Exempt Category 3 is intended for research studies that involve "benign behavioral interventions" (to which participants must prospectively agree) combined with the collection of information from adult subjects through verbal or written responses including data entry, or through audiovisual recording.

The methods of data collection allowed under exempt category #3 are limited to verbal or written responses from subjects (e.g., surveys or interviews, test responses, or data entry), observation, and audiovisual recording. Data cannot be collected via physical procedures such as blood pressure monitoring, EEG, activity trackers (e.g., Fitbit), eye trackers, and blood draws.

Definitions

A "*behavioral intervention*" involves the performance of a cognitive, intellectual, educational, or behavioral task; or the manipulation of the subject's physical, sensory, social, or emotional environment. Because medical interventions are not behavioral interventions, studies that include medical tests, medical procedures, and/or the use of medical devices are not eligible for exemption under Category #3.

"Benign" behavioral interventions must be:

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

Limitations

In order to qualify for Exemption #3, one of the following must be true:

i. **Data are collected anonymously**. This means that no one, not even members of the study team, has the ability to link data with individual subjects at any time, directly or indirectly through the use of coding.
ii. The **study does not collect sensitive information** about subjects that could place them at risk if inadvertently disclosed outside the research. Sensitive information refers—but is not limited—to illegal activities, genetic or medical information, sexual behaviors, negative attitudes/opinions about one's employer or coworkers, etc. Risks include criminal liability, social stigmatization, etc.
iii. The study collects **sensitive and identifiable information** about the subjects. In this case, the IRB will conduct a "limited" IRB review to ensure adequate provisions are in place to protect the subject privacy and the confidentiality of the data. This means that the IRB must review and approve procedures for data management and security where sensitive information is collected with direct identifiers (e.g., name, address, email, phone number, social security (See Data Security section below).

In addition, to qualify for Exempt #3:

- Children cannot be the study population.

- Prisoners cannot be the study population.
- Investigators must seek prospective agreement of subjects to participate.

Examples

Examples of benign behavioral interventions:

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

Required Documentation

Only the URI Human Research Protection Program can make the determination that their research qualifies as Exempt.

Required documentation include:

1. Exempt Research Application
2. Survey and Interview tools
3. Recruitment materials (e.g., emails, flyers)
4. CITI training record(s) for Principal Investigator and Student Investigator
5. If non-URI entities will be used, written authorization from appropriate site authority
6. Informed Consent document (see URI templates for low risk research, child assent, and parental permission).
7. If research will be used for thesis or dissertation, include thesis/dissertation approval form and thesis/dissertation proposal

Data Security

The IRB requires the researchers to describe methodology for data security to ensure adequate protection of the privacy of subjects and to maintain the confidentiality of the data.

Regulatory Language (45 CFR 46.104(d)(3) – Exempt Category 3

(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;

(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 §_.111(a)(7).

(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.