Policy Statement

The University of Indianapolis (UIndy) acknowledges the use of deception and incomplete disclosure in human subjects research as valuable research techniques; however, they present ethical challenges to protecting the rights and welfare of research participants and the responsible conduct of research. Furthermore, the use of deception and/or incomplete disclosure as research techniques will require investigators to educate and/or inform participants via debriefing after data collection is complete. Therefore, the IRB will approve the use of deception and incomplete disclosure only after careful review of methodological and ethical validity.

Definitions

(1) “Deception”: Intentional, deliberate communication of false information about purpose(s) and/or procedure(s) of the research.

(2) “Incomplete Disclosure”: Intentional, deliberate withholding of information about purpose(s) and/or procedure(s) of the research.

Methodological and Ethical Limitations [SACHRP, 2010; 45 CFR 46.102(i)]

Federal authorities have determined the following methodological and ethical limitations of deception and/or incomplete disclosure in human subjects research:

(1) Assess validity of random assignment and stimulus control.

(2) Study low-frequency responses.

(3) Obtain information participants cannot validly self-report.

(4) Valid only when non-deceptive alternatives are not available or applicable.

(5) Valid only when potential social value is commensurate with risks.

(6) Research risks do not exceed regulatory minimal risk threshold. Inasmuch as deception and/or incomplete disclosure alters some or all regulatory requirements of informed consent, investigators must request a waiver for informed consent. A regulatory criterion for approving a waiver for informed consent is the risk of the research must not exceed regulatory minimal risk threshold. Therefore, the use of deception and/or incomplete disclosure is invalid in research exposing participants to greater than minimal risk.

Justifying the Use of Deception and/or Incomplete Disclosure in IRB Review Application

Investigators must justify the use of deception and/or incomplete disclosure by including the following information when completing the IRB Review Application in IRBManager:

(1) In the Research Methods section, justify use of deception and/or incomplete disclosure and explain why deception and/or incomplete disclosure are necessary to achieve the goals of the
study. Explain if alternative methods not involving use of deception and/or incomplete disclosure were considered and why these methods are not being used (Sloan & Hull, 2006).

(2) In the Research Methods AND Informed Consent Procedures section, explain the process to debrief participants. Explain when participants will be debriefed and who will debrief them. Provide copies of the debriefing statement that will be given to participants and the script that will be used by the researchers to orally explain the study.

(3) In the Risks section, explain if use of deception and/or incomplete disclosure is likely to cause the participant psychological, emotional and/or physical discomfort (i.e., stress, loss of self-esteem, embarrassment). Explain how this risk will be minimized during the study and after the study is complete (i.e. full debriefing; Sloan & Hull, 2006).

(4) Inasmuch as deception and/or incomplete disclosure require an alteration of regulatory and statutory informed consent requirements, investigators must complete the Waive of Informed Consent section. When participants are not given complete information about the study in the consent document, the IRB must waive certain required elements of the consent process (i.e. an explanation of the purpose of the research, a description of the procedures involved, etc.).

Informed Consent Requirements
Potential participants should be advised in the consent form that the information they are given is not complete and that they will be debriefed after the research procedures are completed. Investigators must include the following elements in informed consent procedures:

(1) In the “Purpose of this Research Study” section of the informed consent document, provide a truthful and accurate explanation of the purpose of the study to the extent possible, without priming participants or by giving too much of the study away.

(2) In the “What Will be Done/Procedures” section of the informed consent document, add the following template language as appropriate for the study:

*Some research involves deception (misleading information) or incomplete disclosure (not giving all information) in order to study certain reactions and/or behaviors. Although you have been informed about the general nature of the study and the tasks you will perform, you will not receive a complete explanation of the study until you have completed your participation or the entire study is completed. At the appropriate time, you will receive debriefing materials which will include an explanation of the purpose and objectives of the study and why false or incomplete information was given to you. You will receive relevant background information about the study. You will have the opportunity to ask any questions about the study and your participation. After you have been informed about the study and you have received answers to your questions, you can withdraw from the study, and tell the investigators not to use any information they have collected from or about you.*
Debriefing Requirements for Use of Deception in Research

The debriefing is an essential part of the informed consent process and is mandatory when the research study involves use of deception. The debriefing provides participants with a full explanation of the hypothesis being tested, procedures to deceive participants and the reason(s) why it was necessary to deceive them. It should also include other relevant background information pertaining to the study (see below).

