.

# 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 specifically whether you will include any vulnerable populations.

# 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.

# Recruitment and Screening Methods:

Be specific and spell out for the IRB how the recruitment process and any eligibility screening procedures will occur.

Explain step-by-step how you will:

1. locate individuals who might be eligible to participate in your study;
2. how, where, and when contact will be made with 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 will be contacting potential participants directly (by email, letter, phone, etc.) explain how you will obtain their contact information.

# Research Locations:

A research location is defined as a location or place where the research procedures will be conducted. Examples: schools, community centers, public venues, online, etc.

# Multi-site Research (research that involves external collaborating institutions and individuals):

Where there are external institutions or individual external investigators involved in carrying out the research, a plan needs to be in place as to which institutions/individuals need IRB review of their activities, and which IRB will be responsible for reviewing those activities. To make those determinations, the MSI IRB needs to know where activities will take place and who will be doing which activities on the study.

For each institution involved, briefly describe which activities that institution will be carrying out for this study (including recruitment, consent, data collection, data analysis (specify whether data to be analyzed will be identifiable or de-identified)).

If you will be collaborating with an individual who is not affiliated with another institution (e.g., an independent contractor or consultant), describe which study activities will be carried out by that individual.

If the study has grant funding, explain who is the primary grant awardee.

Describe the processes you have in place to ensure successful coordination of activities among collaborating institutions. How will modifications to study procedures be communicated to collaborating institutions and approved prior to implementation? How will participating institutions be kept abreast of any problems, interim results, or the eventual closure of the study?

# Procedures Involved:

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

[ ] One-on-one interviews

[ ] Focus Groups

[ ] Questionnaires/surveys

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

[ ] 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 the timeline of data collection. We need to know how you will collect all of your study data and in what order data collection will occur.

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 will be **analyzing secondary data** as part of your study 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), and which variables will be included in the data. 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 will 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 IRB application as a supporting document.**

# 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 (other populations may be vulnerable as well – that is not an exclusive listing of participants who may be considered vulnerable).

Additional safeguards include (but not limited to) considerations involving:

i) Recruitment: Where/how precisely does recruitment to the study take place? Are participants recruited 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, provide a description of how the study will be verbally explained to them, as appropriate.

# Incomplete Disclosure or Deception:

Please describe if you will be using 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).

# Consent Process:

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 consent will be obtained in different ways for different participant groups or study phases, describe the consent process that will be used for each participant group and/or study phase.

Note: 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 in order to make an informed, voluntary decision on whether to participate in a research study.

# Waiver of Documentation (Participant Signature) on Consent Form:

There are a variety of reasons why a research study might not find it feasible to obtain the participant’s signature on the consent form. If you will not obtain the participant’s signature on the consent, explain why.

# Alteration and Waiver of Consent Information:

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

# Compensation:

There is no requirement to compensate research participants.

If you will compensate participants, describe any financial or other compensation that will be provided to participants. Describe the payment method, including how much money or other compensation will be provided for which activities, as well as when (the timing) compensation will be provided. If you will use a lottery/raffle process to provide compensation, please describe that process and how many participants will receive compensation. **Note** that compensation is NOT a benefit of participation in the research.

# Audio/Video Recording/Photography

* 1. Describe the type of recording being utilized, why the type of recording is necessary to the research, and whether recording is mandatory or optional to participate in the research.
	2. Describe how the recordings will be utilized in the research (e.g., data analysis only or data analysis and presentations). If the intent is to use recordings or images for public presentation or publication, you must obtain the participants’ consent to those uses of the data.
	3. Describe how and where the recordings will be stored, who will have access to them, and if/when they will be destroyed.
	4. If audio/video-recording is mandatory for participation, a rationale must be provided here and the consent form must include this detail.

# Potential Risks to Participants:

* 1. Describe the reasonably foreseeable risks, discomforts, hazards, or inconveniences related to the participants’ 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.

* 1. Describe any hierarchical relationship between the researcher and the participants, such as teacher – student, supervisor – supervisee, employer – employee, etc. that may result in any undue influence with regard to recruitment, consent or participation in the research activities. Note that undue influence is contrary to the ethical principle of ‘respect for persons’ as found in the Belmont report. Undue influence can interfere with the voluntary nature of participation if one feels unable to say ‘no’ or if a ‘no’ could have negative ramifications.
	2. Describe any measures needed to mitigate the risks to the participants.

# 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 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 cannot be described as research benefits in the consent process.

# Provisions to Protect Participant Privacy and Data Confidentiality:

* 1. Participant Privacy:

Describe the steps that will be taken 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 the interview cannot be overheard by others?

* 1. Confidentiality of data:

Describe how you will maintain confidentiality for data throughout the life-cycle of your study, including initial collection, data management (including data transfers), and storage. The IRB needs 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.

# Long-term Data Storage and Sharing:

If data will be stored and shared long-term for future research studies, explain the 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 identifiers will be included with the data when they are shared.

# 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.

Describe any hierarchical relationship between the researcher and the participants, such as teacher – student, supervisor – supervisee, employer – employee, etc. that may result in any undue influence with regard to recruitment, consent or participation in the research activities. Undue influence is contrary to the ethical principle of ‘respect for persons’ as found in the Belmont report. Undue influence can interfere with the voluntary nature of participation if one feels unable to say ‘no’ or if a ‘no’ could have negative ramifications.