

Deception and Incomplete Disclosure in Research Guidance for Investigators

Deception is a method used in social science research that can improve the internal validity of a research study. The intention of deception is to produce a false belief in the participants during the course of the study. Incomplete disclosure of information may also be used in research where telling the subject about some aspect of the study in detail might interfere with the ability to measure the outcome of interest. The use of deception and incomplete disclosure in human subjects research raises special problems for the IRB to consider with regard to informed consent and analysis of risks and benefits. Unethical uses of deception in research can cause distress to those being deceived, and may undermine public trust in the research enterprise.

When studies use deception or incomplete disclosure in their procedures, the IRB needs to determine whether the deception/incomplete disclosure is necessary to make the research scientifically valid and feasible. The IRB will consider whether the study population is appropriate for the study procedures that involve deception or incomplete disclosure of information, and will consider potential harms of these methods. The IRB never allows for deception/incomplete disclosure that might affect the subject's willingness to participate in the study.

DEFINITIONS:

Deception: When an investigator gives subjects false information about some aspect of the research.

Examples:

- Participants complete a quiz, and are falsely told that they did very poorly, regardless of their performance.
- Participants (who don't know they are in a research study) are observed to see how they behave when they find a large amount of cash in a public location.
- In a study of anxiety, participants are told to expect mild pain during the course of the study, but no painful procedures are administered.

Incomplete Disclosure: When the investigator withholds some information about the real purpose of the study, or the nature of the research procedures.

Examples:

- Participants are asked to complete a quiz for research, but not told that the research question involves how background noise affects their performance.
- Subjects are told they are completing study questionnaires to evaluate their satisfaction, when the true purpose of the study is to correlate psychiatric symptoms with patient satisfaction.

Potential Risks/Harms of Deception/Incomplete Disclosure to consider:

- Feel coerced to have acted against one's will
- Might not have chosen to participate if fully informed
- If observed, subject may feel invasion of privacy
- Damage to self-esteem; feeling ashamed, guilty, stressed, embarrassed
- Forced to have knowledge about self that otherwise might not want to know
- Feel loss of control, may be distrustful/suspicious

Deception/Incomplete Disclosure in studies involving minimal risk: The IRB may allow for the modification or alteration of the general requirements for informed consent for research involving deception/incomplete disclosure for studies involving minimal risk as defined by federal regulations. Debriefing may be required in some cases.

Incomplete Disclosure in studies involving more than minimal risk: If a study is of greater than minimal risk, and incomplete disclosure is a crucial part of the study's integrity, it may be sent to the full committee to consider. True deception in research requires a waiver of some or all elements of informed consent, and is permitted only in studies posing no greater than minimal risk.

GENERAL GUIDELINES:

1. Deception/incomplete disclosure is typically only acceptable in studies with no more than minimal risk.
2. The deception/incomplete disclosure should have no adverse effects on welfare.
3. The IRB must determine that the value of the study is sufficient to warrant waiving some aspects of the requirement for full disclosure in the informed consent process.
4. There is no alternative to address the scientific question in a valid manner but to use deception/incomplete disclosure. Other effective, non-deceptive approaches are not feasible.
5. Participants are not deceived about any aspect of the study that would affect their willingness to participate.
6. Debriefing is done, when appropriate, and the deception/incomplete disclosure is explained to the participant before the end of participation in the research.
7. When appropriate, subjects could be informed prospectively of the use of deception/incomplete disclosure and consent to its use: see the suggested consent language:

"In some research studies, the investigators cannot tell you exactly what the study is about before you participate in the study. We will describe the tasks in the study in a general way, but we can't explain the real purpose of the study until after you complete these tasks. When you are done, we will explain why we are doing this study, what we are looking at, and any other information you should know about this study. You will also be able to ask any questions you might have about the study's purpose and the tasks you did. Though we may not be able to explain the real purpose of the study until after you complete the tasks, there are no additional risks to those that have been described in this consent form."

Include the following in the Protocol Summary under the Consent Procedures section:

1. Explain the reason for the use of deception/incomplete disclosure in the study design; specifically how providing specific information to prospective participants about the purpose and methods of the research would compromise the scientific validity of the research.
2. Describe the extent of deception/incomplete disclosure in detail, including how it relates to the study aims and study design.
3. Describe how the research involving deception/incomplete disclosure involves no more than minimal risk to the subjects. Discuss any level of increased harm a participant might experience as a result of the deception/incomplete disclosure.
4. Explain how there are no feasible alternative methods to conduct the research that do not involve deception/incomplete disclosure.
5. If applicable, describe methods for prompt disclosure and debriefing for each participant as soon as is possible after their participation is complete, and how the debriefing will ensure that the subject leave the research setting with a clear and accurate understanding of the deception/incomplete disclosure. Submit a script or written statement of the debriefing if feasible. Describe how participants may withdraw their data at this time if they wish. If debriefing is not planned, discuss why this is the case.