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.

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.

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).

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.

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

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.

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.

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