	University of North Carolina Wilmington Institutional Review Board	Standard Operating Procedure
	Use of Deception in Human Subjects Research	#6.6

The purpose of this SOP is to define different types of deception and clarify the procedures researchers must follow when using deception or incomplete disclosure in human subjects research.

I. General Information

The UNCW IRB recognizes that the use of deception and/or incomplete disclosure as a methodology in human subjects research can be necessary to avoid study bias, particularly in human behavior studies, when a subject would be likely to alter his or her behavior if informed that the behavior is being studied. However, the use of deception and/or incomplete disclosure raises ethical concerns as it may interfere with the ability of a potential subject to give informed consent. The main consideration for IRBs in evaluating studies that involve the use of deception and/or incomplete disclosure is whether the committee has a reasonable expectation that subjects would still consent to participate in the study after the investigator informs them of the study methods that include deception and/or incomplete disclosure.

II. Scope

This SOP pertains to all human subjects research conducted by UNCW investigators, including faculty, staff and student investigators.

III. Applicable Definitions

A. Deception

Deception, as it applies to this SOP, is a research methodology that occurs when an investigator knowingly gives false information to research subjects or intentionally misleads them about some key aspect of the research. The false or misleading information might relate to the purpose of the research, the role of the researcher or other participants, the true nature of the procedures to be followed, or other aspects of the study.

Examples of deception include, but are not limited to, providing subjects with a false description of the purpose of the study, telling a subject he or she performed poorly on a quiz or game regardless of the subject's actual performance, and the use of a "confederate" who poses as a research participant but is a member of the research team whose behavior is part of the experimental design.

B. Incomplete Disclosure

Incomplete disclosure, as it applies to this SOP, is a research methodology that occurs when an investigator withholds information about the specific purpose, nature or other aspect of the study.

An example of incomplete disclosure is an investigator instructing a subject to take a survey for research purposes, but the true research question pertains to how well subjects concentrate when there is background noise.

IV. Procedures

A. Level of Review
   1. When a human subjects study involves the use of deception, it may not be reviewed at the exempt level, even if all other aspects of the study qualify for an exemption.
   2. Studies that involve a form of deception that is designed to intentionally invoke feelings of aggression, stress, anger, rejection or other negative response must always be reviewed by the full board.
   3. Studies involving more benign forms of deception that otherwise qualify for expedited review may be reviewed at the expedited level.
   4. IRB chairs always have discretion to place a study on the full board agenda if they are not comfortable reviewing it at an expedited level.

B. Justification
   1. The principal investigator (PI) must explain in detail in the IRB application the nature of the deception/incomplete disclosure
   2. The PI must justify why this methodology is necessary to achieve the goals of the study.

C. Informed Consent Procedures
   1. Purpose of Informed Consent
      The purpose of the informed consent process is to:
      a. provide subjects with pertinent information about certain aspects of the study so that they can decide if they want to participate in the research or not;
      b. to ensure that subjects understand the information provided, and;
      c. to document that subjects voluntarily agree to participate.

   2. False or Misleading Information Prohibited
      There are circumstances when it is necessary for the PI of a study to either vaguely describe or omit pertinent information about the research in order to avoid bias or altered behavior during participation. While it is acceptable for a PI to provide vague information about study activities on the consent form, the PI may not include false or misleading information about any aspect of the study. Specifically, the PI must fully explain study risks.

   3. Waiver of Consent

When it is necessary for the PI to omit one or more required elements of informed consent (consistent with UNCW IRB policy 03.380 section VI.C.5.), the PI must request approval for a full or partial waiver of consent. The IRB must determine if the request for a waiver meets the criteria set forth in the regulations as applicable.

D. Debriefing Procedures
   1. Preferably, debriefing occurs when an individual subject completes his or her participation in a research study.
   2. Delayed debriefing, for example, debriefing at the completion of the study, may be permitted if standard debriefing would compromise study results.

V. References to Other Applicable SOPs

SOP Title	SOP #
Expedited Review of Research	5.2
Full Board Review of Research	5.3
Informed Consent	6.8

VI. Responsibilities

Title	Responsibility
IRB Co-chair	Responsible for determining the review level of IRB submissions involving the use of deception and/or incomplete disclosure.
IRB Staff	Responsible for interpreting federal regulations, UNCW policies, and Research Integrity SOPs and providing guidance to PIs on requirements.
Principal Investigator	Responsible for fully justifying any use of deception and/or incomplete disclosure and for submitting debriefing scripts, as applicable.

VII. Resources

A. UNCW IRB Website: http://uncw.edu/sparc/integrity/irb.html
B. U.S. Department of Health & Human Services, Office of Human Research Protections website: https://www.hhs.gov/ohrp/
C. 45 CFR 46 ("Common Rule"): https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html
D. Belmont Report: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html