Office of the Vice President for Research at the university of georgia ®

Deception and Incomplete Disclosure in Human Research

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Learning Objectives

- Define Deception and Incomplete Disclosure
- Understand when Deception or Incomplete Disclosure are allowable in human research
- Review APA recommendations

Deception/Incomplete Disclosure

Deception is intentionally misleading prospective participants about the research.

Incomplete Disclosure is not giving participants accurate or adequate information about some aspect of the research.

Both Deception and Incomplete Disclosure interfere with a participant's ability to provide legally effective informed consent.

Use of Deception in Research

- Often necessary to study human behavior.
- *In general, the IRB must consider*:
  - Is the use of deception scientifically and ethically justified?
  - Would the information being withheld from the subjects influence their decision to participate in the research?
  - Is it permissible to alter and/or the exclude a required element of informed consent?
  - Is it appropriate to debrief participants?

Required Elements of Informed Consent

- A statement that the study involves research.
- **An explanation of the purposes of the research.**
- **A description of the procedures to be followed.**
- A description of any reasonably foreseeable risks or discomforts to the subject.
- A description of any benefits to the subject or to others which may reasonably be expected from the research.

Required Elements of Informed Consent

- A description of appropriate alternative procedures.
- A statement describing the extent, if any, to which confidentiality of records will be maintained.
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights.
- A statement that participation is voluntary.

Example

- An investigator wants to examine the importance of slow breathing during a single yoga on conditioned pain modulation responses in young adult women.
- The primary aims of the study are to test the interaction of yoga and slow breathing on conditioned pain modulation, a central nervous system response to the presentation of two standardized noxious stimuli

- Incomplete disclosure will be made about both the study design and the primary outcome. The participants will not be told that the study is designed to examine the effects of slow breathing during yoga. The participants also will not be told that the primary outcome is whether acute yoga influences pain intensity rating in response to standardized noxious stimuli.
- Full knowledge of the study design could influence the outcomes. For example, if a participant read that the study title was the effects of breathing rate during yoga on pain intensity then she might try to control her breathing during yoga in the condition that does not involve slow/controlled breathing. Or she might try to “help” us by rating a noxious stimulus as less painful after yoga in which slow breathing was emphasized.

Alteration of the Elements of Informed Consent

An IRB may approve a consent procedure *which does not include, or which alters, some or all of the elements of informed consent*, or waive the requirements to obtain informed consent provided the *IRB* finds and documents that:

- the research involves no more than minimal risk to the subjects;
- the waiver or alteration will not adversely affect the rights and welfare of the subjects;
- the research could not practicably be carried out without the waiver or alteration; and
- whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Debriefing

- Provide a prompt opportunity for participants to obtain appropriate information about the nature, results, and conclusions of the research, and take reasonable steps to correct any misconceptions that participants may have.

- Participants have the right to withdraw from the study during debriefing.

Thank you

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