

Guidance Document:

Deception and Incomplete Disclosure in Research

Overview:

Deception is when an investigator gives false information to subjects and intentionally misleads them about some key aspect of the research. This might relate to the purpose of the research, the role of researcher or other subjects, the true nature of the procedures, or other parts of the study. Deception is common in studies that evaluate human behavior, and may occur either as a part of the Consent Process or within the study procedures themselves. The rationale for deception in this setting is normally to stimulate behaviors in participants that would not occur without an active manipulation, in contexts where 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 during the Consent Process, 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 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?

- Subjects complete a quiz, and are falsely told that they did very poorly, regardless of their performance.
- Subjects (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, Subjects are told to expect mild pain during the course of the study, but no painful procedures are administered.
- The study includes an investigator's "confederate," an individual who poses as a participant, but whose behavior in the study is actually part of the study's experimental design.

What are some examples of incomplete disclosure?

- Subjects are asked to complete a quiz for research, but not told that the research question involves how background noise affects their performance.
- Subjects read and respond to a short vignette or news article designed to prime particular responses. The Subjects are not informed that this is the purpose of the vignette. Note that the

vignettes are not presented as truth or fact (which would be deception), but rather either as hypothetical information, or the veracity of the information is not discussed at all.

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

- Subject may feel coerced to have acted against one's will.
- Subject may not have chosen to participate if fully informed.
- If observed, subject may feel invasion of privacy.
- Damage to a subject'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?

No. Deception and Incomplete Disclosure in research represents a deviation from the requirement that subjects are fully informed about the nature of the research, and thus requires a waiver of some elements of informed consent. Such a Waiver 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 most cases.

Can I use deception/incomplete disclosure in my Exempt 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 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. Use the following language in the Consent Form for this purpose:

"We cannot tell you everything about what we are doing in this study or why. A full explanation of the purpose of the research and procedures will be provided after you complete the study."

Guidelines to assist in deciding if deception/incomplete disclosure would be an appropriate method to use in a study:

- Deception/incomplete disclosure is 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.
- Subjects 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 subject before the end of participation in the research. Subjects should be provided the opportunity to have their data withdrawn from the study after the debriefing, thus allowing them the full opportunity to determine how they would like the information about themselves that was generated through the use of deception used.
- When appropriate, subjects could be informed prospectively of the use of deception/incomplete disclosure and consent to its use. Suggested language to be used in the Consent Form for this purpose is:
“We cannot tell you everything about what we are doing in this study or why. A full explanation of the purpose of the research and procedures will be provided after you complete the study.”

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

- Describe the extent of deception/incomplete disclosure in detail, including how it relates to the study aims and study design.
- Explain the reason for the use of deception/incomplete disclosure in the study design - specifically how providing specific information to prospective subjects about the purpose and methods of the research would compromise the scientific validity of the research.
- If the study is anticipated to receive an Exempt Determination as discussed above, indicate in the Informed Consent Section that the appropriate template language regarding deception has been included in the Consent Form, and that debriefing will occur when appropriate.
- For research that is not Exempt, , describe how the study meets the requirements for a Waiver or Alteration of Consent Informed Consent section:
 - Describe how the research involving deception/incomplete disclosure involves no more than minimal risk to the subjects. Discuss any level of increased harm a subject might experience as a result of the deception/incomplete disclosure.
 - Discuss any impact on subjects' rights or welfare that may result from the waiver or alteration of consent. There should be none. Describe how subjects may withdraw their data after their participation and being debriefed, if they wish.
 - 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 subject as soon as is possible after their participation is complete, and how the debriefing will ensure that the subject leaves 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. If debriefing is not planned, discuss why this is the case.

What are the goals of debriefing?

- To repair the breach of informed consent entailed by the deception,
- To remove any confusions or defuse any tensions that might have been generated by the deception,
- 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.

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.