GUIDELINE # 15: DECEPTION AND INCOMPLETE DISCLOSURE

I. PURPOSE

This guideline is to ensure that human subjects' research conducted complies with federal, state, and local laws, regulations, directives, and instructions. This guideline provides institutional guidance when investigators determine using deception techniques in human subjects research.

II. STATEMENT

All human subjects research, irrespective of the source of funding, conducted by A&M- SA faculty, staff, and students must be submitted and reviewed in accordance with the Federal research regulations, Texas A&M System Guidelines, A&M-San Antonio (A&M-SA) Institutional Review Board (IRB) policies and local consideration.

The Texas A&M System Guidelines, A&M-San Antonio (A&M-SA) Institutional Review Board (IRB) recognizes the use of deception techniques or incomplete disclosure as an effective tool in certain circumstances conducting human subject related research in compliance with the Federal Regulation [45 CFR 46.104(3, Ciii)].

The A&M-San Antonio (A&M-SA) Institutional Review Board (IRB) recognizes that deception occurs when investigators intentionally deliver inaccurate or false information to research participants.

The A&M-San Antonio (A&M-SA) Institutional Review Board (IRB) recognizes that incomplete disclosure occurs when investigators withhold information about the true study purpose and/or reason to prevent bias in the results.

III. SCOPE

This guideline applies to all research conducted where the A&M-SA IRB serves as the Reviewing IRB.

IV. PROCEDURE

In this guideline, "investigator" means a principal investigator or an individual authorized by the principal investigator and approved by the IRB to obtain consent for the specific protocol, such as a principal investigator, co-principal investigator, additional investigator and or key study personnel.

For applications containing the element of deception or incomplete disclosure to be subject to approval by the A&M-San Antonio (A&M-SA) Institutional Review Board (whether Exempt, Expedited, or Full Review), investigators are discouraged from submitting protocols under the following scenarios:

- The research involves more than minimal risk (this does not include placebo-controlled trials, where the placebo is the only deception).
- Non-deceptive alternatives are available.
- The research intends to trick individuals into participating in something that they would not otherwise want to participate in.
- The research is expected to cause physical pain or severe emotional distress.
- The research places participants in a position of engaging in illegal or stigmatized behavior because of the deception.
- The research places participants at significant financial, physical, legal, psychological, or social risk.
- The participant is not provided with the opportunity to withdraw their participation (and their data) at the completion of the study when the deception is revealed; and/or
- The U.S. Food and Drug Administration regulates the research.

The investigators have the responsibility when conducting research that involves deception or incomplete disclosures to submit an application for review and approval by the IRB prior to implementing any human subjects research activities. The IRB protocol must provide the scientific justification for deceiving or withholding information from participants, provide an explanation of why the research could not practically be carried out without the use of deception or incomplete disclosure, and a description of the debriefing process. This justification may not include that it would be inconvenient to conduct the study without the use of deceptive techniques. Information about when, how and who will conduct the required debriefing process must also be included. When appropriate, the researcher should include additional resources in the debriefing script. Lastly, if the deception is expected to elicit a strong emotional response, study personnel should be trained on how to help diffuse or minimize participants' response with respect and dignity.

An effective way to ensure participants' autonomy in research involving deceptive or incomplete disclosure techniques is through the practice of authorized deception, which involves disclosing the possibility of these during the consent process. In this approach, participants are informed before the research begins that certain aspects of the study may be inaccurately described or that deceptive procedures may be used. This allows participants to decide whether they are willing to participate, knowing that not all details of the research will be fully disclosed.

If researchers are concerned that authorized deception may influence participants' responses, they can instead employ a debriefing protocol. Debriefing, which the A&M-SA IRB expects must be conducted at the conclusion of any study involving deception or incomplete disclosure, provides participants with a clear and simple explanation of the research’s purpose and methods. It also includes relevant resources. The depth and content of the debriefing should correspond to the specifics and risks associated with the study.

V. REVISIONS

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