Guidance and Procedure: Deception or Incomplete Disclosure  
(updated July 7, 2020)

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Overview

Some research, particularly in psychology, neuroscience, and behavioral research, plans to deliberately withhold information about the purpose of research and/or procedures employed or purposely mislead participants by providing false information about some aspect of the research. This guidance describes the special responsibilities imposed on the investigator and the considerations required of the IRB when research involves deception or incomplete disclosure.

*Deception studies* intentionally provide misleading or false information. 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.

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

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.
**Deception Qualifying for Exempt Review**

The 2018 Revised Common Rule allows for deception to be approved as Exempt if participants authorize the deception through a prospective agreement to participate in research in circumstances in which the participant is informed that he or she will be unaware of or misled regarding the nature or purpose of the research and the research falls into one or more Exempt research categories.

**Consent and Debriefing**

The basic principles that guide the ethical conduct of human 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.

Investigators should use the following measures in order to allow participants appropriate autonomy in the consent process for research that involves deception or incomplete disclosure:

- **“Authorized deception” (AD):** Informing participants prior to the study that a study will not be described accurately or that some procedures will be deceptive, provides them 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:** When an investigator uses deception or incomplete disclosure, regulations require that participants be debriefed at the end of the study, when appropriate. Debriefing may be inappropriate if debriefing regarding the deception may cause more harm than the deception itself.

  Debriefing sessions can mitigate the harm and wrong of deception by explaining the rationale for the deception. Participants should be given a simple, clear and informative explanation of the rationale for the design of the study and the methods used, and should have the opportunity to ask questions. Click here for a [sample debriefing script](#).

  The primary goals of a debriefing process are to:
  - inform participants of the true goals of the research study,
  - remove any effects of false information they were given,
  - educate participants about the research process, why deception is sometimes necessary, how false beliefs can sometimes persevere, and
  - make participants feel that they are an important part of the research process.

  The IRB in collaboration with the investigator will determine whether participants should be debriefed either after unwittingly participating in the research or after knowingly participating in research that involved deception.

  The investigator may decide or IRB may require that the debriefing include an option for participants to withdraw their data from the study after they learn the true nature of the research, if it is of a particularly sensitive nature. (e.g., the withheld aim of the study is that the researcher is measuring participants’ racism)
Debriefing may also be used as an educational tool for the participant, even when the study does not involve use of deception.

Participants should be debriefed as early as feasible. If an immediate debriefing may compromise study results, debriefing information can be sent when the study is completed via mail, email or by phone, or participants can be given a URL where they can get debriefing information and a date upon which it will be available.

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 risk/benefit ratio of the research.

The webIRB application must:
- Justify the reasons for deceiving or withholding information from 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 the information will be provided to participants, and include a copy of your 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.

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 federal regulations at 45 CFR 46.116(d). No waiver or alteration of the required elements of consent for the purposes of deception or incomplete disclosure is allowed for FDA-regulated research.

Regulations & References

DHHS Regulations
- Deception Qualifying for Exempt Review: 45 CFR 46.104(3, Ciii)
- General Requirements for Informed Consent: 45 CFR 46.116
- Definition of Minimal Risk: 45 CFR 46.102(i)
UCLA OHRPP References

- Guidance and Procedure: Requesting Waivers and Exceptions to Informed Consent
- Sample Debriefing Script

Change history:
07/07/2020: Updated to reflect 2018 Revised Common Rule; updated links.