**Exemption Category 3**

**Benign Behavioral Interventions** [**45 CFR 46.104(d)(3)**](https://www.ecfr.gov/current/title-45/part-46/section-46.104#p-46.104(d)(3))

This exemption is limited to research involving benign behavioral interventions in conjunction with the collection of data from an adult participant through verbal or written responses (including data entry) or audiovisual recording if the participant prospectively agrees to the intervention and data collection.

**Protocol 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 participant through verbal or written responses (including data entry) or audiovisual recording if the participant prospectively agrees to the intervention and information collection and *at least one* of the following criteria is met:**

(A) The data 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 data 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).](https://www.ecfr.gov/current/title-45/section-46.111#p-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 participant’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 participants

Data collection methods are limited to verbal (oral) or written responses from the participant (such as surveys or interviews, test responses, data entry) or observation of the participant. 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 the protocol meet the definition of a benign behavioral intervention?**

Yes (continue to 3)

No [The protocol does not qualify for Exemption 3.]

**3. Confirm the protocol involves research with adults** **only.**

Yes, adults, 18 and older (continue to 4)

No, the protocol will enroll children under age 18. [The protocol does not qualify for Exemption 3.]

**4. Does the research involve deception?** For instance, participants will be given false information, may be misled about some key aspect of the research or 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 protocol does not involve deception (continue to 5)

Yes, my protocol involves deception (continue to 4a)

**4.a. If yes, will you inform participants prior to their participation they will be participating in a protocol involving deception?**

Yes, participants will be told prior to their participation that the research will involve deception. (continue to 5)

No, participants will not be told the research will involve deception until after their participation. [The protocol does not qualify for Exemption 3.]

**5. Describe the intervention and data collection methods to potential participants.** This exemption does not apply to protocols 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 data about the participant in such a manner that their identity can be readily ascertained by the investigator, directly or through identifiers linked to the participants?** The data is 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 participant 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 participant)(may require Limited Review)

The participant is not identifiable (e.g. deidentifed).

**7. Will the research generate data that, if revealed outside the research, could place the participants at risk of criminal or civil liability, or damage to their financial standing, employability, educational advancement or reputation?** 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, genetic data, or negative opinions/attitudes about employers or teachers that could result in social stigmatization. A disclosure of this data outside of the research (breach of confidentiality) could pose risks to the participants.

Select one:

The data is not sensitive.

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

**8. Provide a summary of your research:**

**8a. Include the study objectives & purpose:**

**8b. Describe the participant population and process for recruitment:**

**8c. Describe study procedures including:** the anticipated time commitment for each study procedure; if procedures are conducted in person or virtually, including on what platforms they are hosted; if any activities are recorded (audio and/or video), please include programs used for recording and transcription**.**

**8d. Data storage and analysis including:** storage locations, physical and electronic security, who has access to the data, how long it will be stored, and data sharing.

*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 .*