**INSTRUCTIONS: Complete Research Protocol**

* *Depending on the nature of what you are doing, some sections may not be applicable to your research. If so, you must provide the reason the section is not applicable for the response. For example, under the Grant Applicability section, many would answer, “This protocol is not funded by a grant or contract.”*
* *When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes.*
* *Do not remove the italics instructions or headings.*
* *If you are pasting information from other documents be sure to use the “Merge Formatting” paste option so that the formatting of the response boxes is not lost. If information is presented outside of the response boxes, it will not be accepted.*
* *If this study involves multiple participant groups participating in different research procedures, consent processes, etc., provide information in each applicable section for each participant group, clearly labeled.*

**PROTOCOL TITLE:**

*Include the full protocol title.*

Response:

**PRINCIPAL INVESTIGATOR:**

*Name*

*Department*

*Telephone Number*

*Email Address*

**FACULTY SPONSOR (for student projects):**

*Name*

*Department*

*Telephone Number*

*Email Address*

**VERSION NUMBER:**

*Include the version number of this protocol.*

Response:

**DATE:**

*Include the date of submission or revision.*

Response:

# Objectives

* 1. *Describe the purpose, specific aims, or objectives for the research.*

Response:

* 1. *State the hypotheses to be tested and research questions to be answered.*

Response:

# 2.0 Background

*2.1 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. Describe the relevant prior experience and gaps in literature.*

Response:

*2.2 Describe any relevant preliminary data.*

Response:

*2.3 Include complete specific citations/references.*

Response:

# 3.0 Exempt, Expedited, or Full Board Status

*3.1 This study will be reviewed as Full Board, unless you provide a justification for Exempt or Expedited review. In that case, include the category of exemption or expedited review you are requesting and discuss the relationship of your study to the criteria for that specified category.*

Response:

# 4.0 Recruitment Methods

*4.1 Describe how you will identify potential participants. (e.g., Psychology Subject Pool). If you are using the Psychology Subject Pool, please upload the authorization to use the Psychology Subject Pool.*

Response:

*4.2 Describe the source of participants.*

Response:

4.3 Describe when, where, and how potential participants will be recruited. Response:

*4.4 Describe materials that will be used to recruit participants. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the HREB reviews the final audio/video tape.)*

Response:

*4.5 Describe any monetary, subject pool credit or other forms of compensation which will be provided to participants and any conditions which must be fulfilled to receive compensation.*

Response:

# 5.0 Inclusion and Exclusion Criteria

*5.1 Describe the criteria that define who will be included or excluded in your final study sample.*

Response:

*5.2 Describe how individuals will be screened for eligibility.*

Response:

*5.3 Indicate specifically whether you will intentionally include or exclude each of the following vulnerable participants. (You may not include members of these populations as participants in your research unless you indicate this in your inclusion criteria.)*

*Adults unable to consent*

*Individuals who are not yet adults (infants, children, teenagers)*

*Pregnant women*

*Prisoners*

*Fetuses*

Response:

*5.4 If vulnerable participants will be intentionally included, provide justification of the need to use these participants in research.*

Response:

*5.5 Indicate whether you will include non-English speaking individuals. Provide justification if you will exclude non-English speaking individuals.
(In order to meet one of the primary ethical principles of equitable selection of participants, non-English speaking individuals may not be routinely excluded from research. In cases where the research is of therapeutic intent or is designed to investigate areas that would necessarily require certain populations who may not speak English, the researcher is required to make efforts to recruit and include non-English speaking individuals; however, there are studies in which it would be reasonable to limit participants to those who speak English, e.g., pilot studies, small unfunded studies with validated instruments not available in other languages, numerous questionnaires, and some non-therapeutic studies which offer no direct benefit.)*

Response:

#  *5.6 If this is an international study, please submit an International Addendum.*

Response:

# 6.0 Number of Participants

*6.1 Indicate the approximate number of anticipated participants.*

Response:

# 7.0 Study Timeline

*7.1 Describe the duration anticipated to enroll all study participants.*

Response:

*7.2 Describe the duration of an individual’s participation in the study.*

Response:

# 8.0 Procedures

*8.1 Explain the study design: Include a description of all relevant variables.*

Response:

*8.2 Describe all research procedures.*

Response:

*8.3 Describe how you are collecting the data about participants. For example, survey photographs, audiotapes and videotapes. State why you need them.*

Response:

*8.4 Attach all surveys, scripts, interview questions, stimuli, and/or data collection forms.*

Response:

*8.5 Document authorization of use or permission to modify a copyrighted instrument, or document access in the public domain of non-copyrighted instruments.*

Response:

8.6 Describe all equipment used with participants, if any.

Response:

*8.7 Specify what factors will lead to cessation of procedures causing physical or emotional stress. Outline procedures for stopping or interrupting the protocol.*

Response:

8.8 *Describe biological samples to be taken, the method for their handling and the qualifications of individuals taking samples.*

Response:

*8.9 Describe any deception (if applicable). Provide a justification. Identify the nature of any information to be purposely withheld from participants and provide justification for the non-disclosure.*

Response:

8.10 *Provide debriefing method, rationale for deception (if applicable) and debriefing protocol.*

Response:

8.11 *Discuss any other aspects of the procedures.*

Response:

# 9.0 Setting

*9.1 Describe the sites or locations where your research team will conduct the research.*

Response:

# 10.0 Data Management and Analysis

*10.1 What data will be recorded, including long-term follow-up?*

Response:

*10.2 Describe how you will analyze your data. For example, for a quantitative study, what statistical analyses will you conduct? For a qualitative study, a what methods of data generation/process of analysis such as coding themes or heuristic engagement with the material, such as journaling and/or field notes?*

