**Colorado College IRB Benign Behavioral Intervention Research**

**Exemption Determination Form Information Sheet**

**[45 CFR 46.104(d)(3)]**

Your research may qualify for exempt status, meaning that it does not require substantial IRB review; your research would most likely be eligible if it is a psychological or marketing study. To have your research considered for exempt status, please read the first two pages carefully then complete the form that begins on page 4. If your study is not eligible for this exemption, please complete the regular application form and your project will receive expedited review.

Because this exemption is very detailed and because many of the details require further explanation, this document begins with the text of the exemption, then continues with the CC IRB’s interpretations of the exemption’s criteria (often supported by federal commentary). The form for you to fill out follows the text and interpretations and begins on page 4. The CC IRB has numbered the important points for clarity in the following regulatory text (otherwise unchanged except for the use of “participants” instead of “human subjects”).

(1) This exemption is for research involving benign behavioral interventions in conjunction with the collection of information (2) from an adult participant (3) through verbal or written responses (including data entry) or audiovisual recording (4) if the participant prospectively agrees to the intervention and information collection and (5) at least one of the following criteria is met:

* (5a) The information obtained is recorded by the investigator in such a manner that the identity of the participants cannot readily be ascertained [either] directly or through identifiers linked to the participants. OR:
* (5b) Any disclosure of the participant responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to their financial standing, employability, educational advancement, or reputation. OR:
* (5c) The information obtained is recorded by the investigator in such a manner that the identity of the participants can readily be ascertained, directly or through identifiers linked to them, and the CC IRB conducts a limited IRB review to make sure that the research has adequate provisions in place to protect the privacy of participants and to maintain the confidentiality of their information.

For the purpose of this provision, benign behavioral interventions are (6) brief in duration, (7) harmless, (8) painless, (9) not physically invasive, (10) not likely to have a significant adverse effect on participants, and (11) the investigator has no reason to think the participants will find the intervention offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the participants 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.

(12) If the research involves deceiving the participants regarding the nature or purposes of the research, this exemption is not applicable unless the participant authorizes the deception through a prospective agreement to participate in the research in circumstances in which the participant is informed that they will be unaware of or misled regarding the nature or purposes of the research.

The Colorado College IRB’s interpretation of the above (based on federal guidelines) follows:

(1) Benign behavioral interventions are limited to procedures involving some combination of the following:

* Communication or interpersonal contact with participants, and/or
* The performance of a cognitive, intellectual, educational, or behavioral task, and/or
* Manipulation of the participant’s physical, sensory, or emotional environment.

Benign behavioral interventions can include physical tasks or manipulations that are minor activities incidental to the behavioral intervention and that do not include any kind of risk of harm. The federal government has suggested the following acceptable examples of physical task or manipulations: use of a computer keyboard, using one’s hands to solve a puzzle, or walking while listening to music. The CC IRB would add, for the example of walking, that the federal government’s listing of it assumes that participants are fit and physically well enough to walk comfortably and without danger of physical harm.

This exemption does not cover physical or medical interventions.

(2) This exemption is only available for research involving adult participants. A benign behavioral intervention project involving children is not eligible for the exemption.

(3) This section lists acceptable methods of data collection and does not require interpretation.

(4) This exemption requires that all participants prospectively agree to participate in the research. This has implications for deception, covered below, but it has other implications as well. Specifically, naturalistic field studies are not eligible for the exemption since potential participants have no way to agree to participate before they encounter the study.

(5) This section provides three criteria that are present in order to ensure the protection of participants (the interaction exemption has the same criteria). Specifically, the research must either guarantee confidentiality to participants (5a), pose no risk of public/social harm to them (as defined in the text above; 5b), or be subject to a limited (minimal) review by the IRB to make sure that privacy and confidentiality practices in the research are rigorous. Note that the limited review only comes into effect if the project is both (a) non-confidential and (b) socially harmful. The IRB chair will carry out the limited review on an expedited basis. If the IRB chair finds that the project does not guarantee sufficient confidentiality/privacy conditions, the chair will work with the researcher to develop such conditions before exempting the project.

(6) The intervention itself must be “brief in duration,” which has been interpreted as meaning that the intervention may not take longer than a few hours and must not occur on more than one day. However, the data collection part of the research is not limited in the same way that the intervention proper is, and there is no guidance about how long or short the data collection should be.

(7) The intervention must be harmless. The CC IRB interprets harmlessness here to refer to all harms covered in the regular IRB application: legal, criminal, financial, political, social, academic, physical, and psychological. The CC IRB will grant exemption to projects that fall below the standard IRB threshold of harm, in which the harm experienced during the intervention is equal to or less than the degree of harm that would be experienced in an equivalent non-research situation in daily life. It should be noted that the description of benign behavioral interventions above implies that such interventions do not have obvious parallels in daily life, meaning that traditional IRB interpretations of the harm threshold may not apply.

(8) The intervention must be painless. Ordinary, mild, transient forms of discomfort, such as the stress associated with completing a timed cognitive task, anxiety about performance on the task, and boredom, are consistent with the intent of the exemption and are therefore acceptable to the federal government. Physical pain is not acceptable.

(9) The intervention must not be physically invasive, which means, as noted above, no medical or bodily interventions. Any introduction or administration of instruments, substances, or energy onto or into the body fall outside of the intent of the exemption and will not be exempted.

(10) The intervention must not be likely to have a significant adverse effect on participants. This clause appears to contradict the criterion that the intervention should be “harmless” (7). The CC IRB will privilege the language in (7) over the language in (10). Only in cases where the IRB determines that the research in question is equivalent with regard to (7) and (10) will the IRB consider this criterion.

(11) The investigator has no reason to think the participants will find the intervention offensive or embarrassing. This criterion should not require interpretation.

(12) The consent process through which participants prospectively agree to participate must include participant acknowledgement of deception if deception is part of the research. Researchers may not rely on the concept of “demand characteristics” to justify deception in the context of this exemption. This criterion includes the phrase “unaware of or misled regarding”, which the CC IRB must interpret as meaning that neither passive deception (“unaware of”) nor active deception (“misled”) are acceptable for purposes of the exemption. Therefore, any project that might otherwise be eligible for this exemption but in which potential participants will not be made aware of either passive or active deception on the part of the researcher is not eligible for the exemption (though it is eligible for expedited review using the regular IRB application form).

The CC IRB has developed a special consent form specifically for use with this exemption. The IRB will not exempt benign behavioral intervention projects that use any other consent forms.