Deception or Incomplete Disclosure

Purpose

The purpose is to outline the policy and procedures for deception or incomplete disclosure used in human research.

Definitions

Deception is an intentional misleading of others through misrepresentation or falsehood. In research, it may happen when an investigator provides subjects (participants) with false information in order to obtain unbiased results in social or behavioral research. Some examples are:

- The investigator provides the subjects with a false description of the study's purpose.
- A member of the research team poses as a fellow participant and interacts with subjects as part of the experimental design.

Incomplete disclosure occurs when an investigator withholds information about the specific purpose(s) or full nature of the research. Some examples are:

- The investigator does not mention one of several activities.
- The investigator presents the purpose of the study or certain procedures in general terms that are true but deliberately vague enough that they do not reveal the researcher’s specific objective.

Informed Consent is a process by which a knowing, legally effective agreement to participate in research is made by any individual or the individual's legally authorized representative (LAR), and which may be obtained only under circumstances that provide the prospective subject or representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

Policy

The use of deception or incomplete disclosure presents challenges in the protection of human participants because it interferes with the requirements for fully informed consent and overall ethical considerations. Therefore, deception may be utilized only when there are no viable alternatives. Employment of such methods requires special consideration by the Institutional Review Board (IRB). The IRB may find the use of deception or withholding of information acceptable when it is unavoidably required to meet research objectives, when it is adequately justified, and when the benefits outweigh the risks. In general, deception is not acceptable if, in the judgment of the IRB, the participating subject may have declined to participate had the subject been fully informed of the true purpose or nature of the research.

Deception may only be permitted where the IRB documents that an alteration of the usual informed consent requirements is justified under the criteria presented in federal regulations at 45 CFR 46.116(f)(3)(i-v). Specifically, the IRB must find and document that all five of the following criteria have been satisfied:

1. The research presents no more than minimal risk to subjects;
2. The research could not practicably be carried out without the requested alteration;
3. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in and identifiable format;
4. The alteration will not adversely affect the rights and welfare of the subjects; and
5. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation (i.e. debriefing).

Subjects must not be deceived about research that could reasonably be expected to cause physical pain or severe emotional distress.

The debriefing process should consist of the following:

- Full disclosure of the deceptive aspects of the study and an explanation of the actual study objectives
- An explanation as to why the deception was necessary
- An opportunity for the subjects to ask questions
- Whenever possible, an opportunity for the subjects to withdraw their data from the study

Review Type

Except for the specific circumstance described below, research involving deception or incomplete disclosure is prohibited from exemption. It therefore must be submitted for review by the IRB. The use of deceptive techniques or withholding of information which places participants at greater than minimal risk is also prohibited.

For research which poses no greater than minimal risk, the appropriate category of review will depend upon:

- The nature of the deception
- The degree of risk present
- The vulnerability of the participating subjects
- Whether or not all activities qualify for a federal expedited category or categories

Exception to Exemption Prohibition

Certain research involving deception or incomplete disclosure may qualify for exemption, but only if it meets all three of the following criteria: (1) it involves benign behavioral interventions with adult subjects through verbal or written responses (including data entry) or audiovisual recording (Exemption Category 3), (2) the information is recorded without identifiers, links or associations, OR disclosure of responses outside the research would not reasonably place subjects at risk of criminal or civil liability or be damaging to their financial standing, employability, educational advancement, or reputation, and (3) **the subjects**

authorize the deception through a prospective agreement to participate in research in circumstances in which they are informed in advance that they will be unaware of or misled regarding the nature or purposes of the research.

Procedures

Investigators planning to employ deceptive techniques or to withhold some information during the informed consent process must include the following information or documentation within their submission:

1. **Form - Request for an Alteration of Informed Consent**
   The IRB may waive some required elements of consent if certain criteria are met. Please see the IRB's Forms & Instructions page for a Waiver or Alteration of Informed Consent Request Form. All five points on the form must be adequately addressed.
2. **Rationale**
   Provide justification for the use of deception or incomplete disclosure. State if subjects would have been less likely to participate had they known the true nature of the study.
3. **Description of Risk**
   Describe any additional risk resulting from the deception or incomplete disclosure. Will it upset or inflict any harm to participants? Explain how this risk will be minimized during and after the research.
4. **Debriefing**
   Debriefing provides participants with a full explanation of the hypothesis being tested, procedures used to deceive participants, and the reason(s) why it was necessary to deceive or withhold information. It should also include any other relevant background information concerning the study.
    1. Explain the debriefing process.
    2. Explain when debriefing will take place.
    3. Explain who will debrief participants.
    4. Provide the debriefing form, or a script to be read to orally.
    5. If there are any elements that will not be revealed to participants, explain and provide a rationale, such as if the debriefing itself would present an unreasonable risk of harm.

5. **Withdrawal Option**
   Include an option for subjects to withdraw their data from the study after they learn the true nature of the research.

Related Policies

- Exempt Review
- Expedited Review
- Full Review
- Informed Consent, Parental Consent and Child Assent

History

11/13/2012 - Created
06/27/2013 - Format and headings updated
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