



Deception and Incomplete Disclosure

Background

The purpose of this guidance is to help researchers identify and plan for the use of deception in research. Research studies occasionally involve the deception of participants. Deception is typically used to promote scientific validity, with participants provided with false or incomplete information about the research in order to obtain unbiased data with respect to the participants' attitudes and behavior. While deception can be an effective tool for the conduct of research, it also raises ethical concerns with participant autonomy and respect for persons, as well as regulatory issues with informed consent requirements.

Deception broadly means the use of deliberately misleading communication with participants about research purposes or activities.

Active deception involves intentionally providing inaccurate or false information to participants (e.g., one study team member tells participants that they will be engaged in a cooperative task with other participants, but instead they will be interacting with other members of the study team).

Examples:

- Participants complete a quiz and are falsely told that they did poorly, regardless of their performance.
- Participants who do not know they are in a research study are observed to see how they behave when they find valuables (e.g., wallet, laptop) unattended in a public location.
- An anxiety study, in which participants are told to expect mild pain during the course of the study, but no painful procedures are administered.

Incomplete disclosure applies when information about the real purpose, nature, or other aspect of the research is deliberately withheld or concealed from participants.

Examples:

- Participants are asked to take a quiz for research, but they are not told the research question involves how background noise affects their ability to concentrate.
- Participants are told they are completing a survey to evaluate customer service when the true purpose of the study is to correlate psychological responses with patient care satisfaction.

Passive Deception (incomplete disclosure plus deception) omits important study information if providing full study details would impact participants' behavior and their choice to participate.

Examples:

- Researchers record participants without knowledge or consent.
- Participants believe a survey evaluates fictional job applicants, when the survey actually assesses participants' tendencies to discriminate.

Points for Consideration

When a research study involves use of deception, the IRB must find that:

- the research involves no more than minimal risk to participants;
- the waiver or alteration of the elements of consent will not adversely affect the rights and welfare of the participants;



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- the research could not practicably be carried out without the alteration or waiver of the elements of consent; and
- when appropriate participants will be provided with additional pertinent information regarding participation.

Protocols that include the use of deception or incomplete disclosure should demonstrate that the investigators are aware of, seeking to minimize, and have a plan to address the possible negative impacts on participants, such as:

- Potential of deception to facilitate unwanted and inappropriate invasion of privacy
- Potential coercion of participants into acting against their own will
- Potential for participants to change their mind about the use of their data after the deception is revealed
- Damage to a participant's self-esteem through feeling ashamed, guilty, stressed, embarrassed, feeling manipulated, or lacking control over their own experience
- Feeling forced to have knowledge about oneself that otherwise one might not want to know
- Creation of suspicion and/or distrust in the investigator and/or a generalized distrust of the broader research enterprise.

Protocols that include the use of deception or incomplete disclosure must justify the use of this method and demonstrate that risks to subjects will be minimized by using procedures that are consistent with sound research design including:

- The study must not involve more than minimal risk to the subjects
- The use of deceptive methods must be justified by the study's significant prospective scientific, educational, or applied value
- The protocol must clearly address why deception or incomplete disclosure are necessary to ensure the research is scientifically valid and feasible and that an alternative, non-deceptive methodology could not be used
- Subjects should not be deceived about any aspect of the study that would affect their willingness to participate

Informed Consent Requirements with Use of Deception or Incomplete Disclosure in Research

The 2018 revised Common Rule regulations include a new Exemption category for research that involves benign behavioral interventions (45CFR46.104(d)(3)). Such interventions are common in psychology, experimental economics, and related fields and include activities such as having subjects play an online game, solving puzzles in various noise conditions, or responding to different experimentally controlled vignettes or innocuous videos.

When research of this type involves deceiving or providing incomplete information to participants with regard to the purpose or nature of the study or activities, the deception or incomplete disclosure must be agreed to by the subject as a part of the consent process. If the investigator chooses not to disclose deception within the consent, the level of IRB review will raise to Expedited.

Sample Language for Consent Materials

- *The purpose of this study is [describe purpose]. All elements of this study have not been fully explained. We will fully explain the research after all participants finish the study.*



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- *We have described the general nature of what you will be asked to do, but the full intent of the study will not be explained to you until after [your participation OR all participants complete the study]. At that time, we will give you more information about the study and an opportunity to ask questions.*
- *Due to the nature of the study, we are not able to disclose the purpose of this research at this time. However, we will hold a debriefing session to answer questions and tell you about the study after your participation.*

Debriefing Requirements

Debriefing is an essential part of the informed consent process and is **mandatory** when the research study involves use of deception or incomplete disclosure. The debriefing provides participants with a full explanation of the hypothesis being tested, procedures to deceive participants and the reason(s) why it was necessary to deceive them. It should also include other relevant background information pertaining to the study. When required elements of informed consent are waived or altered by the IRB, in accordance with criteria provided in the regulations, participants must be debriefed at the end of the study. Debriefing can occur via email, in-person, virtually over Zoom, etc.

At a minimum, the debriefing statement should include the following:

- Label the form as “Debriefing Statement”
- Study title
- PI name and contact information for follow-up questions
- Student researcher’s name and contact information, if applicable, for follow-up questions
- Thank participants for taking the time to participate in the study
- Explain what was being studied (i.e., purpose, hypothesis, aim) in lay terms.
- Explain how participants were deceived
- Explain why deception was necessary to carry out the research
- Explain how the results of the deception will be evaluated
- An opportunity for participants to withdraw consent after the true purpose of the study is revealed. The IRB suggests that participants be given at least 48 hours to make this decision and provide contact information for whom participants should contact regarding their withdrawal from the study.

Debrief Timing

The timing of the debriefing is an important consideration. Generally, the IRB expects that participants will be debriefed immediately following their participation in the study. However, a delay between finishing research tasks and debriefing might be necessary at times. For example, if early participants might reveal study details to subsequent participants, thereby impacting study validity, then a delayed debriefing might be warranted.

In such cases, the consent form must state that subjects will be debriefed later after the study is complete. In addition, the consenting section in the IRB protocol must provide the scientific rationale and/or justification as to why delayed debriefing is necessary.