(1) The Federal Debriefing Requirement

When required elements of informed consent are waived or altered by the IRB, in accordance with criteria provided in the regulations, participants must be debriefed at the end of the study, when appropriate. When a research study involves use of deception, the IRB must find that:

(a) The research involves no more than minimal risk to participants;

(b) The waiver or alteration will not adversely affect the rights and welfare of the participants;

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

(d) When appropriate, participants will be provided with additional pertinent information regarding participation.

As indicated above, the debriefing must occur “when appropriate.” It may be inappropriate when debriefing regarding the deception may cause more harm than the deception itself. For example, if a student is selected for participation in a study based upon certain physical characteristics (e.g., weight), it might not be appropriate for the debriefing to describe that aspect of the selection process.

(2) The timing of the debriefing is also an important consideration. Generally, the IRB expects investigators to debrief participants immediately upon completion of participation in the study. However, it is possible that an immediate debriefing may compromise study results. Participants who have completed the study might tell others about it. If they have been debriefed, then they may share that information with prospective participants, thus compromising the scientific validity of the study. The IRB recommends the use of the following strategies to handle this situation:

(a) If participant names and contact information are collected as part of study procedures, debriefing information can be sent when the study is completed via mail, email or by phone.

(b) If participant names and contact information are not collected researchers can:

   (i) Give participants a URL where they can get debriefing information and a date upon which it will be available.
(ii) Have each participant self-address an envelope before they leave the study session and send them debriefing information when the research is completed.

(3) In most cases, the IRB expects that participants will be given a debriefing statement to take with them after the study is complete and after participants have been given an oral debriefing (script) immediately following completion of the study. Both the debriefing statement and the debriefing script must be reviewed and approved by the IRB.

(4) The process to debrief participants must be explained in the IRBManager “IRB Review Application” form. Address the following elements:
   (a) Specify **who** will debrief participants. The IRB expects that this person is a member of the research team, someone knowledgeable about the research and the deception. If the research is student directed (i.e., related to graduate studies, master’s thesis or doctoral dissertation), the IRB expects that the student researcher will debrief participants.

   (b) Specify **when** participants will be debriefed. Again, the IRB generally expects that participants will be immediately debriefed after they complete the study. Any delay in debriefing must be explained and justified.

   (c) Provide a rationale for any elements of the deception that will not be revealed to participants.

(5) At a minimum, the debriefing statement must include the following:
   (a) Label the form as “Debriefing Statement.”

   (b) Study title.

   (c) PI name and contact information for follow-up questions.

   (d) Student researcher’s name and contact information, if applicable, for follow-up questions.

   (e) Thank participants for taking the time to participate in the study.

   (f) Explain what was being studied (i.e., purpose, hypothesis, aim). Use lay terms and avoid use of jargon.

   (g) Explain how participants were deceived.

   (h) Explain why deception was necessary in order to carry out the research.
(i) Explain how the results of the deception will be evaluated.

(j) If the study involves use of audio or videotaping an individual participant, give the participant an opportunity to withdraw his/her consent for use of the tapes and, potentially, withdraw from the study all together, after the true purpose of the study is revealed. The IRB suggests that participants be given at least 48 hours to make this decision and provide contact information for whom participants should contact regarding their withdrawal from the study. This option must be given to participants even if they were video or audiotaped during a focus group or during an experiment involving other participants. If a participant decides to withdraw, the PI must use video editing tools to make an individual who withdraws unidentifiable. If tools are not available, the PI cannot use the video or audiotape.

(k) Consider adding the following, additional elements, to the debriefing statement:
   (i) Provide references/website for further reading on the topic.

   (ii) Emphasize that it was the not the gullibility of the participant but rather the skill of the experimenter that is responsible for the success of the deception (Sloan & Hull, 2006).

   (iii) If the study did not involve use of audio or videotaping but involves sensitive topics, it may be appropriate to give participants an opportunity to withdraw their consent to participate.

(6) In addition to the elements included in the debriefing statement, consider adding the following elements to the oral debriefing that takes place after the participant has completed the study:
   (a) Relate the research to something participants may have learned in class (methods or theory).

   (b) Explain anticipated or observed results so far.

   (c) Offer to provide them with the study results.

Debriefing as an Educational Tool
Finally, the IRB suggests that the debriefing also be used as an educational tool, even when the study does not involve use of deception. Participants should be given a simple, clear and informative explanation of the rationale for the design of the study and the methods used. Investigators should ask for and answer participant’s questions.
References


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