CAMPBELL UNIVERSITY	**IRB Guidance:** Benign Behavioral Intervention

A Guidance and Educational Tool for Benign Behavioral Interventions
(SACHRP Recommendation Approved July 26, 2017)

The 45 CFR 46.104(d), Category 3 exemption for benign behavioral research in the Final Rule is intended to cover research for which IRB review is likely to add little additional protections because the risk of harm is low and subject autonomy is respected by the requirement for prospective agreement. Certain research that is ineligible for 45 CFR 46.104(d), Category 2 exemption because it includes an intervention might meet the criteria in exemption Category 3, if the intervention is a benign behavioral one. The exemption requires that the intervention only include adults, be brief in duration, harmless, and painless, among other criteria. The brief in duration requirement only pertains to the intervention itself, and not the data collection. Certain research that does not meet the requirements for this exemption may be eligible for expedited review. This exemption makes an important distinction between the research intervention and the means by which data is collected to study that intervention.

The Campbell IRB will use this guidance for projects that qualify for Registration Projects as determined by FLEX-review, Registration Categories 10.

The following ten questions, along with associated guidance, may be used as a learning tool and to assist in the determination of whether human subjects research may be considered exempt under 45 CFR 46.104(d), Category 3(i).

1. Does the human subjects research involve only the participation of *adults*?

[If no, not exempt under 45 CFR 46104(d), Exempt Category 3(i)]

The exemption at 45 CFR 46.104(d)(3)(i) applies only to **adult subjects**.

2. Does the participant have adequate decision-making capacity to agree to participate in the proposed research?

Under this exemption, the potential participant must be able to agree to take part in the research and therefore must have sufficient decision-making capacity to do so. The level of cognitive ability required will vary depending on the complexity of the intervention proposed. Research requiring decision-making on behalf of the participant by a legally authorized representative would not qualify for the exemption.

3. May research involving benign behavioral interventions include vulnerable populations?

Research review under this exemption should evaluate the intended population to see if there are any vulnerabilities that would impact their ability to provide prospective agreement, and whether the research could be offensive or harmful for any prospective participants.

The regulations at 45 CFR 46.104(b) specifically state that in order for individuals who meet the definition of a prisoner to be involved in exempt research, the research should involve a broader subject population that only incidentally involves prisoners. This exemption could include individuals who are covered by subpart B.

4. Does the nature of the research enable *prospective agreement* to participation by the subject; and, if so, is such prospective agreement required?

[If no, not exempt]

The language of the exemption requires subjects to prospectively agree to the specific intervention and the information collection. This means that only research in which the human subject is a knowing participant in research would qualify for the exemption.

Prospective agreement must be meaningful, but it is not the same as a requirement for explicit consent. For example, individuals who are simply made aware that research data will be collected as they voluntarily complete a computer task may be understood as having agreed to participate.

Research for which prospective agreement is not possible would not be eligible for exemption. For example, research involving the videotaping of pedestrians' behavior when the timing of a public Walk/Don't Walk is manipulated would not be exempt under this category unless they agreed in advance to participate.

5. If the research involves deceiving the subjects, does research include *prospective agreement* by the subject to the planned deception?

[If no, not exempt]

As with the requirement for prospective agreement, the exemption permits research involving deception only when the subject agrees to participate in research following disclosure of the fact that he or she will be unaware of or misled regarding the nature or purpose of the research. Researchers should consider debriefing after the intervention, as appropriate.

6. Is the research *intervention* limited to procedures involving:

- **communication or interpersonal contact with the subject,**
- **the performance of a cognitive, intellectual, educational or behavioral task, or**
- **manipulation of the subject's physical, sensory, social, or emotional environment?**

The term ***behavioral intervention*** is used in the language of the regulations to define research procedures that are employed in the study of psychological states and processes, cognition, ideas and attitudes, or behavior, and do not include physical (bodily) tasks or physical manipulations (e.g., range of motion activities, physical exercise) unless these are minor activities that are incident to the behavioral intervention and do not increase risk. For example, manipulating a keyboard, doing a puzzle, or walking while listening to music would be physical activities that could be considered minor activities that are taking place incident to the benign behavioral intervention. Physical interventions that are physically invasive; or, those that could be harmful or painful would not meet the exemption.

Behavioral interventions are not physically invasive when they do not involve the introduction or administration of instruments, substances or energy onto or into the body.

Alterations in the subject's physical or sensory environment may be considered behavioral interventions to this exemption. Such interventions may not be harmful, painful or distressing, such as exposure to extremes of heat, cold, noise or light.

7. Does the human subjects research involve means of collecting data limited to 1) verbal (oral) or written responses by the subject, 2) data entry by the subject, or 3) observation of the subject, including audiovisual recording?

[If no, not exempt]

This category defines a narrow set of the allowable means by which data can be collected. Even very low risk physical procedures such as the application of sensors to the body (e.g. blood pressure monitoring, electroencephalogram, wearable activity trackers), minimally invasive procedures (e.g. blood drawing), and the collection of bodily fluids via introduction of a tool or sensor into the body (e.g. buccal swab) would not be consistent with the language of this exemption. Data entry by a device (e.g., a Fitbit) would not meet this exemption.

8. Does either the intervention or the methods used to collect data introduce risks of harm, physical or emotional discomfort, offense, or embarrassment?

The term ***benign*** describes an intervention that is not expected to cause physical or emotional harm, persistent discomfort, be experienced by the subject as embarrassing, or be offensive. Ordinary, mild, transient forms of discomfort, such as the stress associated with completing a timed cognitive task, anxiety about performance, and boredom, are consistent with the intent of the exemption. Similarly, while research cannot meaningfully eliminate all risk of embarrassment or offense, the research should include only interventions that the researcher has no reason to think subjects will find offensive or embarrassing considering the characteristics of the subject population, the research context, and how they might impact the subject's experience of the research intervention.

9. Is the intervention brief in duration?

[If no, not exempt]

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.

10. Is at least one of the following conditions regarding privacy protections met?

[If no, not exempt]

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 45 CFR 46.111(a)(7).

In addition to the explicit limits on risk of harm described in the regulatory language and implied in the examples, only human subject research that introduces little or no risk of harm to subjects' privacy interests may be exempt from IRB review under this category, or subject to limited IRB review (as described in C). This requires the IRB to review the privacy, confidentiality and safety measures regarding the use and storage of identified information.

Examples:

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, the study would meet the criteria for 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.

   This example fulfills the criteria for exemption as a benign behavioral intervention. 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.

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.

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 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.

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. This example would not be exempt under this category.

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. This example would therefore not meet the exemption criteria.

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. The example is consistent with the exemption under this category.

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.

Adapted from: https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-b-august-2-2017.html