**University of Vermont**

**Exempt 3 – Benign Behavioral Interventions**

This exemption is limited to research involving benign behavioral interventions in conjunction with the collection of information from an **adult subject** through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met Sec.\_\_.104(d)(3)(i):

* The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
* 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
* The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § \_\_.111(a)(7).

A behavioral intervention involves the performance of cognitive, intellectual, educational or behavioral tasks or the manipulation of the subject’s physical, sensory, social or emotional environment. It does not include medical interventions such as medical tests, procedures or use of medical devices. A benign behavioral intervention must be:

* Brief in duration
* Harmless
* Painless
* Not physically invasive
* Not offensive or embarrassing
* Not likely to pose a significant lasting adverse impact on subjects

Data collection methods are limited to verbal (oral) or written responses from the subject (such as surveys or interviews, test responses, data entry) or observation of the subject. Audiovisual recording is permissible with prior consent. Data cannot be collected via physical procedures (e.g. blood pressure monitoring, EEG, activity trackers (Fitbit), blood draws). Examples of behavioral interventions that may qualify for this exemption includes:

* Playing an online game
* Solving puzzles under various noise conditions
* Playing an economic game
* Being exposed to stimuli such as color, light or sound (at safe levels)
* Performing cognitive tasks
* Providing educational materials to participants with the intention of changing their behavior (e.g. smoking cessation, eating habits)

**Protocol/Project Title** Click or tap here to enter text.

**Principal Investigator Name** Click or tap here to enter text.

1. **Based upon the information above, does your project meet the definition of a benign behavioral intervention?**

[ ] **Yes (**continue to 2)

[ ] **No** [The project does not qualify for Exemption 3.]

1. **Confirm that your project involves research with adults** **only.**

[ ] **Yes, adults only** (continue to 3)

[ ] **No, I plan to use children.** [The project does not qualify for Exemption 3.]

1. **Does the research involve deception?** This means that subjects will be given false information, will be misled about some key aspect of the research, or will be misled about the purpose of the research. Examples include: providing false feedback regarding test performance or using a confederate to influence participant’s behavior in the research. Note: Use of experimental controls is not deception.

[ ] **No, my project does not involve deception** (continue to 4)

[ ] **Yes, my project involves deception** (continue to 3a)

**3.a. If yes, will you tell subjects prior to their participation that they will be participating in a project that involves deception?**

[ ] **Yes, subjects will be told prior to their participation that the research will involve deception.** (continue to 4)

[ ] **No, subjects will not be told that the research will involve deception until after their participation**.[The project does not qualify for Exemption 3.]

1. **In order to qualify for this exemption, the researchers must describe the intervention and data collection methods to potential subjects and seek their prospective agreement/consent to participate.**

This exemption does not apply to projects where participants are not aware that they are participating in research, such as videotaping pedestrian behavior when a walk/don’t walk sign is being manipulated for research purposes.

 **Confirm that you obtain prospective agreement/consent to participate.**

[ ] **No** [The project does not qualify for Exemption 3.]

[ ] **Yes** (continue to 4a)

**4.a. Describe how prospective agreement/consent/HIPAA will be obtained. For projects where subjects will be informed about deception, include a description of that process.**

Click or tap here to enter text.

1. **Does the research collect information about the subject in such a manner that their identity can be readily ascertained by the investigator, directly or through identifiers linked to the subjects?** This means that the data are collected with direct identifiers (name, address, email, phone number, social security number, student ID, patient ID) or indirect identifiers, such as a code that can link back to the subject or data elements that could be combined to readily identify an individual (dates, employment history, etc.).

**Select one:**

[ ] **The participant is directly identifiable**

[ ] **The participant is indirectly identifiable (using code to link back to subject)**

[ ] **The participant is not identifiable (e.g. anonymous).**

1. **Will the research generate information that, if revealed outside the research, could place the subjects at risk of criminal or civil liability, or damage to their financial standing, employability, educational advancement or reputation?** This means that the research involves the collection of sensitive information, such as information about illegal behaviors, mental health issues, sexual attitudes, preferences or practices, information about sensitive health conditions (e.g. HIV, STDs), genetic information, or negative opinions/attitudes about employers or teachers that could result in social stigmatization. A disclosure of this information outside of the research (breach of confidentiality) could pose risks to the subjects.

**Select one:**

[ ] **The information is not sensitive. (continue to 7)**

[ ] **The information is sensitive. (requires limited review, continue to 7)**

**7. Will the research involve the access, collection, use, maintenance, or disclosure of University of Vermont Medical Center or University of Vermont protected health information (PHI**

[ ] **Yes** (requires limited review & Data Management and Security Plan, continue to 7a)

[ ] **No** (continue to 8)

7.a. **Investigators are required to only obtain the minimum necessary data in order to achieve the goals of this research. Please explain why the PHI you are obtaining is the minimum necessary to achieve the goals of the research.**

Click or tap here to enter text.

**8. Provide a brief summary of your research (include a description of subject population, process for recruitment, study procedures (including description of the benign intervention and data collection methods), and location of research).**

Click or tap here to enter text.

**9. Will subjects receive payment or other incentives for their participation in the study?**

[ ] **No** (continue to 10)

[ ] **Yes** (continue to 9.1)

**9.1 Estimate the maximum total payment and specify funding source.** Click or tap here to enter text.

**9.2 Please indicate what information you will be collecting from subjects (e.g. social security number, address) to allow payment for their participation.** Click or tap here to enter text.

**10. Upload documents (e.g. survey, information sheet, interview questions, Data Management and Security Plan, Data Use Agreement if sharing data beyond the institution).**