Proposal for Research Review

# 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.

## Full 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

#### 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:**

##### Background

* 1. Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how it will add to existing knowledge. Describe the relevant prior experience and gaps in literature.

**Response:**

* 1. Describe any relevant preliminary data.

**Response:**

* 1. Include complete specific citations/references.

**Response:**

# Exempt, Expedited, or Full Board Status

* 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:**

## Recruitment Methods

## Describe the characteristics of the participants in the study. Include the source of the participants and the criteria that define who will be included or excluded in your final study sample.

**Response:**

* 1. Describe how participants will be recruited. Describe when and where potential participants will be recruited. Provide specific information about your recruitment procedures. For example, if you are using social media to recruit your participants, indicate the social media platform (e.g., Facebook), the individuals or groups that you plan to target, and your plan for communicating your study to them.

**Response:**

* 1. Include materials that will be used to recruit participants. Attach copies of these documents (such as emails and social media posts) with the application in PACS. 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:**

* 1. Indicate specifically whether you will intentionally include or exclude each of the following vulnerable participants.

Adults unable to consent

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

Pregnant women

Prisoners

Fetuses

**Response:**

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

**Response:**

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

**Response:**

* 1. Indicate whether you will include non-English speaking individuals. If yes, please provide translations for all materials (consent information, recruiting materials, surveys).

**Response:**

* 1. Indicate the total approximate number of participants.

**Response:**

* 1. 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:**

* 1. If the study is being conducted anonymously, how will the compensation (monetary, subject pool credit or other form of compensation) be provided without identifying information?

**Response:**

* 1. If you are using the Psychology subject pool to recruit participants, is the Psychology subject pool approval attached?

**Response:**

# Does your study involve collecting data from participants outside of the U.S.? If yes, submit an International Addendum.

**Response:**

# Study Time Commitment

* 1. Provide a timeline and estimate each participants' total time commitment for the following as applicable: study procedures, travel time, enrollment in the study, consent process, follow-up, etc...?

**Response:**

## Procedures

* 1. Explain the study design: Include a description of all relevant variables, including demographic variables.

**Response:**

* 1. Describe your methods and study procedures in detail. For example, will you be conducting an in-person research session, collecting reaction time, computer responses, a web-based survey, online interviews, focus groups, phone interviews, or paper and pencil surveys? What is the timeline of study activities including total duration for your participants?

**Response:**

* 1. Describe how you are collecting the data about participants. If you are conducting interviews or surveys, describe the Interview/Survey administration in detail. For example, will you be conducting a web-based survey, an in-person interview, an online interview (WebEx, Zoom), focus groups, a phone interview, or a paper and pencil survey?

**Response:**

* + 1. If you are conducting your research over the Internet, what web-based application will you use (e.g., SurveyMonkey, Qualtrics, Google Forms, Zoom, or Webex)?

**Response:**

* 1. Explain how confidentiality and privacy will be maintained?

**Response:**

* 1. Describe the sources of data about participants. What specific measures will you use? What demographic data will you be collecting about the participants? Be sure to describe if you will be collecting data using photographs, audiotapes, and videotapes.

**Response:**

* + 1. Attach all surveys, scripts, interview questions, stimuli, and data collection forms.

**Response:**

* 1. Describe all equipment (e.g., computers, digital recorder, etc...) used with participants, if any.

**Response:**

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

**Response:**

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

**Response:**

* 1. Describe any deception (if applicable). Describe any active (direct) deception and passive (indirect deception). Passive/indirect deception occurs when certain information about a study is withheld from participants until the debriefing. Identify the nature of any information to be purposely withheld from participants and provide justification for the non-disclosure. If deception is involved include the rationale for deception

**Response:**

# Provide debriefing method and debriefing statement . Indicate the information in the debriefing that addresses the deception, if applicable.

**Response:**

* 1. Discuss any other aspects of the procedures.

**Response:**

# Setting

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

**Response:**

## Data Management and Analysis

* 1. Describe the format of the data you will store (e.g., excel spreadsheet, SPSS file, video or audio recordings, transcripts, photographs, etc...). Describe data that will be stored temporarily (e.g., a videotape until it is transcribed). Describe data that will be stored over a longer period of time (e.g., codes in an excel spreadsheet).

**Response:**

* 1. Describe how you will securely store, maintain, use, and disseminate all of the data (e.g., training of research assistants, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, separation of identifiers and data, etc...).

**Response:**

* 1. Will any of your data be stored in a web-based application? When and how will the data be removed from the web-based application?

**Response:**

* 1. What information will be included in that data?

**Response:**

* 1. Will participants be identifiable during data collection? (Video and audio recordings, data with a key to the participant's identity, data with names, numbers or other identifiers are considered identifiable.)

**Response: \_\_\_\_\_\_\_\_\_Yes \_\_\_\_\_\_\_No**

* 1. Will participants be identifiable in the final data set? What identifying information will be included in that data?

**Response: \_\_\_\_\_\_\_\_Yes \_\_\_\_\_\_\_\_\_No**

**If yes to either 8.5 or 8.6, you must answer each of the following questions:**

1) What is the justification for collecting data that identifies the participants? Why are the identifiers necessary to conduct the research?

**Response:**

2) What is the sensitivity of the data being collected?

**Response:**

3) What is the retention period for identifiable data? When will the identified data be deleted or destroyed?

**Response:**

4) What security controls do you have in place for the identifiable data (i.e., physical safeguards for paper records or recordings, technical safeguards for electronic records, Secure sharing or transfer of data outside the institution, if applicable)?

