

Simpson University Institutional Review Board Guidelines on Deception and Incomplete Disclosure in Research

A. Overview

The Simpson University Institutional Review Board (SU 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 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 concern as they may interfere with the ability of the subject 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 SU IRB. To determine when certain restrictions apply, the SU IRB will consider the extent to which the deception in a given study interferes with the subject's ability to give informed consent. This includes 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.

Note: as stated in the SU IRB Policy and Procedure Manual, deception in research necessitates full IRB review. The use of incomplete disclosure may or may not be subject to full IRB review.

B. Definitions and Examples

1. Deception occurs when an investigator gives false information to subjects or intentionally misleads them about some key aspect of the research. (This is sometimes referred to as "active deception.")
2. Incomplete disclosure occurs when an investigator withholds information about the specific purpose, nature, or other aspect of the research. Withholding information may or may not be considered deception.

Examples of deception:

- The subject is given a "cover story" which falsely describes the purpose of the study, but provides a feasible account of the researcher's objective.
- The study includes a researcher's "confederate," an individual who poses as a participant, but whose behavior in the study is actually part of the researcher's experimental design.

Example of incomplete disclosure:

- The subject is informed about the purpose of the study or a certain procedure in general terms that are true, but not detailed enough to reveal the researcher's main or specific objective.

Example of incomplete disclosure that is also deception:

- The study involves audiotaping or videotaping of subjects without their knowledge or prior consent.

C. Points to Consider

In keeping with federal regulations and ethical codes established by the Belmont Report and the American Psychological Association, SU IRB will consider the following points when reviewing research involving the use of deception or incomplete disclosure:

1. The study must not involve any more than minimal risk to the subjects.
2. 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).
3. Prospective subjects must not be deceived about any physical or psychological risks, discomforts, or unpleasant emotional experiences of the study.
4. If the study design allows, subjects should be told during the original consent process that some information is being withheld or is incomplete, and that they will receive more information after the research is over. However, researchers often believe that even vague references to hidden purposes will affect subjects' behavior and make the study impracticable. Investigators should either add such language to their consent forms when it is possible or note in their protocols why it is not feasible to do so.
5. In addition, the research must meet the criteria for a waiver of one or more elements of informed consent, as described below in section D, Informed Consent.
6. Whenever appropriate, researchers should debrief participants. The debriefing should take place as early in the study as the design permits, preferably at the conclusion of a subject's participation, but no later than the conclusion of the research. See information about the debriefing process below in section E, Debriefing.

D. Informed Consent

In studies involving deception and/or incomplete disclosure, fully informed consent is not obtained from subjects prior to participation. When the consent process will not disclose pertinent information about the research, the SU IRB must consider whether the research meets all of the criteria for a waiver of one or more elements of informed consent as set forth in federal regulations at 45 CFR 46.116(d).

The criteria for a waiver of one or more elements of informed consent are:

- i. The research involves no more than minimal risk to subjects;
- ii. The waiver or alteration will not adversely affect the rights and welfare of subjects;
- iii. The research could not practicably be carried out without the waiver or alteration;
- iv. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

E. Debriefing

Debriefing the participant is an important aspect of the informed consent process in deceptive studies. It gives the investigator an opportunity to explain any deception or incomplete disclosure involved, as well as to help the subjects deal with any distress or discomfort occasioned by the research. If the study involves deception at the time of subject enrollment or consent that may have influenced the subject's decision about participation, and/or the deception would likely be perceived by subjects as an invasion of privacy (e.g., videotaping without prior consent), the SU IRB may require a re-consent for use of data as part of the debriefing process after study participation.

Exceptions to Debriefing Requirement: There may be rare instances when debriefing would be inappropriate, such as when the debriefing itself may present an unreasonable risk of harm 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 or characteristic, it might not be appropriate for the debriefing to describe the selection process. In such cases, the SU IRB would not recommend or require detailed debriefing.

Delayed Debriefing: In certain 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 SU 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. (In some cases, it may be sufficient to ask the subject being debriefed to not reveal such information to others).

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.

In general, the debriefing process should consist of the following:

1. Disclosure of the deceptive 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. (These reasons should also be clearly explained, in language that is sensitive to subjects' possible discomfort or embarrassment at having been deceived).
3. An opportunity for the subject to ask questions.
4. If indicated, an opportunity for the subject to withdraw the provided data. (The SU IRB will decide on a case-by-case basis whether it is necessary to re-consent subjects to use study data obtained under deceptive premises. For example, in cases that involve only incomplete disclosure, a debriefing form that gives additional information about the study but does not ask for re-consent to use data will usually be acceptable. In contrast, when deception at the time of subject enrollment or consent is likely to have influenced the subject's decision about whether or not to participate in the research, or when the deception would likely be perceived by the subject as an invasion of privacy, the subject's signature to permit use of such data will usually be required.)

See below for an example of an appropriate debriefing form. Note: The debriefing document should be submitted on SU letterhead as part of the consent documentation for SU IRB review.

*Note: These guidelines were adapted from the Committee for Protection of Human Subjects, University of California, Berkeley's "Guidelines on Deception and Incomplete Disclosure in Research."

Debriefing Form [SAMPLE]
(Present on SU letterhead)

Our research actually focuses on the development of "status hierarchies" in small groups. In many small groups such as project teams, ad hoc committees, or juries, some people tend to "take charge" more than others. However, the process by which these small group hierarchies develop is not well understood. In this study, we are attempting to understand what happens when two members of a group disagree as to who should take charge.

To try and obtain unbiased or natural reactions, we had to give you some false information at the beginning of the study. We informed you that, based on your scores on the tests from the prescreening packet, we had determined that you were the most suited to lead the group in the group task, and we told you that you were the only member in the group who received this information. But in fact, we gave this same information to one other group member, i.e., we also told this group member that he or she was the person best suited to lead the group. Thus, each of you was under the impression that you were uniquely suited to lead the group.

This was necessary for us to better understand how status disagreements proceed and how they are resolved. By telling two of you that you were each best suited to lead the group, it was much more likely that a status disagreement would emerge. Without telling two of you, it was more likely that only one person would attempt to "take charge," and thus no status disagreement would occur. We apologize for misleading you, but we believe this was the only way to examine the processes that are the object of our research. In designing this study, we took care to minimize any possible risks or discomforts that might be related to the deception.

[If obtaining re-consent: Now that you understand the true nature of our study, you have the chance to refuse the use of the data we collected from you for research purposes. You are free to ask us not to use your data in our study analysis. If you decline to let us use your data, you will still receive the \$15 payment just as you would if we use your data in our analysis. This is entirely voluntary, but we hope to analyze as much data as possible to better understand the processes by which status hierarchies develop in groups.]

[If appropriate: Because this experiment is ongoing, we request that you not share the true nature and purpose of this experiment with others who might potentially participate in our study.]

If you have any questions about this research you may ask them now, or contact me, NAME OF PRINCIPAL INVESTIGATOR, later at (xxx) xxx-xxxx or emailaddress@simpsonu.edu. If you have any questions regarding your treatment or your rights as a participant in this research project, please contact the Simpson University Institutional Review Board at (530) 226-4639 or irb@simpsonu.edu.

[If not obtaining re-consent, end the form here, e.g.: You may keep this debriefing form for your future reference. Thank you again for your participation in our research!]

[If obtaining re-consent: If you agree to allow us to use the data, please sign this form below. You may keep the other copy of this form for your future reference.]

I have read this debriefing form and I agree to allow the use of my data for research purposes.

Name (printed)

Signature

Date