

Wright State University IRB Guidance for Understanding Research Involving Deception or Incomplete Disclosure

As part of its review and approval process, the Wright State IRB (IRB) must consider the extent to which proposed deception or incomplete disclosure, in any given human subject research study, may interfere with a subject's right to and ability to give fully informed consent. This document was created to help you understand how "deception" and "incomplete disclosure" are defined, what information should be included in your IRB application for research involving deception/incomplete disclosure, and the level of IRB review required for such research.

Research studies occasionally involve the deception of subjects, especially in the fields of psychology, neuroscience, and behavioral research. Deception is typically used when complete or truthful disclosure of the study purpose/procedures to subjects may bias study data. Whereas deception can be an effective tool for the conduct of research, it also raises ethical concerns with regards to subject autonomy and respect for persons, adding complexity to informed consent process requirements.

The **first step** in designing a study involving deception or incomplete disclosure is fully understanding the difference between these two concepts.

Deception is defined as a procedure in which researchers purposely mislead participants by providing them with obvious misdirection or false information about some aspect of the research, whether it is in the procedures or the purpose of the research.

Examples of research scenarios that involve deception:

- Subjects are told that they are working with a group of other subjects on a task, but in actuality, they are the only subject in the study. The other "participants" are actually confederates or study team members acting as subjects or a computer generated 'other subject' and not a real person.
- Subjects are told they scored poorly on a task when, in fact, they are given negative feedback regardless of their actual performance.
- Subjects are told something is real when it is made up specifically for the study, such as a journal article or 'research' facts, etc.
- In order to induce stress, study team members tell subjects that they will give a speech that evaluators will observe on video, when the subjects' speeches will not actually be recorded or observed.
- Study team members tell subjects that they will play a competitive game involving financial rewards based on their performance. In fact, the game is rigged and rewards are not based on performance.

Incomplete disclosure is defined as a procedure in which researchers withhold information about some aspect of the research, whether it is about the procedures or the purpose of the research.

Examples of research scenarios that involve incomplete disclosure:

- Subjects are informed about the purpose of the study in general terms that are true but subjects are not provided with sufficient detail to reveal the true objectives of the study.
- In order to examine how race and gender impact people's perception of conflicts between individuals, subjects are asked to review several hypothetical scenarios describing confrontations between various characters, which include stock photos to represent the individuals involved, subjects are then asked to answer questions regarding their perception of each of the individuals involved. The subjects are not informed that the race and gender of the characters are manipulated by the researchers.
- To further understand how representations of same sex couples depicted in commercials influence consumer behavior, subjects are exposed to advertisements featuring gay couples and straight couples while subjects' heart rate, facial muscle movement, and sweat responses are recorded. Subjects are informed that their reactions to the commercials are being studied, but not that the researchers are examining if the sexual orientation of characters in commercials influences their responses.

Disclosed concealment involves the withholding of certain information from subjects in cases where subjects consent specifically to the lack of disclosure. **It is important to understand that disclosed concealment is not considered deception or incomplete disclosure.**

Examples of research scenarios that involve disclosed concealment include:

- A double-blind, placebo-controlled trial in which subjects will have information regarding their assignment to a particular study arm withheld; however, as part of the initial informed consent process, subjects are informed of the study arms and that their assignment will not be disclosed.
- Subjects are notified in the consent form that a complete description of the research questions and procedures will not be disclosed to them prior to their participation.

The **second step** in designing such a study is providing the IRB with a **detailed justification** for the use of deception or incomplete disclosure as part of the local protocol.

The use of deception or incomplete disclosure may be appropriate to promote scientific validity by enabling investigators to obtain unbiased data about attitudes and behavior in circumstances where truthful disclosure is considered likely to produce biased responses by subjects. In your local protocol you must include a detailed explanation regarding why the deceptive or incomplete disclosure study procedures proposed are necessary and effective at preventing bias and why they are no other procedures (i.e., not involving deception) for collecting the data.

Study procedures involving deception or incomplete disclosure cannot be approved by the IRB if:

- Non-deceptive alternative methodologies are available.
- Procedures are intended to trick people into participating in something they would not want to otherwise participate.
- Procedures place subjects at significant financial, physical, legal, psychological, or social risk.

The **third step** in designing a study involving deception or incomplete disclosure is providing the IRB with a detailed description of the proposed informed consent process which usually needs to include both a request to **alter required informed consent element(s)** and a detailed **debriefing** process.

