

Guidelines for Research Involving Deception or Incomplete Disclosure

Overview:

The IRB recognizes that deception and incomplete disclosure may be valuable research methodologies, yet their use presents special challenges to ensure that the research is conducted ethically. At times, especially in social and behavioral research, deception or incomplete disclosure is necessary to avoid study bias or to test a hypothesis that requires the participant's misdirection. On the other hand, the regulations for obtaining informed consent from research participants (§45 CFR 46.116), in general, require full disclosure of all elements relevant to the subject's participation in the research.

Deception and incomplete disclosure raise concerns as they interfere with the ability of the participant to make a fully informed decision about whether or not to participate in the research. Thus, proposed research involving deception or incomplete disclosure necessitates special considerations by the IRB. To determine when certain restrictions apply, the IRB will consider the extent to which the deception or incomplete disclosure, in any given study, interferes with the participant's right to and ability to give fully informed consent.

These guidelines include distinguishing whether "deception" or only "incomplete disclosure" (without deception) is involved, whether there is sufficient justification for use of such measures, and whether there is an appropriate consent and debriefing process in place.

The purpose for the guidelines on the use of deception and incomplete disclosure is to provide researchers, IRB staff, and IRB committee members with a common understanding of the following:

- Definitions of deception and incomplete disclosure in research;
- When is deception or incomplete disclosure allowed;
- Points to consider when deception or incomplete disclosure may be used; and
- Debriefing participants when deception or incomplete disclosure is utilized.

What is Deception?

Deception is when researchers purposely mislead participants by providing them with overt misdirection or false information about some aspect of the research, whether it is in the procedures or the purpose of the research. Examples include:

- Participants are told they are working with a group of other participants on a task, but in actuality, they are the only participant in the study. The other "participants" are actually confederates or research staff acting as participants.
- Participants are told they scored poorly on a task, when in actuality, they are scored poorly regardless of their performance

What is Incomplete Disclosure?

Incomplete disclosure is when researchers withhold information about some aspect of the research, whether it is in the procedures or the purpose of the research. Examples include:

- Participants are informed about the purpose of the study in general terms that are true, but are not detailed enough to reveal the true objectives of the study.

When is Deception or Incomplete Disclosure permitted?

Deception or incomplete disclosure will only be permitted when the researcher documents that an alteration of the usual informed consent requirements is justified under the criteria presented in the federal regulations at 45 CFR 46.116(d). Specifically, the IRB must find and document that all four of the following criteria have been satisfied:

1. The research presents no more than minimal risk to participants.
2. The alteration will not adversely affect the rights and welfare of the participants.
3. The research could not practicably be carried out without the alteration. The use of deceptive techniques must be justified by the study's prospective value and there should be no reasonable alternative method that would be equally effective (i.e., the researcher must demonstrate that the deception is necessary to conduct the study).
4. Where appropriate, the participants will be provided with additional pertinent information after participation.

In keeping with federal regulations and ethical codes established, the IRB will consider the following points when reviewing research involving the use of deception or incomplete disclosure:

- The use of deception or incomplete disclosure must be justified in the protocol to show that the research cannot be performed in the absence of deception and the benefits of the research will sufficiently outweigh any risks that deception may create;
- Research participants cannot be deceived about significant aspects of the research that would affect their willingness to participate or that would cause them physical or emotional harm; and
- Deception or incomplete disclosure must be explained to participants (debriefed) as early as feasible. A debriefing script must be included in the protocol and should include a detailed description of the ways in which deception was used and why; when and by whom the debriefing will be administered should also be included

What is Debriefing?

- Debriefing provides participants with a full explanation of the hypothesis being tested, the procedures used 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. Debriefing is an essential part of the consent process and is mandatory when the research study involves deception. Participants should be debriefed immediately following completion of the study. However, debriefing may be inappropriate if debriefing regarding the deception may cause more harm to the participant than the deception itself.

- Debriefing sessions can mitigate the betrayal, the harm, and the wrong of deception or incomplete disclosure by explaining the rationale for incorporating it in the research. Participants should be given a simple, clear and informative explanation of the rationale for the use of deception and should have the opportunity to ask questions.
- The process to debrief participants must be explained in your IRB protocol. Your protocol must indicate how participants will be debriefed, who will debrief participants, where participants will be debriefed, and when participants will be debriefed. The IRB expects that this person is a member of the research team who has knowledge about the research and the deception.

Debriefing participants when Deception or Incomplete Disclosure is utilized in research

In most cases, when an investigator uses deception or incomplete disclosure, regulations require that participants be debriefed at the end of the study. Debriefing may be inappropriate if debriefing regarding the deception may cause more harm to the participant than the deception itself.

