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Quick Reference Guide for Research Involving Deception or Incomplete Disclosure

Overview:
MedStar Health recognizes that deception and incomplete disclosure, especially in social and behavioral research, may be necessary to avoid study bias or to test a hypothesis that requires the participant's misdirection. On the other hand, the regulations for obtaining informed consent from research participants (§45 CFR 46.116), in general, require full disclosure of all elements relevant to the subject's participation in the research.

Proposed research involving deception or incomplete disclosure necessitates special considerations by the IRB. To determine when certain restrictions apply, the IRB will consider the extent to which the deception or incomplete disclosure, in any given study, interferes with the participant's right to and ability to give fully informed consent.

The purpose for the guidelines on the use of deception and incomplete disclosure is to provide researchers, ORI staff, and IRB committee members with a common understanding of the following:

- Definitions of deception and incomplete disclosure in research**;**
- When is deception or incomplete disclosure allowed;
- Points to consider when deception or incomplete disclosure may be used; and
- Debriefing participants when deception or incomplete disclosure is utilized.

What is Deception?
Deception is when researchers purposely mislead participants by providing them with overt mis-direction or false information about some aspect of the research, whether it is in the procedures or the purpose of the research. Examples include:

- Participants are told they are working with a group of other participants on a task, but in actuality, they are the only participant in the study. The other "participants" are actually research staff acting as participants.

What is Incomplete Disclosure?
Incomplete disclosure is when researchers withhold information about some aspect of the research, whether it is in the procedures or the purpose of the research. Examples include:

- Participants are informed about the purpose of the study in general terms that are true, but are not detailed enough to reveal the true objectives of the study

When is Deception or Incomplete Disclosure permitted?
Deception or incomplete disclosure will only be permitted when the researcher documents that an alteration of the usual informed consent requirements is justified under the criteria presented in the federal regulations at 45 CFR 46.116(f)(3). Specifically, the IRB must find and document that the following criteria have been satisfied:

1. The research involves no more than minimal risk to the subjects;
2. The research could not practicably be carried out without the requested waiver or 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 an identifiable format;
4. The waiver or 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.

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What does the IRB deliberate/take into consideration?
In keeping with federal regulations and ethical codes established, the IRB will consider the following points when reviewing research involving the use of deception or incomplete disclosure:

- The use of deception or incomplete disclosure must be justified in the protocol to show that the research cannot be performed in the absence of deception and the benefits of the research will sufficiently outweigh any risks that deception may create;
- Research participants cannot be deceived about significant aspects of the research that would affect their willingness to participate or that would cause them physical or emotional harm; and
- Deception or incomplete disclosure must be explained to participants (debriefed) as early as feasible. A debriefing should include a detailed description of the ways in which deception was used and why; when and by whom the debriefing will be administered should also be included

What is Debriefing?
Debriefing provides participants with a full explanation of the hypothesis being tested, the procedures used 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. Debriefing is an essential part of the consent process. Participants should be debriefed immediately following completion of the study.

Note there are times when debriefing may be inappropriate if debriefing regarding the deception may cause more harm to the participant than the deception itself. A request not to debrief participants is an exception to the general rule and will only be considered by the IRB with appropriate justification.

Debriefing participants when Deception or Incomplete Disclosure is utilized in research
In most cases, when an investigator uses deception or incomplete disclosure, participants would be debriefed at the end of the study. Participants should be given a simple, clear and informative explanation of the rationale for the use of deception and should have the opportunity to ask questions. The process to debrief participants should be explained in the protocol. The protocol should indicate how participants will be debriefed, who will debrief participants, where participants will be debriefed, and when participants will be debriefed. This person is usually a member of the research team who has knowledge about the research and the deception

Example Debriefing Process A debriefing form is read aloud to the participant once he or she has completed the study, and includes the following details:

1. Disclosure of the deceptive/incomplete disclosure aspect(s) of the study, and what the actual study objective was. (This should be presented in simple, clear lay terms, similar to the consent document. Extremely technical/detailed explanations of study hypothesis, intentions of each task, etc., are not typically required).
2. An explanation of the reasons for the deception/incomplete disclosure. (These reasons should also be clearly explained, in language that is sensitive to subjects' possible feelings of betrayal, discomfort, and/or embarrassment at having been deceived).
3. An opportunity for the subject to ask questions.
4. An opportunity for the subject to withdraw the provided data.

Online Debriefing: Some research requires a debriefing after participants have completed an online survey. The debriefing page usually comes immediately after the last question on the survey. Participants should also be given the option to withdraw their data at this point (now that they have been fully informed as to the intent and purpose of the study). If they agree to have their data used for the study then they should have an “I Agree” button to click. If they do not agree to have their data used in the study they should have an “I Do Not Agree” button to click. If someone does not agree to have their data used, their data must be removed from dataset and discarded. Please check with the online survey program you are using to ensure that these capabilities are allowed.