Grand Valley State University Institutional Review Board (IRB)

G-15: Guidance on the use of deception and incomplete disclosure in research

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Research studies sometime require investigators to deceive participants or to withhold specific study details from participants. While such procedures can be effective tools for conducting research, they also raise ethical concerns regarding subject autonomy and respect for persons, as well as regulatory issues regarding informed consent.

This guidance document is intended to help investigators differentiate between deception and incomplete disclosure, and understand what considerations need to be taken into account when using either of these techniques in their research.

Definitions and examples

Deception involves intentionally providing inaccurate or false information to participants. This may occur either as part of the consent process or within the study procedures themselves. Examples include:

- The participant is given a "cover story" that falsely describes the purpose of the study, but provides a feasible account of the researcher's objective.
- Study participants are told they will be playing a competitive game in which they will receive financial rewards based on performance, but instead the game is rigged and rewards are not based on performance.
- The study includes an investigator's "confederate," an individual who poses as a participant, but whose behavior in the study is actually part of the investigator's experimental design.

Incomplete disclosure involves withholding information about the study purpose and/or reason for the procedures during the consent process, in order to prevent biasing the results. Examples include:

• The participant is informed about the purpose of the study or a certain procedure in general terms that are true, but not detailed enough to reveal the researcher's main or specific objective.

- Study participants are asked to view a series of images but are not told that their memory will be tested.
- Study participants read and respond to short vignettes designed to prime particular responses. The participants are not informed that this is the purpose of the vignette. (Note the vignettes are not presented as truth or fact [which would be deception], but rather either as hypothetical information, or the veracity of the information is not discussed at all.)

Limitations of incomplete disclosure:

Incomplete disclosure does not extend to withholding information from subjects about what they will be asked to do. In this case, disclosure to participants is entirely absent, not merely incomplete. Studies involving this type of non-disclosure may be categorized as deception and/or may not be eligible for exempt review. Examples include:

- A consent form indicates the length of time required for the participant's involvement, but does not provide information about what the involvement entails.
- Studies that involve manipulating an individual's environment, without the participant prospectively agreeing to participate in the research.

Disclosed concealment involves withholding certain information about the study from participants in cases where subjects consent specifically to the lack of disclosure. Disclosed concealment is considered neither deception nor incomplete disclosure. Examples include:

• Participants enroll in a double-blind, placebo-controlled trial in which participants will have information regarding their assignment to a particular study arm withheld, but the participants are informed of the study arms during the consent process and are told during the consent process that their assignment will not be disclosed.

Deception in Exempt Research

- Protocols that involve **incomplete disclosure** are eligible for exemption, assuming they would otherwise be eligible.
- Protocols that involve **deception** are not eligible for exemption unless participants are informed, before they agree to participate, that the study involves deception. Examples of consent language to use for obtaining prospective agreement from the participant to utilize deception include:

- Due to the nature of the study, we are not able to disclose the purpose of this
 research at this time. However, we will hold a debriefing session to answer
 questions and tell you about the study after your participation.
- The full purpose of this research cannot be disclosed before you participate, but will be told to you at the end.
- The purpose of this research project is to examine [insert purpose]. We are not able to provide you with all of the details about the study at the beginning of the study, but we will provide you more information during/after your participation.

Additional Points to Consider

- Use of deception or incomplete disclosure must be justified by its impact on the potential scientific value to the research. Investigators should clearly state that the study involves deception and/or incomplete disclosure in the IRB application, and provide a justification for using these techniques.
- Deception or incomplete disclosure should only be used when no reasonably effective, alternative methods are available or feasible to achieve the goals of the research.
- Only study procedures that involve minimal risks (as determined by the IRB) can include deception or incomplete disclosure. The use of such techniques represents a deviation from the requirement that participants are fully informed about the nature of the research, and therefore requires a waiver or alteration of informed consent. Waivers/alterations of informed consent are only permitted in studies posing no greater than minimal risk.
- Investigators must debrief subjects at the conclusion of their participation unless an acceptable explanation for why the debriefing cannot practically be conducted is provided. The debriefing must include the rationale for the study design, the study purpose, and a description of the information that was false or incomplete.
- In studies where the deception involves a description of activities to participants, the description of the risks may not understate the actual risks.
- Whenever possible, subjects should be informed that the description of the study includes inaccurate or incomplete information, and that they will be provided with complete and accurate information when they have completed their study participation.

*This guidance was adapted with permission from Indiana University (https://research.iu.edu/compliance/human-subjects/guidance/deception.html).