



Guidance and Procedures: Using Deception and Incomplete Disclosure in Research (03/15/2023)

The use of deception and incomplete disclosure are valuable research techniques used to answer scientific inquiries in human subjects research. Deception takes place when participants are intentionally given false information about some aspect of the research. While incomplete disclosure occurs when the investigator withholds information about the purpose of the research and/or procedures employed.

Respect for persons is one of the fundamental principles of the Belmont Report and it recognizes that all individuals have the right to fully exercise their autonomy. This principle mandates that research participants enter into a research voluntarily and with adequate information to make an informed decision pertaining to their participation in the research. Providing research participants with misleading or incomplete information compromises the integrity of the consent process. For this reason, the use of deceptive techniques places a special burden of responsibility on researchers to provide scientific justification for the deception and ensure there are sufficient safeguards in place to protect the rights and welfare of the participants.

Definitions and Examples

Deception occurs when researchers intentionally provide inaccurate or false information to research participants. Examples include:

- In order to induce stress, study personnel tell study participants that they will give a speech that evaluators will observe on video, when the participants' speeches will not actually be recorded or observed.
- Study personnel tell study participants that they will play a competitive game involving financial rewards based on their performance. In fact, the game is rigged and rewards are not based on performance.

Incomplete disclosure involves withholding information about the true study purpose and/or reason for procedures, in order to prevent biasing the results. Examples include:

- Participants are asked to rate the credibility of a presenter but the participant is not told that the research question involves identifying how the age and gender of the presenter affects the participants' observations of the presenter.
- Participants are asked to write about their current mood but are not told that the research personnel have purposely altered the ambient lighting to impact the participant's overall sense of calm.

When is deception or incomplete disclosure acceptable?

Deception and incomplete disclosure are permissible in research with scientific value that would not be otherwise feasible without the use of deceptive procedures.

Deception or incomplete disclosure in research cannot be approved if:

- The research involves more than minimal risk (this does not include placebo-controlled trials, where the placebo is the only deception);
- Non-deceptive alternatives are available;
- The research intends to trick individuals into participating in something that they would not otherwise want to participate in;
- The research is expected to cause physical pain or severe emotional distress;
- The research places participants in a position of engaging in illegal or stigmatized behavior because of the deception
- The research places participants at significant financial, physical, legal, psychological, or social risk
- The participant is not provided with the opportunity to withdraw their participation (and their data) at the completion of the study when the deception is revealed; and/or
- The research is regulated by the U.S. Food and Drug Administration

Deception in Exempt Research

Protocols that include ***incomplete disclosure*** are eligible for exemption, assuming they would otherwise be eligible.

Protocols that involve ***deception*** are not eligible for exemption unless the participants are informed during the consenting process that the study procedures include deception. Prospective agreement to participate in research that includes deception may only be approved for benign behavioral interventions eligible for exemption under category Exempt 3.

Consent and Debriefing

Providing research participants with sufficient information to make an informed decision about their participation in a study is one of the guiding principles of human subjects research. The use of deceptive techniques often requires that information related to the true purpose of the research and/or study procedures be omitted from the informed consent document (including information sheets). This practice effectively prevents participants from prospectively providing fully informed consent.

An effective practice to ensure that the participant's autonomy is upheld in research involving deceptive techniques includes disclosure of the deception during the consenting process. A practice known as authorized deception. ***Authorized deception*** occurs when participants are informed *prior* to the start of the research that certain aspects of the research will not be described accurately or that some procedures will be deceptive. The use of authorized deception gives participants the opportunity to decide whether or not they want to participate in a study where all aspects of the research are not disclosed.

Researchers concerned that incorporating authorized deception may alter or bias the participants' responses should instead implement a debriefing protocol. ***Debriefing*** is a process that can be undertaken at the conclusion of any research activity, regardless of whether or not deceptive techniques were utilized. During the debriefing process, participants should be provided with a simple, clear, and informative explanation of the research purpose and the methods used, as well as a list of any pertinent resources. The content and the extent of the debriefing should align with the details and risk of the study. If the study involves deception, a plan for effective and respectful debriefing and dehoaxing is necessary to minimize risk to participants.

The primary goals of the debriefing process include:

- Informing participants of the true goals of the research study and repair the breach of informed consent created by the deception
- Remove any confusion or defuse any tension that might have been generated by the deception
- Educate the participants about the research process and point them to relevant educational resources
- Inform participants why deception is sometimes used in research to obtain scientifically valuable data
- Dehoaxing participants with dignity and unconditional positive regard for the range of emotions participants may have experienced in response to the deception.

It is important for researchers to understand that debriefing participants may not be sufficient to ameliorate the negative consequences of the deception. There are instances where the deception may place such a high burden (e.g., shame, emotional distress) on the participant that even when the deception is revealed, the participants may not be able to overcome the false beliefs generated by the deception or distrust the intent of the researcher and/or research community at large. In these instances, the IRB will evaluate whether the long-term risk to study participants merits implementing additional safeguards to protect the welfare of the study participants. If the risk posed by the deception is determined to be too great, the IRB may request that the researcher identify an alternative to the use of deception prior to obtaining IRB approval.

