| Deception and Incomplete Disclosure | Version | 1.0 |
|---|---|---|
| | Effective Date | April 23, 2015 |
| | Last Revised | |



## Overview

Purdue University (PU) Institutional Review Boards (IRBs) recognize that deception and incomplete disclosure can be valuable research methodologies. However these methodologies present special challenges to ensure the ethical conduct of human subjects research. This guidance defines the standards for the use of deception and incomplete disclosure in research as well as describes the special responsibilities imposed on the investigator and the considerations required of the IRB in reviewing these methodologies.

## Definitions

*Deception* occurs when an investigator intentionally gives research participants misleading or false information about some aspect of the research.

*Incomplete Disclosure* occurs when an investigator intentionally withholds information from participants about the true purpose or nature of the research.

*Priming* is a psychological process in which exposure to a stimulus activates a concept in memory that is then given increased weight in subsequent judgment tasks. Priming works by making the activated concept accessible so that it can be readily used in evaluating related objects. For example, hearing news about the economy may prime individuals to focus on economic considerations when assessing a president's performance because economic concepts are activated, accessible, and presumably relevant for this type of evaluation. In this way, priming affects the opinions that individuals express, not by changing their attitudes, but by causing them to alter the criteria they use to evaluate the object in question.

## Use of Deception and Incomplete Disclosure in Research

Deception or incomplete disclosure may be appropriate to promote scientific validity by enabling investigators to obtain unbiased data about attitudes and behavior in circumstances considered likely

to result in biased responses or behaviors by participants. Deception or incomplete disclosure involves the use of false beliefs that interfere with the informed consent process.

This is commonly accomplished by deliberately misinforming participants or by omitting or withholding key information about the research such as using an elaborate false cover story, by concealing information about the procedures, or providing information so vague so as to mislead participants' understanding of the true nature of the research.

Although false beliefs about any aspect of a study can potentially be used, they are typically related to one of the following:

- purpose of the research,
- research procedures, and/or
- risks and benefits of participation.

**Deception may only be used:**

- when the risk is no greater than minimal; and
- when the research is not feasible without the deception; and
- when debriefing is provided.

**Examples of deception include:**

- Participants complete a quiz and are falsely told that they did poorly, regardless of their actual 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, etc.) 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 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.

**Examples of incomplete disclosure 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.

It is generally not considered deception when investigators do not inform participants about the study hypothesis, treatment groups, or any information beyond what is required for informed consent.

## Information to Include in the IRB Application

Federal regulations prohibit the use of deceptive techniques that place participants at greater than minimal risk. An investigator proposing to use deception or incomplete disclosure should justify its use in the IRB application. Address the following when preparing the application:

- In the Procedures section, justify use of deception and explain why deception is necessary to achieve the goals of the study. Explain if alternative methods not involving use of deception were considered and why these methods are not being used (Sloan & Hull, 2006).
- In the Informed Consent section, explain the process of debriefing, including when, how and by whom participants will be debriefed. Provide copies of the debriefing statement that will be given to participants and the script that will be used by the investigators to orally explain the study (see below for guidance regarding the debriefing).
- In the Risks section, explain if use of deception is likely to cause the participant psychological discomfort (i.e., stress, loss of self-esteem, embarrassment) while the deception is taking place. Explain how this risk will be minimized during the experiment and after the experiment is complete (i.e. full debriefing) (Sloan & Hull, 2006).
- In the Benefits section, describe how the potential benefits of the research justify the deception.
- Request a Waiver or Alteration of Informed Consent. When participants are not given complete information about the study in the consent document, the IRB must determine that research qualifies for a waiver or alteration of the required elements of the consent process (i.e. an explanation of the purpose of the research, a description of the procedures involved, etc.).

## Ethical Concerns and IRB Review

The basic principles that guide the ethical conduct of human subjects research support complete informed consent that provides participants with sufficient information in an understandable format to allow them to choose what will happen to them. However research designs using deception or incomplete disclosure do not allow participants to provide complete informed consent prior to their participation in the study.

When reviewing research that involves deception or incomplete disclosure, the IRB must evaluate the required information discussed in the above-section of this guidance 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 investigator 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.

The IRB must determine that the research qualifies for a waiver or alteration of the required elements of informed consent, in accordance with criteria provided in the federal regulations at 45 CFR 46.116(d).

## Exempt Research

Research involving incomplete disclosure but no deception (e.g., participants not informed about the true purpose of the research) may be reviewed as exempt provided the study meets all criteria required for the exemption category. Exemption requests involving incomplete disclosure are reviewed on a case-by-case basis. Investigators who believe their study may qualify for exemption are encouraged to consult with the HRPP office prior to submission.

Research involving deception may **not** be reviewed as exempt.

