**Exempt Category 3: Benign Behavioral Interventions – Tip Sheet**

**What is a Behavioral Intervention?**

Behavioral interventions involve data collection through cognitive, intellectual, educational, or behavioral tasks; or the manipulation of the participants physical, sensory, social, or emotional environment.

**What is a Benign Behavioral Intervention?**

Data is collected from **adult** research participants through verbal or written responses or audio-visual recording. To qualify as a Benign Behavioral Intervention, the subject must agree to the intervention and information collection ahead of time, be able to consent to research participation without a legally authorized representative, and one of the following criteria must be met:

1. The information obtained from the participant is recorded in such a manner that the identity of the participant cannot readily be ascertained directly or indirectly
2. Any disclosure of the participant’s responses outside of the research would not place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation
3. The information obtained is recorded by the researcher in such a manner that the identity of the human subjects can be readily ascertained, directly or indirectly, and IRB conducts a limited IRB review to make the determination

Benign Behavioral Interventions must be brief in duration, only include adults, be harmless, painless, not physically invasive, not likely to have a significant adverse impact on participants, and not offensive or embarrassing to the participants. They can only include deception if the participants agree to participate following the disclosure of the fact that they will be unaware of or misled regarding the nature or purpose of the research. Data collection procedures for this category are limited to the following:

• verbal (oral) or written responses by the subject

• data entry by the subject

• observation of the subject, including audiovisual recording

Physical procedures that are low risk, such as the application of sensors to the body (e.g. blood pressure monitoring, electroencephalogram (EEG), wearable activity trackers), minimally invasive procedures (e.g. blood drawing), the collection of bodily fluids via introduction of a tool or sensor into the body (e.g. buccal/cheek swab), and data entry by a device (e.g., a Fitbit) would not qualify for this exemption category.

Examples of benign behavioral interventions include:

* Online games and puzzle solving under various noise conditions
* Being exposed to stimuli such as light, color, sound at safe levels
* Having participants decide how to how to allocate a small amount of cash between themselves and someone else
* Being randomly assigned to respond to different advertisements or scenarios

**Application Tips**

Be sure to carefully describe all study procedures in your application and outline whether participants will be randomly assigned to different study conditions. Also provide a complete explanation of the intervention and data collection procedures in the application. Make sure that the consent form describes the intervention and data collection procedures, and lets participants know that they will see a different scenario or stimuli than others or deception.

The HRPP recommends using the following language in the consent if deception will be involved: “We have described the general nature of what you will be asked to do but the full intent of the study will not be explained to you until after [your participation/the completion of the study]. At that time, we will give you more information about the study and give you an opportunity to ask questions.

All deception studies must include a debriefing statement the reiterates the purpose of the study, explains the deception, and let’s them know who to contact if they have further questions or don’t want to be involved in the research.

If you have further questions about benign behavioral intervention please contact the UTK HRPP at (865) 974-7697 or email us at utkirb@utk.edu