The timing of the debriefing is important to consider when using deception. Participants should be debriefed as early as possible. For example, research conducted online permits the researcher the opportunity to provide participants with a debriefing form immediately after the end of the data collection. However, if an immediate debriefing might compromise study results, debriefing information can be sent when the study is completed via mail, email or phone, or participants can be provided with a link where they can get debriefed. Regardless of when the debriefing occurs, participants should be provided with an opportunity to withdraw their consent and/or the use of their data after learning the true nature of the research.

Suggestions for Debriefing a Participant:

- Provide the study title and the name(s) of the principal investigator(s).
- Explain the following:
 - Study's true goals and purpose,
 - Why the study was developed,
 - Any predictions/hypotheses of the study,
 - What the researcher(s) expect(s) to learn from the study
 - The research questions being studied, etc.
- Reveal any deception employed in the study and the reasons why
- Provide withdrawal procedures and information on the opportunity to withdraw
- If available, provide the participant with the results of the study thus far
- Offer resources for research participants, including:
 - Researchers' contact information,
 - TAMU IRB's contact information (irb@tamu.edu; 979.458.4067),
 - Additional useful resources and/or support services, as needed (e.g., relevant crisis hotlines, mental health facilities, and outreach services),
 - Thank the individual for participating in the study.

Investigator Responsibilities

When conducting research that involves deception or incomplete disclosures, investigators must submit an application for review and approval by the IRB prior to implementing any human subjects research

activities. The IRB protocol must provide the scientific justification for deceiving or withholding information from participants, and provide an explanation of why the research could not practically be carried out without the use of deception or incomplete disclosure. This justification may not include that it would be inconvenient to conduct the study without the use of deceptive techniques. Information about when, how and whom will conduct the debriefing process must also be included. When appropriate, the researcher should include additional resources in the debriefing script. Lastly, if the deception is expected to elicit a strong emotional response, study personnel should be trained on how to help diffuse or minimize participants upset with respect and dignity. For online research, participants should be provided with the contact information of the researcher and a list of resources for the participant to reach out if they experience lasting emotional distress.

IRB Considerations

Under 45 CFR 46.116(d), the IRB may waive the requirement for obtaining informed consent or approve a consent procedure that leaves out or alters some or all of the elements of informed consent, provided that the IRB finds and documents that all of the following four criteria are met:

1. The research involves no more than minimal risk to the subjects;
 - Investigators and the IRB must ensure incomplete disclosure/deception are only used in minimal risk research and do not increase risks beyond what participants would agree to had they been fully informed about the research;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects
 - Investigators must provide sufficient information for the IRB to determine that the research questions could not be answered without the use of incomplete disclosure/deception
3. The research could not practicably be carried out without the waiver or alteration; and,
 - Investigators and the IRB must ensure incomplete disclosure/deception do not compromise participants' privacy, interests, or well-being.
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation
 - Participants should be debriefed after participation unless doing so would harm them. For example, if an individual is selected for participation in a study based upon undesirable hygiene characteristics (e.g., body odor, unwashed hair, wearing soiled clothing), it might not be appropriate for the debriefing to describe that aspect of the selection process. In such cases, the investigator must explain why it would not be appropriate to provide additional information after participation. The IRB must weigh the harms that may result from debriefing with the ethical concerns of not fully informing participants about the research after their participation.

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.

[HRP-411 Waiver or Written Documentation of Consent](#)

Sample Language

Authorized Deception 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.

- We have described the general nature of what you will be asked to do but the full intent of the study will not be explained to you until after [your participation] [the completion of the study]. At that time, we will give you more information about the study and give you an opportunity to ask questions.
- Due to the nature of the study, we are not able to disclose the purpose of this research at this time. However, we will hold a debriefing session to answer questions and tell you about the study after your participation.
- The full purpose of this research cannot be disclosed before you participate, but will be told to you at the end.
- The purpose of this research project is to examine how decisions are made in negotiation. We are not able to provide you all details about the study at the beginning of the study, but we will provide more information during/after your participation.

Debriefing Sample Language (debriefing script taken from University of California, Los Angeles):

Thank you for your participation in our research study, *[insert name of study]*.

I would like to discuss with you in more detail the study you just participated in and to explain exactly what we were trying to study.

Before I tell you about all the goals of this study, however, I want to explain why it is necessary in some kinds of studies to not tell people all about the purpose of the study before they begin. *[alternate language for deception studies: "... to not tell people all about the procedures in which they will be asked to participate."]*

As you may know, scientific methods sometimes require that participants in research studies not be given complete information about the research until after the study is completed. Although we cannot always tell you everything before you begin your participation, we do want to tell you everything when the study is completed.

We don't always tell people everything at the beginning of a study because we do not want to influence your responses. If we tell people what the purpose of the study is and what we predict about how they will react, then their reactions would not be a good indication of how they would react in everyday situations.

[insert explanation of study purpose, describe the information about the study purpose or the study procedures that was withheld and explain the reason why the information was withheld, as applicable.]

If other people knew the true purpose of the study, it might affect how they behave/answer questions, so we are asking you not to share the information we just discussed.

Now that the study has been explained, do you agree to allow the investigator to use the data that we collected from your participation in this study? Please know that even if you withdraw your participation and/or the use of your data, you will still be compensated for your time.

I hope you enjoyed your experience and I hope you learned some things today. If you have any questions later please feel free to contact me. *[provide sheet with contact names, addresses, telephone numbers, emails, for Principal Investigator, Faculty Sponsor, other co-investigators]*

Do you have any other questions or comments about anything you did today or anything we've talked about?