**Response:**

5) What is the potential risk for harm that would occur if the security of the data was compromised?

**Response:**

* 1. Who will have access to the data?

**Response:**

* 1. Describe the ways in which the data will be analyzed. For example, for a quantitative study, a description of any statistics should be provided. For a qualitative study, a description of the methods of data generation/process of analysis such as coding themes or heuristic engagement with the material, such as journaling and field notes, should be provided.

**Response:**

* 1. Many peer-reviewed journals are now insisting that the raw data set from a study be publicly archived. Have you considered this possibility? Will the deidentified data be stored in a publicly available repository once the data are published? Have you included this possibility in your informed consent statement?

**Response:**

# Risks to Participants

* 1. List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the participants that could result from participation in the research. Describe the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks. Keep in mind that loss of confidentiality and privacy are considered risks. Please note that no study is considered to involve “no risk.” Minimal risk is defined as risk that is not greater than that encountered in everyday life.

**Response:**

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

**Response:**

# 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:**

## Potential Benefits to Participants

* 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:**

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

**Response:**

* 1. Describe any alternatives to participation in the study which might be advantageous to the participant.

**Response:**

# Compensation to Participants

* 1. Describe any compensation or reward an individual may earn for participation in the study. If the participants are to receive academic credit for research participation, describe the alternatives available to earn equivalent academic credit.

**Response:**

## Sharing of Results with Participants

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

**Response:**

### External Approvals

* 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 required to be submitted directly to the H.R.E.B. either on letterhead or their workplace e-mail; **after** pending approval of the proposal is received.

**Response:**

# Consent Process Options

Indicate which of the following options best describes your consent process.

\_\_\_\_\_\_\_\_Option 1 Participants will sign a consent document that includes all of the required key elements of consent based on 45CFR46. Go to 15.

\_\_\_\_\_\_\_Option 2 Informed consent will be obtained, but not documented with a signature in writing. If this option is chosen, then you need to request a waiver of "Written Documentation of Consent" and provide a justification. Go to 16.

\_\_\_\_\_\_\_Option 3 Requesting that informed consent or key elements of informed consent be waived. Go to 17

\_\_\_\_Option 3a Requesting that all informed consent be waived.

\_\_\_\_Option 3b Requesting that only specific elements of informed consent be waived.

## Consent Documentation including all Key Elements and Signatures

## Describe your consent process. For Full-board and Expedited studies you must include all of the key elements required by the federal standards. *Note: the consent process is more than just the form.*

**Response:**

## How will you obtain consent? How will you approach potential participants, what will you say?

**Response:**

* + 1. How will youdocument consent? What are your procedures for getting signatures on the forms and for directing participants how to return the signed consent documents, etc..

**Response:**

* + 1. Describe where the consent process will take place.

**Response:**

* + 1. Describe any process to ensure ongoing consent.

**Response:**

## Attach a consent form (See Informed Consent Template) that includes a signature line.

* 1. 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:**

## Requesting a Waiver of Written Documentation of Consent

## A "waiver of documentation of informed consent" means that while researchers must still obtain informed consent from participants, they do not need to collect a signed consent form, allowing participants to verbally agree to participate (in person or online).

## A waiver of documentation is permissible when:

## The signature on the informed consent document would be the only record linking the subject to the research and the principal risk of harm to the subject would be a breach of confidentiality. For example, for research on sensitive topics, such as domestic violence or illegal activities; OR

## The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context. For example, minimal risk research that involves surveys/interviews conducted via telephone or online.

## Request a waiver of documentation and provide a justification

**Response:**

## A copy of the consent script, statement, or document is attached.

\_\_\_\_\_ Yes

## Request a Waiver of Informed Consent or Specific Elements

## To waive in total or to alter informed consent elements, the HREB must determine that:

## The research involves no more than minimal risk to subjects;

## The research could not be carried out practicably without the waiver or alteration;

## The waiver or alteration will not adversely affect the rights and welfare of the subjects; and,

## Where appropriate, the participants should be provided with additional information after their participation.

## Do you plan to waive all of the consent process or particular elements?

\_\_\_\_\_\_\_All consent go to 17.3

\_\_\_\_\_\_\_Specific elements of consent (please specify).

**Specified Elements:**

* 1. Give a full justification to waive the informed consent process or specific elements.

**Response:**

* 1. Describe the steps you will take to provide that participants or their legally authorized representative are adequately informed about the study.

**Response:**

* 1. Describe your process for debriefing. Debriefing should be used when participants are deceived about the purpose of the research and/or when prior consent is not possible.

**Response:**

1. **Special Informed Consent Circumstances**
   1. **Non-English-Speaking Participants**
      1. Indicate what language(s) other than English are likely to be spoken/understood by your prospective study population or their legally authorized representatives.

**Response:**

* + 1. 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 the appropriate language. Indicate the language that will be used by those obtaining consent.

**Response:**

* 1. **Participants who are not yet adults (infants, children, teenagers)**
     1. 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:**

* + 1. Describe whether permission will be obtained from individuals other than participants and, if so, who will be allowed to provide permission (e.g., parent, guardian, legally authorized representative). Describe the process used to determine these individuals’ authority to consent.

**Response:**

* + 1. 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.

**Response:**

* 1. **Cognitively Impaired Adults and Adults Unable to Consent**
     1. Describe the process to determine whether an individual is capable of consent.

**Response:**

* + 1. 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:**

* + 1. 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:**

* + 1. 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:**