Guidance: Using deception in research

Overview

The IRB accepts the need for certain types of studies to employ strategies that include deception. However, employment of such strategies must be justified. In general, deception is not acceptable if, in the judgment of the IRB, the participant may have declined to participate had they been fully informed of the true purpose of the research.

Definitions

Deception is a research technique that involves intentionally misleading or withholding full information about a research study from participants.

Debriefing a written statement and description of the deception and an explanation about why it was necessary.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Purpose of deception in research

Misleading or omitted information might relate to the purpose of the research, the role of the researcher or other participants, the true nature of the procedures to be followed, or any other part of the study. While it is an accepted research technique, deception raises ethical concerns because it interferes with the ability of the participant to give informed consent. However, deception is arguably necessary for certain types of research where participants' full knowledge is likely to bias the results by causing participants to act differently than they naturally would.

Regulatory requirements, §46.116(d)

If the subjects will be deceived, the ethical and regulatory requirement to fully inform subjects must be waived by the IRB. Per §46.116(d), three criteria that must be met in order for the waiver to be approved in addition, it is usually necessary to debrief subjects after the research.

- The research involves no more than minimal risk to the subjects.
- The waiver or alteration will not adversely affect the rights and welfare of the subjects.

- The research could not practicably be carried out without the waiver or alteration;

Debriefing

Debriefing descriptions should be written in lay language and provide sufficient details about how and why participants were deceived. For studies that involve multiple deceptions, the IRB protocol is to include a description for each.

if participants were filmed without their knowledge they must be given the option to ask that the researchers do not use the records.

Delayed debriefing

Delayed debriefing is an option if participants are part of a group that may share information about their experience in the research.

if researchers intend to delay debriefing, the consent form must state additional information will be available after the completion of the study. Contact information from participants will need to be retained and kept separate from study records.

IRB protocol

The IRB protocol must address the following when deception is employed:

- Justification for the deception
- A description of the manner of deception and how the deception will take place
- An explanation as to why deception is necessary to this protocol
- A description of whether the deception results in any increased risk to participants
- An indication of whether the deception may affect a subject's willingness to participate in research
- A description of the post-study debriefing that includes offering the participant the option to withdraw their data from the study
- If an exception to the requirement for a debriefing is requested, the study must be reviewed by the full board

- A description of any previous use of deception in similar research and a summary of any actual harms or reactions from participants to the use of deception
- A description of alternatives to deception that were considered and an explanation as to why these alternatives were rejected.

IRB considerations

In addition to the regulatory requirements detailed in §46.116(d),there are certain items an IRB must consider when deception is part of a research protocol.

- Is deception necessary to conduct the study?
- Would participants be less likely to participate should they know the withheld information?
- Is the deception likely to upset or inflict any kind of harm to participants?
- Will subjects be debriefed after the experiment is completed, and is the debriefing adequate?
- Is the study "minimal risk"? (Regulations do not allow elements of consent to be waived when a study poses greater than minimal risk to participants.).

Regulatory limitations

An exempt determination cannot be considered for research involving deception.

Studies governed by FDA regulations cannot be approved if deception is involved because the required waivers of consent can only be granted under limited conditions involving emergency, life threatening situations for participants under.

Resources & References

American Psychologist Association: Ethical principles of psychologists and code of conduct

Code of Federal Regulations: General requirements for informed consent [§46.116(d)]

Food & Drug Administration, [21 CFR 50.23]

Duke University

Oregon State University

Iowa State University