Debriefing Process A debriefing form is typically read aloud to the participant once he or she has completed the study, and includes the following details:

1. Disclosure of the deceptive/incomplete disclosure aspect(s) of the study, and what the actual study objective was. (This should be presented in simple, clear lay terms, similar to the consent document. Extremely technical/detailed explanations of study hypothesis, intentions of each task, etc., are not typically required).
2. An explanation of the reasons for the deception/incomplete disclosure. (These reasons should also be clearly explained, in language that is sensitive to subjects' possible feelings of betrayal, discomfort, and/or embarrassment at having been deceived).
3. An opportunity for the subject to ask questions.
4. An opportunity for the subject to withdraw the provided data.

Online Debriefing: Some research requires a debriefing after participants have completed an online survey. Online debriefing forms should be similar to the debriefing process done during in-lab experiments. The debriefing page should come immediately after the last question on the survey. The researchers contact information and information about other resources (IRB info, Health Services, Local Resources) should be provided, and participants should be reminded to print a copy of the debriefing form for their records. Participants should also be given the option to withdraw their data at this point (now that they have been fully informed as to the intent and purpose of the study). If they agree to have their data used for the study then they should have an "I Agree" button to click. If they do not agree to have their data used in the study they should have an "I Do Not Agree" button to click. If someone does not agree to have their data used, their data must be removed from dataset and discarded. Please check with the online survey program you are using to ensure that these capabilities are allowed.

Delayed Debriefing: In rare cases, debriefing immediately after a subject's participation would compromise study results (e.g., the study is ongoing and early subjects might tell others about it, making it impossible for the researchers to obtain valid/unbiased results from later subjects). Under such circumstances the IRB may approve a delayed debriefing process, such as sending debriefing

information to participants via email or regular mail (if subjects' contact information is kept) or giving subjects a website URL where they can get debriefing information when the study has been completed. If delayed debriefing is utilized, you must re-consent participants to get permission to use their data (this would be done in the same manner participants were originally consented to the research).

Debriefing as an Educational Tool: Some University schools or student subject pools recommend that feedback be provided at the conclusion of the study to further the education of the participants (as opposed to giving information that was previously withheld or falsified). In such cases, the original consent may mention this will be done, and the debriefing form may include bibliographical citations advising subjects where they can obtain additional information on the topic if they wish.

Exceptions to 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 participant 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 or require detailed debriefing.

Example Debriefing form:

Thank you for your participation in our study. Your participation is greatly appreciated.

Purpose of the Study:

Earlier in our consent form we informed you that the purpose of the study was [insert brief sentence about original stated purpose of study]. In actuality, our study is about [insert statements describing i) what the true purpose of the study is, ii) the actual deceptive activities (this includes any fake articles or research stimuli that were utilized) and iii) the results/findings you were/are looking for].

In order to properly test our hypothesis, we could not provide you with all of these details prior to your participation. This ensures that your reactions in this study were spontaneous and not influenced by prior knowledge about the purpose of the study. [Insert statement reiterating any fabricated research activities or stimuli to ensure participants do not leave study believing false materials.] If we had told you the actual purposes of our study, your ability to [insert study activity] could have been affected. We hope you understand the reason for it.

Confidentiality:

Please note that although the purpose of this study has changed from the originally stated purpose, everything else on the consent form is correct. This includes the ways in which we will keep your data confidential. [Insert sentence reiterating how data is secured and maintained].

Now that you know the true purpose of our study and are fully informed, you may decide that you do not want your data used in this research. If you would like your data removed from the study and permanently deleted please [insert instructions on how participant can have study data deleted].

If Applicable: Whether you agree or do not agree to have your data used for this study, you will still receive [insert compensation for study] for your participation.

If Applicable: Please do not disclose research procedures and/or hypotheses to anyone who might participate in this study in the future as this could affect the results of the study.

Useful Contact Information:

If you have any questions or concerns regarding this study, its purpose or procedures, or if you have a research-related problem, please feel free to contact the researcher(s), [insert name(s) and phone number(s)].

If you have any questions concerning your rights as a research subject, you may contact the Northwestern University Institutional Review Board office by calling (312) 503-9338 or emailing irb@northwestern.edu

If you feel upset after having completed the study or find that some questions or aspects of the study triggered distress, talking with a qualified clinician may help. If you feel you would like assistance please contact [Only include if applicable: insert the appropriate contact information for local or national psychological/mental health services; In the case of an emergency please call 911.

Further Reading(s):

If you would like to learn more about [insert research topic] please see the following references: [list out related citations]

Please keep a copy of this form for your future reference. Once again, thank you for your participation in this study.