Exempt Form: Benign Behavioral Interventions

# 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 indicate "Not Applicable" and provide the reason the section is not applicable for the response.

## When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes.

## Do not remove the instructions or headings.

## If you are pasting information from other documents, be sure to use the "Merge Formatting" ("Paste & Match Formatting" on a Mac) paste option so that the formatting of the response boxes is not lost.

## 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. It may be easier to submit an application for each participant group if the procedures, consent process, etc... vary greatly.

## Exemption 104 (d)(3): 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.

# Researchers should complete the Benign Behavioral Exemption Application if any manipulation or deception is involved in the procedure, even imbedded into a survey.

# 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 participants; OR  |
|  | 2. | Any disclosure of the participants’ responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants’ 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 participants can be readily ascertained, directly or through identifiers linked to the participants and data security procedures are used to protect confidentiality and privacy. |

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Yes** | **No** | **Not Applicable** | **#** | **Statements** |
|  |  |  | 1. | The level of risk to which participants are exposed in the benign behavioral intervention does not exceed minimal risk. |
|  |  |  | 2. | The benign behavioral intervention will not have a lasting adverse impact on the participants. |
|  |  |  | 3. | The intervention is brief in duration, harmless, and painless; not physically invasive. |
|  |  |  | 4. | The investigator has no reason to think the participants will find the interventions offensive or embarrassing (e.g., playing an online game, solving puzzles, etc.). |
|  |  |  | 5. | Only oral or written responses (including data entry) or audiovisual recording (if the participant prospectively agrees) will be collected. No physiological measurements or measurements tracking location will be collected. |
|  |  |  | 6. | The study involves either no deception or the participant is informed that they may be misled or not made fully aware about the nature or purposes of the research.  |
|  |  |  | 7. | Study participants will only be persons 18 years of age and older. |
|  |  |  | 8. | Prisoners will not intentionally be included in the study. |
|  |  |  | 9. | 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. |
|  |  |  | 10. | The population used in this study is not considered otherwise vulnerable to coercion (e.g., the researcher's clients, students, employees). |
|  |  |  | 11. | Confidentiality will be protected by proper secure storage of data. |
|  |  |  | 12. | If applicable, external site approval is needed. |
|  |  |  | 13. | If applicable, Psychology subject pool approval is attached. |

**If Statements 1-11 are answered Yes and 12-13 are Yes or Not Applicable, then the study can be certified as Exempt under 45CFR46.104(d)(3).**

# 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:**

### Table of Contents

1.0 Objectives

2.0 Description of Participants and Recruitment Methods

3.0 Study Timeline

4.0 Procedures Involved

5.0 Data Analysis and Management

6.0 Risks to Participants

7.0 Potential Benefits

8.0 External Approvals

#### 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

## 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 the participants will be recruited. Describe when and where potential participants will be recruited.

Response:

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

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. 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:

# 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:

# Study Timeline

3.1. Describe the duration of an individual’s participation in the study. Will you be collecting data at two or more time periods? (for example, conducting follow-up sessions).

**Response:**

3.2 If you are doing two or more sessions, how will you link the data?

**Response:**

## Procedures

* 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 for your participants?

**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 your consent process and include your informed consent statement. (See the [Exempt Informed Consent Policy](https://www.newpaltz.edu/media/sponsored-programs/Informed%20Consent%20for%20Exempt%20Studies%20Policy.docx) and [Template](https://www.newpaltz.edu/media/sponsored-programs/NP%20Template%20Informed%20Consent%20for%20Exempt%20Studies.docx))

**Response:**

* 1. Describe the data (including all dependent variables) you are collecting about participants. Include a description of all demographic variables you plan to collect. Attach all surveys, interview questions, and data collection forms. Be sure to describe if you will be collecting data using photographs, audio recordings, and video recordings.

**Response:**

* 1. Explain the benign behavioral intervention (your independent variable) 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 (active and passive deception) in your study, please explain how you plan to 1) deceive the participants in your study and 2) receive authorization from the participants through a prospective agreement that they may be unaware of, misled, or not fully informed about the nature or purposes of the research.

Response:

* + 1. If your study involves any deception, please describe how you will debrief your participants. Include a script or written debriefing statement.

Response:

* 1. During the experimental session, if you are using a web-based application, describe the security of the application and options that you will use to enhance security.

Response:

# Data Analysis & Management

* 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 (codes in an excel spreadsheet).

**Response:**

* 1. Once your study is complete, describe your plan for the data that is stored in a web-application. For example, if you are using Qualtrics, will you permanently delete the data in the Qualtrics application once you downloaded it.

Response:

* 1. Describe how you will securely store, maintain, and use the data.

Response:

* 1. Will participants be identifiable? (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. **If yes, 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? Would disclosure of the data pose a risk to the participants including reputation, employability, legal, financial, health, personal privacy, etc.?

**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. If others have access to the data, describe how you will securely share the data among researchers (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. 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:

1. **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:**

# Potential Benefits

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

**Response:**

#  External Approvals

# If applicable, 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 HREB Office either on letterhead or their workplace e-mail after pending approval of the proposal is received.

**Response:**