

Guidance Document: Deception and Incomplete Disclosure in Research

Background

Deception is when an investigator gives false information to participants about some aspect of the research. Deception is common in studies that evaluate human behavior. The rationale for deception in this setting is that it is not possible to obtain accurate information about how people behave when they know they are being observed or evaluated.

Incomplete disclosure is when the investigator withholds some information about the real purpose of the study or the nature of the research procedures, to avoid biasing results. The use of deception/incomplete disclosure in human subjects research raises special concerns 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.

What are some examples of deception?

- 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.

What are some examples of incomplete disclosure?

- Participants are asked to complete a quiz for research, but not told that the research question involves how background noise affects their performance.
- Participants 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.

What potential risks/harms of deception/incomplete disclosure should I consider?

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

Can I use deception/incomplete disclosure if my study is 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 panel 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.

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.

The following are some general guidelines to assist you in deciding if deception/incomplete disclosure would be an appropriate method to use in your study:

- Deception/incomplete disclosure is typically only acceptable in studies with no more than minimal risk.
- The deception/incomplete disclosure should have no adverse effects on subjects' welfare.
- 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.
- 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.
- Participants are not deceived about any aspect of the study that would affect their willingness to participate.
- Debriefing is done, when appropriate, and the deception/incomplete disclosure is explained to the participant before the end of participation in the research.
- When appropriate, Participants could be informed prospectively of the use of deception/incomplete disclosure and consent to its use.

Suggested consent form language:

In some research projects, the investigators cannot tell you exactly what the study is about before you finish the study. We will describe what you will be doing in the project in a general way. We can't explain the real purpose of the project until you finish. When you have finished, we will explain why we are doing this project. We will tell you what we are looking at. We will tell you any other information you should know about this project. You will be able to ask any questions you have about the project's purpose and what you did. Even though we may not be able to explain the real purpose of the project until after you have finished, there are no additional risks beyond those that have been described in this consent form.

What should I include in my protocol if I plan to use deception/incomplete disclosure?

- 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.
- Describe the extent of deception/incomplete disclosure in detail, including how it relates to the study aims and study design.
- Describe how the research involving deception/incomplete disclosure involves no more than minimal risk to the participants. Discuss any level of increased harm a participant might experience as a result of the deception/incomplete disclosure.
- Explain how there are no feasible alternative methods to conduct the research that do not involve deception/incomplete disclosure
- 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.

What should I include in my debriefing form?

- An explanation of why the deception/incomplete disclosure was necessary;
- Offer the subjects a chance to ask questions or work through any confusion they may have;
- A description of the extent the study can ensure confidentiality of the data gained from the deception;
- Inform the subjects that they have the right to have the data obtained from the research destroyed instead of used for data analysis.

What are the goals of debriefing?

1. To repair the breach of informed consent entailed by the deception,
2. To remove any confusions or defuse any tensions that might have been generated by the deception,
3. To repair (as much as possible) the breach of trust that has occurred not only between the investigator and the subject, but (potentially) between all researchers and all subjects.