Institutional Review Board
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Deception

Brief Overview of Deception

What is deception?	**What is NOT deception?**
Deception: an alteration of consent (45 CFR 46.116(f)) and includes omitting some, or altering some or all of the basic elements of informed consent. Deception includes: providing a completely false purpose of the research and/or providing false information about the procedures to be followed. *Required:* debriefing script; opportunity to withdraw data; apology	Deception does NOT include withholding an element of the purpose and/or presenting false/manipulated information during participation. *Recommended:* debriefing script; PI contact information for additional information

To decide whether deception is being used, determine whether all of the elements of informed consent at 45 CFR 46.116(b) and (c) are met. If they are, it is not deception.

What is deception?

Deception is intentionally providing inaccurate or false information to participants. Note that deception is not explicitly listed in the regulations. Deception is considered an alteration of consent (45 CFR 46.116(f)) and includes omitting some, or altering some or all of the basic elements of informed consent (45 CFR 46.116(b) and (c)), primarily the criteria at:

> 45 CFR 46.116(b)(1): A statement that the study involves research, **an explanation of the purposes of the research** and the expected duration of the subject's participation, **a description of the procedures to be followed**, and identification of any procedures that are experimental;

Most studies at UMD will include an accurate description of the duration and the procedures, but will omit information about the true purpose or provide false/manipulated information (see What is NOT deception? below). Most UMD studies involving deception will likely be related to providing a completely inaccurate explanation of the purposes of the research.

When is deception acceptable?

Deception should only be used when:

- The research is deemed minimal risk (per the IRB)
- There are no alternative methods that can yield scientifically valid results
- The deception does not deprive participants the opportunity to protect their own interests
- The missing information does not affect participants' ability to assess the risks related to participation
- The missing information would not have impacted a person's decision to participate had they had it before they agreed to participate

What is required for deception to be approved?

In order to waive or alter consent per 45 CFR 46.116(f)(3), the IRB must find and document that:

> (i) The research involves no more than minimal risk to the subjects;
> (ii) The research could not practicably be carried out without the requested waiver or alteration;
> (iii) 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;
> (iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
> (v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

When is debriefing not appropriate?

- If the debriefing would present greater harm to the participant than the deception itself
- Example: people were selected for participation in a study based on certain "negative" behaviors/characteristics, it may not be appropriate to include this component in the debriefing

How soon should debriefing happen?

- Ideally, it should happen immediately following participation
- There are some circumstances where an immediate debriefing may compromise study results
    - Example: if the study population is a group of students, they may tell others about it, compromising the scientific validity of the study
- In these instances, a *delayed debriefing* is acceptable, such as sending debriefing information to participants via email or SONA when the study has been completed
- Justification for *delayed debriefing* should be provided in the Initial Application Part 2 Section 7

What level of review is required?

- If a study does not fit into an exempt category, deception will need to undergo at least Expedited review
- Under Exempt 3 (45 CFR 46.104(d)(3)(iii)), only authorized deception is permissible.
    - Authorized deception involves including a statement in the consent form that participants will be unaware or misinformed about the nature or purposes of the research.
- Examples of authorized deception statements:
    - This research requires that the full purpose of the study not be explained to you before you participate. We will give you a full explanation when you have finished participating in the study/at the end of the study.
    - For scientific reasons, this consent information does not include a complete description of the research questions tested in this study. When you have completed the study, we will give you more information about the study and an opportunity to ask questions.

What might deception look like in a study?

False purpose

- Sometimes investigators provide a false purpose of the study to participants to avoid priming/biasing them
- This is different from incomplete disclosure in that in these instances, the purpose of the study is completely different from what the investigators are truly studying
- Participants are fully misled about the purpose as opposed to incomplete disclosure, where an element of the purpose/hypothesis is withheld but the purpose is still generally accurate
- This alters informed consent criteria at 45 CFR 46.116(b)(1) which states that participants will be provided with an explanation of the purposes of the research, since the purpose will be false

Example

Purpose provided to participants	**Purpose of study**
The purpose of the study is to understand how age impacts pattern recognition	The purpose of the study is to understand the impact of anxiety on ability to multitask

False/withholding information about procedures

- Investigators may provide false information or withhold information about what will happen during the study through the informed consent process (this will be rare at UMD)
- This alters informed consent criteria at 45 CFR 46.116(b)(1) which states that participants will be provided with a description of the procedures to be followed

