UMSL Research
University of Missouri–St. Louis

Institutional Review Board (IRB)

GUIDELINES FOR RESEARCH INVOLVING BENIGN BEHAVIORAL INTERVENTIONS

This guidance document aims to provide examples of interventions that are considered 'benign' and to outline the limitations on the use of Exempt Category 3 at University Missouri-St. Louis.
How do the federal regulations describe this exemption category?

"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 § 46.111(a)(7).

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. The interventions are limited to communication or interpersonal contact with the subject; performance of a cognitive, intellectual, educational or behavioral task; or manipulation of the subject's environment.

Provided all applicable criteria are met, examples of 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.

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 in the recruitment statement that he or she will be unaware of or misled regarding the nature or purposes of the research.

What are the limits on the use of Exempt Category 3?

- Participants must be adults who are able to prospectively agree to the research. Subjects who require a legally authorized representative may not be enrolled.

- The overall duration of the study must be brief. It should occur in a single day and not exceed more than a few hours.[1]

- Research activities must be behavioral in nature; they cannot include medical interventions, even if those interventions are minimal risk.

- Data collection must only be through verbal and written responses by the subject, data entry by the subject or observation of the subject which may include audiovisual recordings. Data from electronic sensors or devices would not be allowable in this exemption category.

- Changes to the subject's physical environment are allowed, provided they do not involve extremes of heat, cold, noise or light.

- Appropriate privacy protections are required.

[1]Brief in duration is intended to refer to the intervention as opposed to the intervention and the data collection activities together. Thus, the data collection activities could proceed over a longer period of time without precluding the applicability of this exemption. If the intervention and the data collection are intertwined or difficult to separate, the entirety of the activity should be brief in duration. To meet the requirement of brief in duration, the benign behavioral intervention should last a few minutes to a few hours. While it does not have to occur in a single session, the entire time for the intervention should occur on a single day and not exceed a few hours in its entirety. (SACHRP Recommendation Approved July 26, 2017).

What are examples of 'benign interventions?

Example*	**Benign Intervention, Yes, or no?**
Graduate business students are asked to participate in research examining the influence of surfing a social media site on measures of self-control. Students are randomly assigned to browse a popular social networking site or a popular news site and then, as a measure of self-control and persistence, are timed in their efforts to solve a complex word puzzle (for which there is no solution). No identifiable information is recorded.	**Yes.** Subjects will agree to participate, and the data is anonymous.
To study the influence of restaurant gratuity policies on overall satisfaction, customers calling for reservations are asked to take part in a research study involving the completion of an anonymous survey following their meal. Those who agree are randomly assigned to either a suggested service charge group or a group where there are no suggested gratuity amounts identified. Individuals are informed about a survey but not about the subject of the survey or the random assignment. All are told that certain aspects of the research will only be revealed to them at the conclusion of their involvement.	**Yes.** The study involves deception, and subjects are informed of this aspect in advance. Also, the intervention is brief and not expected to have a negative impact.
Adult learners agree to be videotaped while reading a passage from a standard text alone in a quiet room. Ratings of vocal inflection and tone are assessed as predictors of comprehension and compared with the results of a written test of the subject's ability to understand the same reading material. The procedures take 90-120 minutes.	**Probably yes.** Subjects are alone in the room, so the potential for embarrassment in public speaking has been avoided. A limited IRB review might be required if the study involved a population who could be negatively impacted by an unintended disclosure of results.

Nursing home staff interview patients to complete a brief self-report scale measuring mood and anxiety at baseline and two weeks after music is played nightly in-patient rooms on half of the wards. All subjects are informed that a study of the effect of music is planned, and music is played only in the rooms of those patients who agree to the intervention and ratings.	**No.** Although the changing of the subjects' environment is allowed, and the intervention is likely benign, the two-week duration would not qualify as 'brief' for this exemption category. This project would require review as Expedited research.
Healthy adult subjects are asked to take part in two, two hour-long assessments of memory, attention, and information processing speed before and after 1 hour of cognitive enhancement exercise using specially designed computer software. The procedures are conducted during a single visit, and subjects are encouraged to take breaks when desired.	**Yes.** The intervention lasts one hour and the data collection lasts 4 hours. This would meet the definition of brief, and the study is not likely offensive or harmful.
Recordings of blood pressure and pulse are obtained along with the collection of a saliva specimen for the measure of cortisol levels from adult subjects in a study linking physiological arousal to cognitive performance on a standard series of computer games. The procedure lasts 75 minutes.	**No.** The intervention is brief, but the study involves collection of blood pressure, pulse, and saliva samples. This exemption category does not allow medical interventions, even if there is minimal risk. Also, the study data would involve more than oral or written responses.
College students take part in a study involving computer simulation of an online dating app in which each student is rejected by a prospective date who in fact is a member of the study team. The students are asked to agree to the research and are told that aspects of the research goals and methods are being withheld from them until after their participation.	**No.** Although subjects are informed of the deception, the aim of the study is to simulate rejection and elicit an emotional response. The experience of rejection may cause distress and embarrassment, and therefore the intervention would not be considered benign.
A study seeks to measure how individuals attend to visual stimuli with different emotional meanings. Each subject places his/her head on a chin rest in front of a computer monitor while being shown a matrix of 6 magazine photos of people with mildly sad, happy, surprised, frightened, and worried expressions. Subject eye movements/fixation are recorded by a digital camera. No identifying data is recorded.	**Yes.** The intervention is brief. The mild emotions in the photos are unlikely to be disturbing or elicit a strong negative response.

Clients at a health club are asked to participate in a study looking at the impact of a two-hour session on the benefits of exercise. Clients are provided with a free Fitbit and then asked to come to the club every other day to have a reading taken of their daily steps as recorded on the Fitbit.	**No.** The study data would involve more than oral or written responses because a Fitbit is being used. This project would require review as Expedited research.

*Examples and recommended answers are abstracted from guidance by the Secretary's Advisory Council on Human Research Protections published at https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-b-august-2-2017.html

Source: Saint Louis University