**Supplemental Form for**

**Exemption Category 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.

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

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

**Faculty Sponsor Name (if applicable)** Click or tap here to enter text.

1. **Please check only one of the following Exempt 3(i) criteria you are applying for:**

**(i) 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:**

(A) 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; **or**

(B) 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**

(C) 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 §46.111(a)(7).

*(Criterion (3)(i)(C) requires a limited IRB review to determine that adequate provisions are in place to protect the privacy of subjects and the confidentiality of data. Please attach a data safety management plan)*

**(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.**

**(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.**

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. 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)

Data cannot be collected via physical procedures (e.g. blood pressure monitoring, EEG, activity trackers (Fitbit), blood draws).

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

**Yes (**continue to 3)

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

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

**Yes, adults only** (continue to 4)

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

**4. 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 5)

**Yes, my project involves deception** (continue to 4a)

**4.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 5)

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

**5. Describe the intervention and data collection methods to potential subjects.** 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.

Click or tap here to enter text.

**6. 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 (may require Limited Review)**

**The participant is indirectly identifiable (using code to link back to subject)(may require Limited Review)**

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

**7. 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.**

**The information is sensitive. Please describe:** Click or tap here to enter text.

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

*If you are applying for Exemption 3(i)(c) The Research Data Management and Security Plan form is required to be submitted and attached to the Click record .*