When a study uses deception, fully informed consent cannot be obtained from subjects prior to their participation because they are not provided with all elements required to make an informed decision. Therefore, in the Initial Review Application, researchers must request a partial waiver of informed consent (e.g., to waive the requirement to provide an accurate description of a procedure and/or study purpose). Sufficient justification for the waiver of informed consent will need to be provided by the principal investigator. Even though the IRB may agree to alter one or more of the required elements of consent, this is not equal to a full waiver of the normal consent process.

Debriefing is an essential part of the informed consent process and is mandatory (unless sufficient justification exists to waive the debriefing) when a research study involves use of deception. The debriefing process provides subjects with a full explanation of the hypothesis being tested, procedures to deceive subjects and the reason(s) why it was necessary to deceive them. Deception must be explained to subjects as early as feasible. The researcher can decide, or the IRB may require, that the debriefing includes an option for participants to withdraw their data from the study after they learn the true nature of the research.

Your proposed process to debrief subjects must be explained in your local protocol. It must include a full description of how subjects will be debriefed, who will debrief subjects, and when subjects will be debriefed. The IRB expects that the person conducting the debriefing process is a member of the research team who has knowledge about the research. A debriefing script must be included with the initial IRB submission. The following sections provide additional information regarding how to address debriefing for certain research situations:

Debriefing for Online Research:

Some research requires a debriefing after subjects have completed an online survey/task. Online debriefing information should be similar to a debriefing process done in-person. The debriefing information should be available immediately after the final survey/task.

Delayed Debriefing:

Delayed debriefing is an option if subjects are part of a group that may share information about their experience in the research. If researchers will use a delayed debriefing, the consent form must state additional information will be available at the end of the study and subjects' contact information should be collected. The contact information should not be linked to the study data.

Exceptions to Debriefing Requirement:

If you plan to use deception and are requesting to not debrief subjects, you must provide a compelling rationale in your local protocol for not debriefing. There may be rare instances when debriefing would be inappropriate, such as when the debriefing itself may present an unreasonable risk of harm to the subject without a countervailing benefit. For

example, if an individual were selected for participation in a study about group behavior based on a previously measured "negative" behavior such as bias or bigotry or an unattractive physical characteristic, it might not be appropriate for the debriefing to describe the selection process. In such cases, the IRB would not recommend nor require a detailed debriefing.

The **final step** in designing a study involving deception or incomplete disclosure is understanding and planning for what type of IRB review will be required for approval. Research involving deception and incomplete disclosure may require review at a convened meeting for which additional planning may be needed to meet submission dates and deadlines. However, some of these human subject research studies may also qualify for an exemption determination or expedited review. See the following sections or more information.

Deception Research that Qualifies for an Exemption Determination:

The 2018 Revised Common Rule allows for some research involving benign behavioral interventions in adults that also uses deception to be exempt from IRB review when subjects provide prospective agreement to participate and they are prospectively informed that they will be unaware of or misled regarding the nature or purpose of the research.

Normally, exempt research does not require a formal informed consent process. However, to meet the prospective notification and agreement requirements an informed consent process/form will likely be required. See the following example of consent language for such situations:

“For scientific reasons, this consent information does not include a complete description of the research questions [and/or study procedures] being tested. When you have finished participating in the study, we will give you more information about the study and an opportunity to ask questions.”

Deception Research that Qualifies for Expedited Review:

Typically, when the deception in a study is minor and the deception does not affect the risks of the study, then it may be reviewed and approved using expedited procedures. Most incomplete disclosure and minor deception studies will qualify for expedited review.

Examples of research scenarios that may qualify for expedited review include, but are not limited to:

- Attributing statements to or providing feedback from non-existent individuals or confederates in another room. Using actors in videos presented to subjects.
- 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.”
- Priming designed to focus subjects’ attention or awareness, but not on a sensitive topic. For example, having participants complete sentence scramble tasks with words affiliated with different goals.
- Presenting false scientific “facts,” articles, or profiles of individuals or companies.
- Studies that activate stereotype threat.

- Experiments in which subjects are told that two studies are unrelated when the first study is the manipulation, depending upon population and nature of manipulation.

Deception Research that Requires Convened/Full Board Review:

Deception studies that involve more than minor deception or that effects subject risks will need to be reviewed by the convened IRB.

Examples of research scenarios that may require full board review include, but are not limited to:

- Any use of confederates in which the confederate engages in in-person dialog with a subject. For example, attempting to persuade a participant to make a certain decision or enter into a negotiation process.
- Studies in which subjects 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.
- Covert observation and/or videotaping.
- Mood manipulations designed to induce feelings of guilt, sadness, depression.
- Any study in which subjects are given false information about themselves in phase one of a study that is not corrected until a later session.
- Any deception of minors.
- Any study in which the researcher assumes a false identity.
- Manipulations designed to elicit behaviors about which subjects may feel shame or other strong negative emotions.