IRB Policy 37: Research Involving Deception
Creation Date April 4, 2008, revised October 15, 2015, revised April 4, 2018, revised Feb 7, 2019

I. Summary Policy

It is the policy of both the East Tennessee State University Campus Institutional Review Board (ETSU IRB) and the East Tennessee State University/ Veterans Affairs Institutional Review Board (ETSU/VA IRB) that the basic principles outlined in the Belmont Report (respect for participants, beneficence, and justice) guide the ethical conduct of research. When investigators plan to withhold information or provide participants false information about some aspect of the research, the proposed use of deception imposes additional responsibilities on the investigator and the IRB.

II. Requirements

The federal regulations do not allow the IRB to approve a study involving deception if that study does not meet the criteria for granting a waiver or alteration of the requirement for informed consent. For studies subject to the 2018 Common Rule, deception research is allowed under exempt category 3 if specific requirements are met. Refer to Exempt Policy 7 for those requirements.

Those criteria are:

1. The research involves no more than minimal risk to the subjects. (Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Note that the definition of minimal risk for prisoner at 45 CFR 46.303(d) differs from the definition of minimal risk for other research- see Policy 15)
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects.
3. The research could not practicably be carried out without the waiver or alteration.
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation. (Source: 45 CFR 46.116(d))
5. The research is not FDA-regulated.
6. For studies subject to the 2018 Common Rule, "If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format"

In addition, the IRB requires that studies involving deception meet the following criteria:

1. Information to be withheld would not influence the decision of prospective subjects about participating in the research. (Source: OHRP IRB Guidebook, Chapter III, Section B)
2. Incomplete disclosure is truly necessary to accomplish the goals of the research. (Source: Belmont Report, April 18, 1979)
3. Investigator's plan regarding debriefing is appropriate. (Source: OHRP Guidebook, Chapter V, Section A, Behavioral Research)
4. The proposed subject population is suitable. (Source: OHRP Guidebook, Chapter V, Section A, Behavioral Research)
5. The use of deception in this research is justified by the study's significant prospective scientific, educational, or applied value. (Source: APA Ethical Principles of Psychologists and Code of Conduct)

III. Responsibilities

A. IRB Administration Responsibilities

1. The IRB Coordinator will verify that a Supplemental Form for Deception xform section is included in any deception study submission.

B. Principal Investigator Responsibilities

1. The PI will complete the Submission Form for Deception xform section and submit in his/her xform.

B. IRB Committee Responsibilities

1. Assigned Primary Reviewers or Expedited Reviewers complete the Deception section of the Reviewer xForm for studies Involving Deception.