Definition

Deception is the intentional misleading of subjects (telling subjects something that is not true). Concealment is the withholding of full information about the nature of the experiment (not telling the whole truth). Misleading or omitted information might include the true title of the research, the purpose of the research, the role of the researcher, or what procedures in the study are actually experimental. Deception and concealment increase ethical concerns because they interfere with the ability of the subject to give informed consent. However, they are arguably necessary for certain types of behavioral research. Because humans act differently depending on circumstances, full accurate knowledge by the subject might bias the results.

Regulations

Federal regulations permit but establish limitations on the use of deception. The Investigator must provide scientific and ethical justification for deceptive procedures for the IRB review and approval. The missing information should not increase the risks of the study, and subjects must be fully debriefed. Subjects must have the opportunity to ask questions about the new information and be given the opportunity to withdraw from the study and have their data removed. Deception may not be utilized to obtain enrollments.

Use of Deception/Concealment during the Consent Process

Since voluntary informed consent cannot truly occur if the participant is not told that they will be deceived, strong justification must be provided for procedures calling for deception or concealment. Also participants must be fully informed at the conclusion of the activities with an opportunity to withdraw their data if they are troubled by the deception or concealment.

According to guidance provided by the Office for Human Research Protections (OHRP) the use of deception requires a request to waive certain elements of informed consent. According to the regulations the IRB may approve a consent procedure, which does not include, or which alters, some or all of the elements of informed consent IF it finds and documents that:

(1) The research involves no more than minimal risk to the subjects;
(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(5) The research is not FDA-regulated.

The UA IRB will allow deception/concealment to be used in human subject studies only when the investigator has met ALL of the following conditions:

1. The investigator provides compelling justification for the deception or concealment to the IRB and the board approves the project;

2. The investigator specifically states within the procedures section of the protocol that a waiver of the requirement to include an explanation of the purposes of the research within the informed consent form is being requested;

3. The investigator addresses and provides adequate justification for each of the four waiver criteria listed above;

4. The investigator does not expose subjects to more than minimal risk.

5. The investigator fully and honestly informs participants about the requirements of their participation as approved by the board before they take part in the study. This is documented by using the traditional Consent Form.

6. The investigator, as soon as possible after the deception, fully informs the participant about the fact and exact nature of the deception and the reason for the it. After full disclosure, the investigator presents the participant with a second consent form that fully explains the deception and its purpose. Participants are then given 2 choices: The opportunity to have their data used or to have the data not used and all data immediately destroyed.

Investigators submitting an application involving deception/concealment should complete and attach supplementary FORM: Request for Waiver or Alteration of Consent. Deception/concealment involves an alteration in standard consent contents and procedure. Also, describe the procedures related to deception/concealment in the procedures section of the application.
**Additional Procedures to be Considered when using Deception/Concealment in Research**

Research participants should never be deceived about significant aspects that would affect their willingness to participate such as physical risks, discomfort, or unpleasant emotional experiences.

Studies involving active deception should have a clear and defensible scholarly motivation—and each of the deceptive elements of the study should be *necessary*, with a clear rationale to back this up.