# 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 who participate in different research procedures, consent processes, etc., be certain to provide information in each applicable section for each participant group and clearly label each participant group within a section or subsection.*

# EXEMPTION 104.d3: Benign Behavioral Intervention

This application should be used only for Benign Behavioral Intervention research that meets the criteria at 45CFR46.104(d)(3):

**Benign Behavioral Intervention:** Low risk behavioral [not biomedical] interventions in conjunction with collecting information from an adult subject through oral or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and certain conditions are met:

Basic Benign Behavioral Intervention Determination Criteria (select one of the following):

|  |  |  |
| --- | --- | --- |
|  | 1. | The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained, directly or through identifiers linked to the subjects; OR |
|  | 2. | Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; OR |
|  | 3. | The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can be readily ascertained, directly or through identifiers linked to the subjects. |

In order to use this form, you must be able to check “YES” to the following statements:

|  |  |  |
| --- | --- | --- |
| Yes No | 1. | The level of risk to which participants are exposed in the benign behavioral intervention does not exceed minimal risk. |
| Yes No | 2. | The intervention is brief in duration, harmless, and painless; not physically invasive. |
| Yes No | 3. | The benign behavioral intervention will only be given to persons 18 years of age and older. |
| Yes No | 4. | The population used in this study is not considered “vulnerable to coercion”. |
| Yes No | 5. | Prisoners will not intentionally be interviewed/surveyed. |
| Yes No | 6. | Individuals who lack the capacity to provide informed consent (e.g., Alzheimer’s patients, individuals with certain mental disabilities) will not be used in this study. |
| Yes No | 7. | Confidentiality will be protected by proper secure storage of data. |
| Yes No | 8. | The benign behavioral intervention will not likely to have a significant adverse lasting impact on the subjects. |
| Yes No | 9. | The investigator has no reason to think the subjects will find the interventions offensive or embarrassing (e.g., playing an online game, solving puzzles, etc.). |
| Yes No | 10. | All researchers have completed CITI training. |
| Yes No  Not Applicable | 11. | External site approval, if needed, is attached. |
| Yes No  Not Applicable | 12. | Faculty Assurance Addendum is attached. |
| Yes No  Not Applicable | 13. | Psychology subject pool approval is attached. |

***If Statements 1-10 are answered Yes and 11-13 are Yes or Not Applicable, then the study can be certified as Exempt under 45CFR46.104(d)(3).***

*Include the full protocol title.*

Response:

# PRINCIPAL INVESTIGATOR:

*Name*

*Department*

*Telephone Number*

*Email Address*

Response:

# FACULTY SPONSOR (for student projects):

*Name*

*Department*

*Telephone Number*

*Email Address*

Response:

# VERSION NUMBER:

*Include the version number of this protocol.*

Response:

# DATE:

*Include the date of submission or revision.*

Response:

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# 1. Objectives

* 1. *Describe the purpose and specific aims, for the research. If applicable, state specific hypotheses to be tested.*

Response:

# Description of Participants and Recruitment Procedures

* 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. *If applicable, describe how individuals will be screened for eligibility.*

Response:

* 1. *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:

* 1. *Indicate the total approximate number of participants.*

Response:

* 1. *Describe when, where, and how potential participants will be recruited.*

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:

# Study Timeline

* 1. *Describe the duration of an individual’s participation in the study. Will you be conducting surveys at two or more time periods? (for example conducting follow-up surveys).*

Response:

If you are doing two or more surveys, how will you link them?

Response:

# 4. Procedures

* 1. *Describe the methods of the benign behavioral intervention administration in detail. For example, will you be conducting a web-based survey, an in-person interview, focus groups, a lab-based experiment, or a paper and pencil survey?*

Response

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

Response

* 1. *Explain the benign behavioral intervention you plan on using in your study completely. If you plan on using specific stimuli in your study (e.g., videos, images, scripts, etc.), please explain the stimuli here and attach copies. If you plan on using confederates in your study, please explain clearly what their role will be and how they will be trained?*

Response

* 1. *If you plan on using deception in your study, please explain how you plan to 1) deceive the participants in your study; 2) receive authorization from the participant through a prospective agreement to participate in research, and how you will inform the participant that they will be unaware of or they will be misled regarding the nature or purposes of the research.*

Response

# Data Analysis & Management

* 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? If yes, answer the following: 1) What is the justification for needing identifiers in order to conduct the research? 2) What is the sensitivity of the data being collected? 3) What is the* *likely retention period for identifiable data? 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)? 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. **Risks to Participants**
   1. *List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the participants related the participants’ participation in the research. Include, as may be useful for the HREB’s consideration, 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:

# Potential Benefits

# *Describe the anticipated benefits to participants, society and/or others. (There must be some benefit described)*

Response:

# External Approvals

# *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: