

SACHRP Recommendation Approved July 26, 2017ⁱ ((OHRP), 2017)

Category 3 Exemption Examples of Benign Behavioral Interventions.

Below are examples of research activities that would be considered benign behavioral interventions, as well as several examples of research activities that would not be considered benign behavioral interventions. This list will continue to be updated as more guidance becomes available.

For more information on benign behavioral interventions or other changes in the Common Rule, visit the SACHRP [website](#).

1. Graduate business students are asked to participate in research examining the influence of surfing a social media site on measures of self-control. Students were randomly assigned to browse a popular social networking site or a popular news site and then, as a measure of self-control and persistence, were timed in their efforts to solve a complex word puzzle (for which there was no solution). No identifiable information is recorded.

This example describes a behavioral intervention (the random assignment to browse the web site) followed by the collection of data on persistence on a complex task (by direct data entry). The intervention is benign, in that it involves no appreciable risk of harm or pain or emotional distress for the subjects. Assuming student agreement was obtained for participation and the data were anonymous, **this example fulfills the criteria for exemption as a benign behavioral intervention.**

2. 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 assignment to one of these groups. All are told that certain aspects of the research will only be revealed to them at the conclusion of their involvement.

Since knowledge of the study purpose may influence customer responses to the anonymous survey, the research employs deception. Subjects are informed of the research, of the fact that the research includes deception, and they prospectively agree to take part. The random assignment to one of two commonly employed policies on gratuities is brief, harmless, painless, not likely to have a significant adverse impact on the subject, and not likely to cause offense or embarrassment. **This example fulfills the criteria for exemption as a benign behavioral intervention.**

3. Adult learners agree to be videotaped while reading a passage from a standard text while 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.

This would be brief in duration. The intervention here requires the subject to read a passage. While public reading or the performance of math problems in front of an audience of strangers may be used to provoke a stress response in some research, the subject in this example is alone in a quiet room and reading from a standard text. If characteristics of the population suggest that an unintended disclosure of the subject's responses would be damaging to employability or reputation or be significantly embarrassing, there would have to be a limited IRB review to ensure that there are protections in place to address the possibility of unintended disclosure. **This example fulfills the criteria for exemption with a limited review conducted by the IRB, as a benign behavioral intervention.**

4. 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 the rooms of those patients who agree to the intervention and ratings.

This intervention involves the manipulation of the subjects' environment and the collection of data using a self-report measure of mood and anxiety. The intervention is benign and the methods of collecting data are consistent with the exemption criteria. Considering the nature of the study (the playing of background music), the duration of exposure does not alter the fundamentally benign nature of the intervention. Nonetheless, it would not be considered brief. **The study would not meet the requirements for exemption.**

5. Healthy adult subjects are asked to take part in (2) two (2) 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.

The intervention in this example requires healthy adult subjects to take part in a five-hour research study in which the benign behavioral intervention lasts one hour and the data collection lasts four hours. This would then meet the definition of brief in duration, and the research itself is not likely to be offensive or harmful. **This example fulfills the criteria for exemption as a benign behavioral intervention.**

6. Recordings of blood pressure and pulse are obtained along with the collection of a saliva specimen for the measure of cortisol level from adult subjects in a study linking physiological arousal to cognitive performance on a standard series of computer games. The procedures last 75 minutes.

The computer game intervention is brief and is likely to be benign (depending on the content of the games), but the collection of blood pressure, pulse, and serum cortisol data would be considered medical interventions and so not consistent with the exemption. In addition, the data collection proposed is not consistent with the exemption which requires data collection by oral or written responses only. **The study would not meet the requirements for exemption.**

7. College students take part in a study involving computer simulation of an online dating app in which each student is ultimately 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.

While the students agree to take part in the study and are told that deception is involved, the aim of the intervention is to simulate rejection and elicit emotional responses. While some may assume that their experience of rejection was an experimental manipulation, many will likely react to the intervention (and to the post-study debrief) with shame, embarrassment, and humiliation. **The study would not meet the requirements for exemption.**

8. A study seeks to measure how individuals attend to visual stimuli with different emotional meaning. Each subject places his 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.

The intervention is brief, and data collection involves only visual recording. Given the description of the photos, the intervention is not likely to be harmful, frightening, likely to have a significant adverse lasting impact, or be considered offensive. **This example fulfills the criteria for exemption as a benign behavioral intervention.**

9. 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.

This would not meet the exemption because the data recording by the Fitbit is not consistent with the requirement that data may only be collected using verbal or written responses or audiovisual recording. **The study would not meet the requirements for exemption.**

ⁱ Hhs.gov. (2017, November 09). Attachment B - Recommendations on Benign Behavioral Intervention. Retrieved January 14, 2019, from <https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-b-august-2-2017.html>