# RESEARCH INVOLVING BENIGN BEHAVIORAL INTERVENTIONS

Beginning in January 21st, 2019, the federal government will change the types of human subjects research that are considered "exempt." A new category of exempt research will be those projects involving benign interventions (Exempt Category #3). This guidance document aims to provide examples of interventions that are considered 'benign' and to outline the limitations on the use of the exemption category.

**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 §__.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 tasks; or manipulation of the subject's environment.

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."

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

- Participants must be adults who are able to prospectively agree to the research. Children and subjects who require a surrogate decision-maker may not be enrolled.

- The overall duration of the intervention must be brief. It should occur in a single day and not exceed more than a few hours.
- The research activities must be behavioral in nature; they cannot include medical interventions, even if those interventions are low risk.
- Data collection must only be through verbal and written responses by the subject, data entry by the subject or observation of the subject. The data collection can include audio or video recordings.
- Data from electronic sensors or devices would not be approvable 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.

**What are examples of 'benign interventions'?**

| **Example*** | **Benign Intervention, Yes or No?** |
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| 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. | Yes. Subjects will be agreeing to participate, and the data will be 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 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. | Yes. The study involves deception, and subjects are informed of this aspect in advance. Also, the intervention is brief and not expected to be have negative impact. |
| 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. | 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 |

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| | 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 the rooms of those patients who agree to the intervention and ratings. | No. Although the changing of the subjects' environment is allowed and intervention is likely benign, the two-week duration of the intervention 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 is completed in a single day and the study is not likely to be seen as offensive or harmful. |
| 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. | 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; also the study data would involve more than oral or written responses. This project would require review as Expedited research. |
| 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. | 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. Therefore the intervention would not be considered benign. |
| 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 and fixation are recorded by a digital camera. No identifying data are recorded. | Yes. The intervention is brief. The mild emotions in the photos are unlikely to be disturbing or elicit a strong negative response. |

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| 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 | |