Response:

*10.3 Describe the final form of the data (i.e. excel spreadsheet with codes, de-identified transcripts, video clips) that you plan to maintain and the steps that will be taken to 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 dissemination.*

*10.4 What information will be included in that data?*

Response:

*10.5 Will participants be identifiable during data collection? Will participants be identifiable in the final data set?*

Response:

*10.6 Who will have access to the data?*

Response:

*10.7 How will you protect and maintain the confidentiality of your data records and participants?*

Response:

# 11.0 Risks to Participants

*11.1 List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to participants related the participants’ participation in the research. Include a description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks. Please note that no study is considered “no risk.” Minimal risk is defined as risk not greater than that encountered in everyday life.*

Response:

*11.2 For all studies involving greater than minimal risk, specify the procedures for preventing or minimizing any potential risks.*

Response:

*11.3 If the study involves greater than minimal risk, provide a description of any alternative procedures and why you, nevertheless, have chosen the specified procedures.*

Response:

# 12.0 Potential Benefits to Participants

*12.1 Describe the potential benefits that individual participants may experience from taking part in the research. Include, as may be useful for the HREB’s consideration, the probability, magnitude, and duration of the potential benefits. Indicate if there is no direct benefit. Do not include benefits to society or others.*

Response:

*12.2 Describe the anticipated benefits to society and/or others.*

Response:

*12.3 Describe any compensation or reward an individual may earn for participation in the study.*

Response:

*12.4 Describe any alternatives to participation in the study which might be advantageous to the subject. If the participants are to receive academic credit for research participation, describe the alternatives available to earn equivalent academic credit.*

Response:

# 13.0 Sharing of Results with Participants

*13.1 Will you share study results or individual subject result with participants or others and, if so, describe how.*

Response:

# 14.0 Prior Approvals

*14.1 Describe any approvals that will be obtained prior to commencing the research, e.g., school or external sites. Note: If this is an external agency or organization, a letter of cooperation from the highest ranking official is necessary to be submitted directly to the H.R.E.B. Office either on letterhead or their work place e-mail*; ***after*** *pending approval of the proposal is received.*

Response:

# 15.0 Consent Process

*15.1 Indicate how you will obtain consent and how you will be documenting consent. Note: the consent process is more than just the form. How will you approach potential participants, what will you say, what are your procedures for returning consent documents, etc… Please note: consent documentation can only be waived under specific conditions—see 15.6 below.*

Response:

*15.2 Describe where the consent process will take place.*

Response:

*15.3 Describe any process to ensure ongoing consent.*

Response:

*15.4* *Describe how the federal requirement for consent forms to be retained for three years following the conclusion of the project will be met. (If an institution/organization requires retention of consent forms on site, then the investigator may request a waiver of this requirement.)*

Response:

***Non-English Speaking Participants***

*15.5 Indicate what language(s) other than English are likely to be spoken/understood by your prospective study population or their legally authorized representatives.*

Response:

*15.6 If participants who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those participants will be in that language. Indicate the language that will be used by those obtaining consent.*

Response:

***Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)***

***Under the following conditions you can request a waiver of documentation of the informed consent process:***

*1****)*** *The research involves no more than minimal risk to the subjects,*

*2) The waiver or alteration will not adversely affect the rights and welfare of the subjects, and*

*3) The research could not practicably be carried out without the waiver or alteration. When possible, the subjects should be provided with additional pertinent information after participation.*

*15.7 Give a full justification for a request for waiver of the informed consent process.*

***Special Informed Consent Circumstances***

***Participants who are not yet adults (infants, children, teenagers)***

*15.8 Describe the criteria you will use to determine whether a prospective subject has attained the legal age for consent relevant to the jurisdiction in which the research will be conducted (e.g., individuals under the age of 18 years). See “Policy for Research Involving Minors.”*

Response:

*15.9 Describe whether permission will be obtained from 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.*

Response:

*15.10 Describe the process for assent of participants (if applicable).*

*Indicate whether assent will be required of all, some, or none of the participants. If some, indicate which participants will be required to assent and which will not.*

*If assent will not be obtained from some or all participants, explain why not.*

Response:

*Describe whether assent of the participants will be documented and the process to document assent. The HREB 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.*

Response:

***Cognitively Impaired Adults and Adults Unable to Consent***

*15.11 Describe the process to determine whether an individual is capable of consent.*

Response:

*15.12 When a person is not capable of consent due to cognitive impairment, a legally authorized representative should be used to provide consent and, where possible, assent of the individual should also be solicited.*

*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, or adult child. For research conducted in NY state, review “Legally Authorized Representatives, Children, and Guardians” to be aware of which individuals in the state meet the definition of “legally authorized representative.”*

Response:

*15.13 Describe the process for assent of participants (if applicable).*

*Indicate whether assent will be required of all, some, or none of the participants. If some, indicate which participants will be required to assent and which will not.*

*If assent will not be obtained from some or all participants, explain why not.*

*Describe whether assent of the participants will be documented and the process to document assent. The HREB 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.*

Response:

# *Process to Document Consent in Writing*

*15.14 If you will document consent in writing, attach a consent document. If you will obtain consent, but not document consent in writing, attach a consent script. You may use the “Informed Consent” template to create the consent document or script.*

*15.15 If your research presents no more than minimal risk of harm to participants and involves no procedures for which written documentation of consent is normally required outside of the research context, you may request a waiver of documentation of written consent.*

*Request a waiver of “Written Documentation of Consent” and provide a rationale. Describe how consent of the subject will be obtained*

Response: