**University of Wisconsin-Oshkosh**

**Institutional Review Board (IRB)**

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| STANDARD OPERATING PROCEDURES (SOP) |
| **SOP Number: 17**Effective Date: 05/25/22Last IRB Review: 05/25/22Last Updated: 05/25/22Prepared By: K. Schill, A. Miron | **Title:** **Human Subjects Research Involving Methodological Deception or Incomplete Disclosure**  |

**Human Subjects Research Involving Methodological Deception or Incomplete Disclosure**

1. **Introduction**

Some types of behavioral and social science research may involve the use of methodological deception or incomplete disclosure in order to accomplish the goals of the study. Methodological deception involves intentionally misrepresenting one or more elements of a research study by providing research subjects with misleading or false information. Incomplete disclosure involves withholding information about the study purpose or study details.

Methodological deception and incomplete disclosure may be used in cases where being told the true nature or purpose of the study may: 1) cause participants to change how they would normally respond, 2) create bias in participants responses, and 3) challenge the scientific validity of the study. Since the use of methodological deception and incomplete disclosure alter the informed consent process and the Belmont principle of respect for persons, researchers must provide justification for employing methodological deception and provide information to subjects about the study following participation by debriefing research subjects.

1. **Informed Consent for Research Involving Methodological Deception or Incomplete Disclosure**

An informed consent document provides details for a prospective subject to determine whether or not to participate in a research study. If a research design involves methodological deception or incomplete disclosure, researchers may obtain informed consent in one of the following manners:

1. Acknowledge the use of methodological deception in the study during the informed consent process, OR
2. Request an alteration of the consent process

**Informed consent documents and scripts cannot contain false statements about the research**. The researcher may request to withhold information about the true purpose of the study by requesting an alteration of the consent process [45 CFR 46.116(f)](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.116), as long as all of the following criteria are met:

* The research involves no more than \*minimal risk to the subjects;
* The research could not practicably be carried out without the requested waiver or alteration;
* If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
* The waiver of alteration will not adversely affect the rights and welfare of the subjects; and
* Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

\*Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

If a researcher is not able to provide the true purpose of the study, general statements about the purpose of the research as well as description of the activities the participant will be asked to complete should be included in the consent form.

1. **Debriefing Subjects after Participation**

Debriefing participants upon completion of a study is used to mitigate any harms that could be caused by the use of methodological deception or incomplete disclosure. Debriefing involves providing information about the use of methodological deception or incomplete disclosure and an explanation for why it was necessary for the study.

The researcher may choose to have a debriefing discussion in person with the participant or provide the participant with a written form describing the methodological deception and the reasons for it and allowing participants an opportunity to ask questions about the elements discussed/conveyed in the debriefing statement.

The debriefing process should be presented in simple, clear language and the researcher must:

* Allow participants an opportunity to ask questions.
* Provide participants with the principal investigator’s contact information for future potential questions.
* Have a procedure for ameliorating any possible negative effects of methodological deception and correct any false feedback given to participants. Researchers should be particularly mindful of the possibility of **perseverance effects** (i.e., participants believing study-related false information or false feedback even after the methodological deception was explained to them during debriefing). In this case, researchers may wish to include in the debriefing document information about the perseverance effect to make participants aware they may persist in their study-induced beliefs even after those beliefs have been debunked during debriefing.
* Allow participants the option to withdraw their data from analysis if they desire.
* Give participants the option to ask that the researchers do not use the film/recording if participants were filmed/recorded without their knowledge.
1. **Review Type for Protocols Involving Methodological Deception**

**Research that may be determined to be Exempt by the IRB:**

The 2018 Revised Common Rule allows research employing methodological deception to be exempt under specific conditions. In order to qualify as exempt, 1) the research must fall under the following exemption category [45 CFR 46.104(d)(3)](https://www.ecfr.gov/on/2018-07-19/title-45/subtitle-A/subchapter-A/part-46#p-46.104(d)(3)), 2) participants must be adults, and 3) participants must agree to the use of methodological deception:

* (3)(i): Research involving benign behavioral interventions (i.e., interventions that are not expected to cause physical or emotional harm, persistent discomfort, be embarrassing, or offensive) 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)](https://www.ecfr.gov/on/2018-07-19/title-45/section-46.111#p-46.111(a)(7)).
* (3)(ii) 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. Provided all such criteria are met, examples of such 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.
* (3)(iii) 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.

**Generally, research using the following methodological deceptions may be reviewed using Expedited Review:**

**(List adapted from Duke IRB examples)**

* Confederates: Attributing statements to or providing feedback from non-existent individuals or confederates in another room. Using actors in videos presented to participants.
* Giving people impersonal false information:  Information about the performance of groups that participants will use to measure their own performance, for example, “Most students can solve these anagrams in 3-7 minutes.”
* Studies involving subliminal priming on a non-sensitive topic.
* Studies that activate stereotype threat.
* Covert or low-intensity mood manipulations designed to induce feelings of sadness, other-oriented emotions, anger, or fear.
* Experiments in which participants are told that two studies are unrelated when the first study is the manipulation, depending upon population and nature of manipulation.
* Presenting participants with misleading information about a fictitious event that they viewed/heard in the context of the experiment as long as the event does not instigate strong negative emotions, motivations, and/or behaviors.

**Generally, research using the following methodological deceptions will be reviewed by the Full IRB: (List adapted from Duke IRB examples)**

* Active participation/interaction with a confederate.
* Studies in which participants are given false feedback about their own attributes, performance, or abilities, for example, a manipulation in which students are told that their performance falls in the lowest quartile of students following the completion of a task.
* Any study in which debriefing cannot be undertaken because to do so would cause more harm than good or when participants cannot be contacted, e.g., some types of Internet research.
* Any study involving subliminal priming on a sensitive topic.
* Covert observation and/or videotaping of which participant is not informed.
* Covert manipulations designed to evoke strong negative emotions, motivations, and behaviors such as guilt, shame, anxiety, phobias, prejudice, or aggression.
* Presenting false scientific “facts,” articles, or profiles of individuals or companies.
* Any study in which participants are given false information about themselves in phase one of a study that is not corrected until a later session.
* Any methodological deception of minors or vulnerable populations.
* Any study in which the researcher assumes a false identity.
* Covert manipulations designed to elicit behaviors about which participants may feel shame or other strong negative emotions.
* False information that suggests that participants’ performance will be evaluated as part of the study if that information could instigate strong negative emotions, motivations, and/or behaviors.

**Resources used in developing this SOP:**

American Psychological Association:

  <http://www.apa.org/ethics/code/>

Duke University IRB:

 [Using Deception in Research | Institutional Review Board (duke.edu)](https://campusirb.duke.edu/irb-policies/using-deception-research)

The University of Texas at Dallas IRB:

[Deception and Incomplete Disclosure – Office of Research and Innovation (utdallas.edu)](https://research.utdallas.edu/researchers/human-subjects-research/researchers/deception-and-incomplete-disclosure#:~:text=Use%20of%20deception%20and%20incomplete%20disclosure%20generally%20goes,useful%20tool%2C%20especially%20in%20behavioral%20and%20social%20research.)

Indiana University IRB:

[Deception or incomplete disclosure in research: Guidance: Human Subjects & Institutional Review Boards: Compliance: Research: Indiana University (iu.edu)](https://research.iu.edu/compliance/human-subjects/guidance/deception.html)

Oregon State IRB:

[Research involving Deception | Research Office | Oregon State University](https://research.oregonstate.edu/irb/research-involving-deception)

University of Chicago IRB:

 <http://www.uchicago.edu/search/?GSAq=deception>