Guidance for Deception and Incomplete Disclosure

According to the Common Rule (45CFR46.104.3.iii) research involving deception or incomplete disclosure of the true purpose of a study may only be exempt (i.e., qualify for accelerated review) if the participant provides prospective informed consent to being misled or deceived. However, the common rule does not provide specific guidance about the review of studies involving incomplete disclosure or deception when prospective consent has not been obtained. This document provides: (1) definitions of the key terms related to deception and incomplete disclosure, (2) discusses the review mechanisms for studies involving deception/incomplete disclosure, (3) summarizes the common rule requirements regarding informed consent for research involving deception or incomplete disclosure, and (4) offers guidance on how to obtain prospective informed consent should the PI wish to have their study qualify for accelerated review.

Definitions of Key Terms

Deception involves misleading participants about one or more aspect of the study. For example, deception might involve telling participants that they will be rating the flavor of different alcohol beverages when in fact the PI is interested in how much of the beverage participants are consuming.

Incomplete Disclosure involves withholding information about certain aspects of a study. In this case, the participant is not fully informed about the full purpose of the study. For example, incomplete disclosure might involve telling participants that you are interested in attitudes toward a variety of controversial topics when in fact you are interested in studying attitudes toward a specific topic (e.g., drug addiction).

Benign Behavioral Intervention refers to experimental manipulations or procedures that are brief, harmless, painless, not physically invasive, and not likely to have significant or lasting adverse impacts on the participant. In this definition, harmless means that the study will not negatively impact the participant physically, psychologically, or emotionally and is not expected to cause offense or embarrassment. It is important to note that the term "intervention" is misleading. Rather than referring to a therapeutic intervention exclusively, the term is meant to be interpreted more broadly as referring to any experimental manipulation or procedure that is intended to influence a participant's attitudes, beliefs or behaviors.

Categories of Review for Studies Involving Deception/Incomplete Disclosure

Regardless of the review category, approval for studies involving deception/incomplete disclosure depends on the IRB's determination that (1) the deception/incomplete disclosure is justified and (2) the risk/benefit ratio is favorable (i.e., the risks are outweighed or justified by the anticipated benefits). Thus, the PI has the responsibility to explain clearly and in detail in their application why withholding information from or deceiving participants is necessary to meet the study aims. Moreover, the PI must clearly outline the steps they will take to mitigate any risks associated with <u>all</u> study procedures, <u>including</u> the need to deceive/mislead participants.

Approval via Accelerated Review. Studies involving deception or incomplete disclosure can only be approved via accelerated review IF the PI obtains prospective informed consent from participants to take part in a study in which they will be misled or deceived about its true purpose. In addition, the

study must: (1) involve no more than minimal risk; (2) any behavioral interventions must meet the criteria for benign.

The decision whether to obtain prospective consent from participants depends on the extent to which the PI believes that informing participants that they may be deceived or misled about the purpose of the study will:

1. negatively impact the study's integrity thereby compromising its internal validity and /or
2. reduce the likelihood that participants will consent to participate in the study thereby compromising its external validity.

For additional guidance on getting studies involving deception/incomplete disclosure approved via the accelerated route, see "**Obtaining Prospective Consent for Deception and Incomplete Disclosure,"** below.

Approval via Standard or Full Board Review. PI's not wanting to obtain prospective informed consent can still have their study reviewed, and potentially approved, by the IRB either via standard review (for minimal risk studies) or full board review (for more than minimal risk studies).

Informed Consent Requirements for Studies Involving Deception or Incomplete Disclosure

Consistent with the principle of Respect for Persons, the purpose of informed consent is to inform participants about the risks, benefits, and procedures of the study so that they may make fully informed decisions about whether to participate. As such, studies involving deception or incomplete disclosure require IRB approval of an alteration or waiver of the informed consent process because they involve withholding information from participants that might influence their decision regarding participation. The Common Rule states that waivers or alterations of informed consent can be approved by IRBs under the following circumstances:

- The research involves no more than minimal risk;
- The waiver or alteration of informed consent will not adversely affect the rights and welfare of participants;
- The research could not reasonably be carried out without the waiver or alteration; and
- Participants are provided with additional information about the study after their participation (i.e., fully debriefed).

Factors to Consider when Requesting Approval for an Alteration to Informed Consent to Permit Deception/Incomplete Disclosure

Debriefing. If an alteration or waiver of informed consent is approved to permit deception or incomplete disclosure, then the PI is responsible for ensuring that participants are properly debriefed after their participation. The debriefing form should include the following information:

- an explanation about the true or full purpose of the study as well as why deception or incomplete disclosure was necessary;
- how participants were deceived;
- contact information for the PI should they have any questions about the study;

- contact information for the IRB should they have questions about their rights as a research participant; and
- a list of resources to contact should they feel upset as a result of the study or for any reason.

Ideally, debriefing will occur immediately after the participant completes their participation. However, in the event that the PI has concerns that the integrity of the study will be compromised if debriefing occurs immediately, then they can request permission to delay debriefing until all data collection has been completed.

***Requirements for Delayed Debriefing*.** The PI must provide adequate justification that the integrity of the research can only be maintained if debriefing is delayed. If the IRB agrees that this is the case, the PI must also recognize that the study cannot be anonymous because a list of names and contact information for participants will need to be maintained so that a debriefing statement can be sent out. Moreover, the PI will have to describe the steps they will take to ensure participants' confidentiality given the need to maintain their contact information. *It is important to note that delayed debriefing may preclude the study from being reviewed via the accelerated review process*.

Obtaining Prospective Consent for Deception and Incomplete Disclosure

Any PI who wants accelerated review and approval for a study involving deception or incomplete disclosure must follow the guidance above as well as include the language below in their consent form.

In the Study Procedures section, please include the following language:

"Sometimes, researchers are required to withhold some or all information about the true purpose of a research study from potential participants. If you are not fully informed about the true or full purpose of the study in which you participated, the researchers are obligated to provide you with an explanation about the true or full purpose of the study after [your participation] [data collection is completed]. By signing this consent form, you are indicating that you are consenting to participate in this research study even if there is a possibility that you were not informed about its true or full purpose."

**Please note that PI's should use "your participation" if debriefing will occur immediately or "data collection is completed" if debriefing will be delayed.

In the Disclosures Section, immediately before the signature line, add the following statement:

"I understand that I may not have been fully informed about the true purpose of the study and if this is the case I will be fully informed at some time after my participation."