OBJECTIVE

To describe policies and procedures for the use of deception in research involving human participants.

GENERAL DESCRIPTION

The Institutional Review Board (IRB) at Nova Southeastern University (NSU) is guided by the Common Rule, 45 CFR 46. The NSU IRB treats deception seriously but recognizes that some deception is necessary to provide deeper understanding of human behavior when no viable alternatives exist. 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.

With deception, real and prospective informed consent is not possible, because participants are not given all the necessary information to make a fully informed decision before being debriefed. Therefore, the IRB administratively manages research-involving deception through alterations to the informed consent process as provided for in the Common Rule. This SOP describes the use of deception in research and the requirements of such alterations. All research involving deception will be closely reviewed by the IRB Office, IRB Chair, and/or convened IRB.

Definitions

Deception: The intentional misleading of research participants by providing false or misleading information concerning some aspects of the research. False or misleading information may 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 other parts of the study. Examples include:

- Participants are asked to complete a quiz and are falsely told that they did poorly, regardless of their performance.
- Participants who do not 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: Occurs when the researcher withholds information from participants concerning some aspects of the research (typically, about the real purpose or nature of the study). 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.

Debriefing: The process occurring after deception is no longer necessary that includes explaining the deception to the participant, dealing with any responses by the participant about the use of deception, and obtaining true informed consent.

Risks: The potential to expose a participant to danger, harm, or loss. There are certain risks to participants in research involving deception. Those risks include, but are not limited to:

- Temporary or long-term psychological discomfort (i.e. stress, loss of self-esteem).
- Physiological symptoms associated with stress/discomfort (sweating, elevated heart rate, etc.).resulting from deception
- Embarrassment resulting from deception
- Guilt from having performed regrettable acts
- Participant may not have provided consent without deception
- Invasion of privacy if information was disclosed as a result of deception

RESPONSIBILITY

Execution of SOP: Principal Investigator (PI)/Research Personnel, Institutional Review Board (IRB) Office Staff, IRB Members, IRB Chairs

PROCEDURES

A. Protocol Submission

1. *Justification for the use of deception*: Investigators must clearly justify that equally effective non-deceptive procedures are not feasible means of conducting the proposed research.

2. *Pain or severe emotional distress*: Investigators must not use deception when there is a reasonable belief that such deception may cause severe emotional distress or physical pain. Research studies with the potential of creating brief psychological distress must minimize such discomfort, via the debriefing process.

3. *Debriefing*: Investigators are required to inform participants of the deception or incomplete disclosure and provide them with a debriefing document, as soon as practicable. The IRB prefers face-to-face debriefing immediately following participation, although researchers may justify delays or the use of email or telephone. (See Section B of this SOP for more information regarding debriefing participants.)

4. *Alteration of Informed Consent*: A researcher must request from the IRB an alteration to the informed consent process. An alteration can only be granted if the IRB documents all of the following (see §45 CFR 46.116(d)):
    a. The research involves no more than minimal risk to the subjects;
    b. The waiver or alternation will not adversely affect the rights and welfare of the subjects;
    c. The research could not practically be carried out without the waiver or alteration;
    d. Whenever appropriate, the subjects will be provided with additional pertinent information after the procedure.

5. *Waiver of use of collected data*: The study must provide an opt-out for participant data after they learn the true nature of the research methods.

B. Debriefing Participants

1. Investigators are required to inform participants of the deception or incomplete disclosure and provide them with a debriefing document, as soon as practicable.

2. The investigator must submit the debriefing document to the IRB for review with their protocol submission.

3. If a personal interview is used for debriefing, the investigators must provide a script as part of the submission for IRB review.

4. The debriefing document/script should be labeled “Debriefing Statement” and include the following:
    a. Study title.
    b. Complete contact information for the principal investigator (name, address, phone, and email, as applicable). If the principal investigator is a student, the contact information of the faculty advisor/dissertation chair must be provided.
    c. A statement thanking the participants for their time and efforts.
    d. Details about the components of the study that involved deception and provide the rationale for the use of this deception, while avoiding complex terminology or jargon.

e. Discuss how the data gathered from the deceptive components will be evaluated and remind the participant of their right to withdraw from the study and to request their data not be used. If a participant wishes to exercise this right, the principal investigator must assure the participant that their data will be deleted/destroyed within 24 hours after the participant informs the researcher of his/her decision.

5. If the researcher seeks an exception to debriefing participants, the study will be automatically reviewed by convened IRB.

C. Levels of Review for Research Involving Deception

1. Research involving incomplete disclosure or deception may be exempted at the College Level of Review only if the investigator informs all participants up front regarding the use of deception prior to consenting and enrolling them in the study.

2. Research involving deception may be reviewed at the expedited level if there is a unanimous consensus from the IRB Chair, an IRB Vice Chair (or designated voting member if a Vice Chair is not available), and the IRB Office. A record of the voting process will be included in the research file. All members of the convened IRB will be informed of this decision through the next meeting minutes.

3. If this subcommittee fails to reach a unanimous consensus, or in any situation not covered above, the study will be reviewed by convened IRB.

REFERENCES

45 CFR 46

America Psychological Associations' Ethical Code