19.0 Deception or Incomplete Disclosure in Research Policy

19.1 Overview

Some research, particularly psychology and behavioral, deliberately withholds information about the purpose of the research and /or the procedures employed or purposely misleads participants by providing false information about some aspects of the research. This policy describes the special responsibilities imposed on the investigator and the considerations required of the IRB when research involves deception or incomplete disclosure.

19.2 Definition(s)

Deception: occurs when an investigator gives false information to subjects and intentionally misleads them about some key aspect of the research. A key aspect includes but is not limited to a primary endpoint.

Incomplete disclosure: occurs when an investigator withholds information about the specific purpose, nature, or other aspect of the research.

See Section 19.8 for Examples

19.3 When Deception May be Used

The following guidelines from The American Psychological Association (APA) explain when deception is appropriate in research:

- Researchers do not conduct a study involving deception unless they have determined that the use of deceptive techniques is justified by the study's significant prospective scientific, educational or applied value and that effective non-deceptive alternative procedures are not feasible.
- Researchers do not deceive prospective participants about research that is reasonably expected to cause physical pain or severe emotional distress.
- Researchers explain any deception that is an integral feature of the design and conduct of an experiment to participants as early as is feasible, preferably at the conclusion of their participation, but no later than at the conclusion of the data collection, and permit participants to withdraw their data.

19.4 Elements of Waiver of Informed Consent

In studies involving deception or incomplete disclosure as determined by the IRB, fully informed consent is not obtained from participants prior to participation. When the consent process will not fully inform participants about the research, the IRB must consider whether the research meets all of the criteria for a waiver of one or more elements of informed consent as set forth in federal regulations at 45 CFR 46.116(d).

The criteria for a waiver of one or more elements of informed consent are:

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

A waiver or alteration of informed consent request must be included in the application to the IRB if deception or incomplete disclosure in research is used in a study.

19.5 Goals of Debriefing

When a researcher uses deception, a debriefing at the end of the study is required, when appropriate. Debriefing may be inappropriate if debriefing regarding the deception may cause more harm than the deception itself.

Debriefing after deception has several goals: (1) to repair the breach of informed consent entailed by the deception, (2) to remove any confusions or defuse any tensions that might have been generated by the deception, (3) to make it clear especially to younger participants that deception is permissible only in exceptional circumstances, and (4) to repair (as much as possible) the breach of trust that has occurred not only between the investigator and the participant, but (potentially) between all researchers and all participants.

19.5.1 Debriefing Guidelines

Ethical Principles of Psychologists and Code of Conduct guidelines discuss debriefing participants of the deception used in research.

- Researchers provide a prompt opportunity for participants to obtain appropriate information about the nature, results, and conclusions of the research, and they take reasonable steps to correct any misconceptions that participants may have of which the psychologists are aware.

- If scientific or humane values justify delaying or withholding this information, researchers take reasonable measures to reduce the risk of harm.
- When researchers become aware that research procedures have harmed a participant, they take reasonable steps to minimize the harm.

19.6 Investigator Responsibilities

The application and protocol submitted to the IRB must include the following:

- Justify the reason for deceiving or withholding information from the participants. This includes an explanation of the research's benefits and why the deception or incomplete disclosure is necessary.
- Explain why the deception or incomplete disclosure is necessary
- Outline the process of debriefing, if applicable; including when, how and by whom the information will be provided to participants
- Provide a copy of your debriefing script, if available/applicable.

19.7 IRB Considerations

The IRB must consider the following when reviewing research with deception or incomplete disclosure:

- 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)
- The scientific value and validity of the research
- The efficacy of alternative procedures
- The certainty that deception or incomplete disclosure does not extend to influence participant's 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 the deception or incomplete disclosure to facilitate unwanted and inappropriate invasions of privacy
- Whether the researcher has the skill and resources to address participants' who become upset
- If the study does not involve a de-briefing, the IRB must consider and document the reasoning of why the risks do not outweigh the benefits in not de-briefing participants.

19.8 Examples of Deception and Incomplete Disclosure in Research

- Participants complete a quiz, and are falsely told that they did very 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 a large amount of cash in a public location.
- In a study of anxiety, participants are told to expect mild pain during the course of the study, but no painful procedures are administered.

19.8.2 Incomplete Disclosure Examples

- Participants are asked to complete a quiz for research, but not told that the research question involves how background noise affects their performance.
- Subjects are told they are completing study questionnaires to evaluate their satisfaction, when the true purpose of the study is to correlate psychiatric symptoms with subject satisfaction.