## Informed Consent Requirements

Potential participants should be advised in the consent form that the information they are given is not complete and that they will be debriefed after the research procedures are completed. Address the following when preparing the consent form/information sheet:

- In the "Why is this study being done?" section, provide a truthful and accurate explanation of the purpose of the study to the extent possible, without priming participants or by giving too much of the study away.
- Include the following statement in the "What will I be asked to do?" section, "Some research requires that the full purpose of the study not be explained before you participate. We will give you a full explanation at the end of the study." Please note: the last sentence can be further customized to say, "We will give you a full explanation as soon as you complete the study."

## Debriefing Participants

When required elements of informed consent are waived or altered by the IRB, in accordance with criteria provided in the regulations, participants must be debriefed at the end of the study, when appropriate. When a research study involves use of deception, the IRB must find that:

- the research involves no more than minimal risk to participants
- the waiver or alteration will not adversely affect the rights and welfare of the participants;
- the research could not practicably be carried out without the alteration or waiver; and
- when appropriate participants will be provided with additional pertinent information regarding participation.

**Functions of Debriefing**

- De-hoaxing: setting the record straight so that participants do not leave the study with experimentally induced false beliefs that may cause distress, e.g., given false information about performance on an ability test. Participants must be told during debriefing the results were fabricated and no way indicative of their true ability.
- Desensitizing: answering questions about the research and the use of deception, addressing any concerns that arise, and seeking to alleviate any distress that may occur as the result of the deception. Some participants, for example, may feel foolish for having "fallen for" the deception.

### Exceptions to Debriefing Requirement

There are certain circumstances under which the IRB may waive the requirement for full disclosure when a study involves deception. An example of a circumstance in which debriefing may not be appropriate occurs when debriefing regarding the deception may cause more harm than the deception itself. For example, if a student is selected for participation in a study based upon certain physical characteristics (i.e., weight, or physical unattractiveness), it might not be appropriate for the debriefing to describe that aspect of the selection process.

The timing of the debriefing is also an important consideration. Generally, the IRB expects that participants will be debriefed following their participation in the study. Oftentimes debriefing occurs immediately after a participant completes the study activities, however debriefing at that time may compromise study results because those participants could divulge that information to other prospective participants, thus compromising the scientific validity of the study. The IRB recommends the use of the following strategies to manage such situations.

If participant names and contact information are collected as part of study procedures, debriefing information can be sent when the study is completed via mail, email or by phone.

If participant names and contact information are not collected researchers can:

- Give participants a URL where they can get debriefing information and a date upon which it will be available.
- Have each participant address an envelope to himself/herself before leaving the study session. Then send mail the debriefing information when the research is completed.

## Experimental Manipulation Versus Deception

Quite probably all research contains elements of deception, whether by overtly misleading participants or just omitting some of the information (incomplete disclosure). There are some distinctions to be made, however, between deception and the use of experimental controls. In common social science laboratory research, investigators are either comparing variables to each other or are comparing some sort of treatment to a non-treatment condition.

For example, researchers studying the effects of caffeine on short term memory may randomly assign participants to groups, some of which receive caffeine and others a placebo. Participants are informed that they will be randomly assigned to groups, that they won't know which group they are assigned to, and that they may or may not receive the caffeine. After consuming the particular substance, each is then administered a memory task.

The above example demonstrates experimental manipulation. Each group is administered a different level of the independent variable, in this case caffeine, with one group assigned to the placebo (control) condition. Participants are not misled, they are aware of the possibility of receiving caffeine or no caffeine, and are fully informed in the consent document.

Now, change the above experiment to one in which participants do not receive caffeine but some are told the substance they are consuming have high concentrations of caffeine and they will respond with alertness and increased performance on the memory task. That is deception. They are deliberately misled both about the substance they are consuming and about the purpose of the research. In this case, the researchers are not investigating the actual effects of caffeine, but rather

the effects of participant's *beliefs* about the effects of the caffeine (also known as placebo responding). In this case, the deception is justified as there is no other way to test placebo effects.

In this second example, participants must be debriefed as to the actual conditions of the research as well as the experimental hypothesis. Participants will also be asked to complete a debriefing consent form.

## Regulations and References

### DHHS Regulations

- Definition of Minimal Risk: 45 CFR 46.102(i)
- General Requirements for Informed Consent: 45 CFR 46.116
- Documentation of Informed Consent: 45 CFR 46.117

### References


United States. (1978). *The Belmont Report - Ethical Principles and Guidelines for the Protection of Human Subjects of Research.* Bethesda, MD: The Commission.

Parkin, M. 2008. Priming. In P. J. Lavrakas (Ed.), *Encyclopedia of Survey Research Methods* (pp.612-613). Thousand Oaks, CA: SAGE Publications, Inc. doi: http://dx.doi.org/10.4135/9781412963947.n399

Sloan, L and Hull, J. 2006. Deception of Research Subjects 2nd Edition. In E. A. Bankert and R. J. Amdur (Eds.), *Institutional Review Board Management and Function* (210-215). Sudbury, Massachusetts: Jones and Bartlett Publishers.