

Guidance: Deception and Incomplete Disclosure

Overview

The UC Merced IRB recognizes that deception and incomplete disclosure may be valuable research methodologies. 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. 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 but the UC Merced IRB. This includes distinguishing whether "deception" or only incomplete disclosure" is involved, whether there is a sufficient justification for use of such measures, and whether there is an appropriate consent and debriefing process in place.

Definitions and Examples

Deception studies intentionally provide misleading or false information. (This is sometimes referred to as "active deception.")

Deception examples include:

- Participants complete a quiz and are falsely told that they did 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 valuables (e.g., wallet, laptop) unattended in a public location.
- An anxiety study, in which participants are told to expect mild pain during the course of the study, but no painful procedures are administered.
- The participant is given a "cover story" which falsely described 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 experimental design.

Incomplete disclosure studies withhold information about the true purpose or nature of the research.

Incomplete disclosure examples include:

- Participants are asked to take a quiz for research but they are not told the research question involves how background noise affects their ability to concentrate.
- Participants are told they are completing a survey to evaluate customer service when the true purpose of the study is to correlate psychological responses with patient care satisfaction.

When is deception or incomplete disclosure acceptable?

The use of deception or incomplete disclosure may be appropriate to promote scientific validity by enabling investigators to obtain unbiased data about attitudes and behavior in circumstances where truthful disclosure is considered likely to produce biased responses by participants.

The use of deception or incomplete disclosure results in a consent process where participants are provided with an incomplete and/or inaccurate explanation of the purpose of the research and description of the procedures to be followed. This altered consent process can only be approved if the IRB determines that the research is minimal risk.

Deception or incomplete disclosure in research cannot be approved if:

- Non-deceptive alternatives are available;
- It is intended to trick people into participating in something they would not want to participate in; and/or
- It places participants at significant financial, physical, legal, psychological, or social risk

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 UC Merced 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 the federal regulations at 45 CFR 46.116(d).

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

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

Authorized deception: It is possible to inform participants of deception prior to the start of a study by informing the subjects that the study will not be described accurately or that some procedures will be deceptive. This provides the participants an opportunity to decide whether or not to participate on these terms. Sample Language: *For scientific reasons, this consent form does not include complete information about the study hypotheses and the research questions being tested. You will be fully debriefed following your participation in the research.*

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 UC Merced IRB may require 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 UC Merced 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 UC Merced 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 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. The reasons should be clearly explained, in language 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 UC Merced 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.

Investigator Responsibilities

When conducting research that involves deception or incomplete disclosure, investigators must ensure that the research meets their discipline's professional code of ethics, and convey in their application to the IRB how particular consideration has been given to the consent and debriefing process and the risk/benefit ration of the research.

The protocol submission must:

- Justify the reasons for deceiving or withholding information from the participants;

- Explain why the deception is necessary;
- Describe how the potential benefits of the research justify the deception; and
- Outline the process of debriefing, including when, how and by whom information will be provided to participants, and include a copy of the debriefing script.

IRB Considerations

When reviewing research that involves deception or incomplete disclosure, the IRB must evaluate the above information and consider the following:

- The scientific value and validity of the research
- The efficacy of alternative procedures
- The certainty that deception does not extend to influence participants' willingness to participate
- The possibility of experimentally induced harm and the ability of the proposed procedures to remove such harm through debriefing
- The potential of deception to facilitate unwanted and inappropriate invasions of privacy
- Whether the researcher has the skill and resources to minimize participants' upset

The IRB may not approve research that entails more than minimal risk where participants are deceived or not given complete information that they would consider material to the decision to participate in the study.

Regulations and References

45 CFR 46.116