Example

Procedures provided to participants	**Procedures in the study**
In a study on the impact of anxiety on ability to multitask, participants will be asked to switch between solving math problems and verbally providing phone numbers from a	No painful procedures are administered in the study

phone book, and informed that they may receive mild pain while in the process	

What to include in a study with deception

Initial Application Part 2 Section 7

- Investigators should state that there is deception in the study, describe how participants are deceived, and why it is necessary to conduct the study
- Investigators also need to address the criteria required for an alteration of consent:
    - The research involves no more than minimal risk to the subjects;
    - The research could not practicably be carried out without the requested waiver or alteration;
    - 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;
    - The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
    - Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.
- Investigators need to describe the debriefing process per the last criteria, including:
    - When and how participants will be debriefed, and
    - Whether they will be presented with the option to withdraw their data after being fully informed

Debriefing

- Participants should be debriefed in most studies that include deception (see When is debriefing not appropriate? for guidance).
- The debriefing statement should include the following:
    (1) an acknowledgement that participants were deceived
    (2) an apology for the deception
    (3) state the reason for the deception
    (4) provide an explanation of how the deception occurred (false purpose of the research, false information about procedures)
    (5) give participants an opportunity to withdraw their data from the research should they choose to do so. In a survey with deception (particularly an anonymous survey), investigators may want to include the debriefing statement as the last item in the survey and give participants the option to proceed with having their data used for research or withdraw their data from analysis.

What is NOT deception?

Presenting false/manipulated materials

- Investigators may use some materials they have manipulated or created in order to elicit certain responses from participants

- This would not be considered deception as long as the study includes all of the basic elements of informed consent, including informing participants through the consent form about the purpose of the research and the procedures to be followed, per 45 CFR 46.116(b)(1)

Example

Information given to participants	**What was false/manipulated**
In a study on the impact of anxiety on ability to multitask, participants are told that 95% of people are able to switch between the given tasks without making any errors	95% of people are ***not*** able to switch between the given tasks without making any errors

What to include in a study that employs some false/manipulated information

Initial Application Part 2 Section 7

Investigators should state whether participants will receive any information after participating informing them that the materials they saw were created/altered by the investigators. This is recommended as a risk minimization strategy, particularly if the information might be harmful (e.g. related to vaccines causing autism).

Debriefing

No traditional debriefing required, but as a recommended way to mitigate risks, investigators should provide a post-participation information document that "corrects the record" stating that the true purpose of the research was not altered, describes what was created/altered by the researchers, and provides the PI's contact information for any further questions.

Withholding an element of the true purpose (incomplete disclosure)

- Sometimes investigators need to withhold an element of the study purpose or reason for the procedures in order to prevent biasing the result
- This would not be considered deception as long as the study includes all of the basic elements of informed consent, including being informed about the purpose of the research, even if the purpose of the research is slightly altered (e.g. one element is withheld so investigators do not reveal their specific hypothesis)
- It is not considered deception as long as they have an accurate (albeit incomplete) description of the purpose

Example

Purpose provided to participants	**Purpose of study**
The purpose of the study is to understand how different conditions impact ability to multitask	The purpose of the study is to understand the impact of anxiety on ability to multitask

What to include in a study that includes withholding an element of the true purpose:

Initial Application Part 2 Section 7

Investigators should state why participants are not informed of the missing element (e.g. priming).

Debriefing

None. Investigators may choose to inform participants or not inform them of the hypothesis after their participation.

Both withholding an element of the true purpose and using false/manipulated materials

- Investigators may also use the strategies above in conjunction
- These elements combined do not necessarily mean that the study includes deception, as long as the study includes all of the basic elements of informed consent at 45 CFR 46.116(b), including being informed about the purpose of the research and the procedures to be followed, per 45 CFR 46.116(b)(1)
- As long as the purpose of the research is accurate, even if it is slightly incomplete, this would not be considered deception

Example

Purpose provided to participants	**Purpose of study**	**Information given to participants**	**What was false/manipulated**
The purpose of the study is to understand how different conditions impact ability to multitask	The purpose of the study is to understand the impact of anxiety on ability to multitask	In a study on the impact of anxiety on ability to multitask, participants are told that 95% of people are able to switch between the given tasks without making any errors	95% of people are ***not*** able to switch between the given tasks without making any errors

What to include in a study that both withholds an element of the true purpose and uses false/manipulated information

See above under What to include in a study that employs some false/manipulated information.