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

## 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:**

##### Background

* 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:**

* 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

* 1. 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 your consent process and include your informed consent statement. (See the [Exempt Informed Consent Policy](file:///C%3A%5CUsers%5Ccrockeju%5CAppData%5CLocal%5CMicrosoft%5CWindows%5CINetCache%5CContent.Outlook%5C2L1FYKMW%5CInformed%20Consent%20for%20Exempt%20Studies%20Policy.docx) and [Template](file:///C%3A%5CUsers%5Ccrockeju%5CAppData%5CLocal%5CMicrosoft%5CWindows%5CINetCache%5CContent.Outlook%5C2L1FYKMW%5CNP%20Template%20Informed%20Consent%20for%20Exempt%20Studies.docx))

**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. If applicable, 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 when, where, and how 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. 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:**

* 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 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 Timeline

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

**Response:**

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

**Response:**

## Procedures

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

**Response:**

* 1. Describe all research procedures.

**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. Describe the sources of data about participants. Attach all surveys, scripts, interview questions, stimuli, and data collection forms. Be sure to describe if you will be collecting data using photographs, audiotapes, and videotapes.

**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)? Describe the data security of the web-based application and how it will meet the needs of your study. Please be sure to describe options that you will use to enhance security.

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

**Response:**

# Provide debriefing method and debriefing protocol (including the rationale for 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. What data will be recorded, including long-term follow-up? Describe the data (e.g., excel spreadsheet, video or audio recordings, transcripts, photographs, etc...) that you will collect and store. Describe data that will be stored temporarily (e.g., a videotape until it is transcribed) and data that will be stored longer. 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...). 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. 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.

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

**Response:**

**If yes, you must answer each of the following questions:**

1) What is the justification for needing identifiers in order to conduct the research?

**Response:**

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

**Response:**

3) What is the likely retention period for identifiable data?

**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:**

# Risks to Participants

* 1. List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to participants related to 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:**

* 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 subject.

**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. Office either on letterhead or their workplace e-mail; **after** pending approval of the proposal is received.

**Response:**

#  Consent Process

* 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:**

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

**Response:**

* 1. Describe any process to ensure ongoing consent.

**Response:**

* 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:**

## 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:**

**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.

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

**Response:**

# Special Informed Consent Circumstances

**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 parents and, if so, who will be allowed to provide permission. 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.

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

* 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.

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

* 1. If you will document consent in writing, attach a consent form that includes a signature line.
	2. If you will obtain consent, but not document consent in writing, attach a consent script or document. You may use the “Informed Consent” template to create the consent form, document and/or script.
	3. 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:**