SOP 1.3.8 **Deception Research**

General Description:

Federal regulations permit but establish limitations on the use of deception in research. Deception can include, but is not limited to, intentionally misleading participants about their role as a research participant, providing the participant with false information about the researchers or the purpose of the research, or omitting information about the true purpose of the research. The Investigator must provide scientific and ethical justification to the IRB for deceptive procedures used during the course of the research project. The deception should not increase the risks of the study, and subjects should be fully debriefed and have the opportunity to ask questions about the new information in most cases. When appropriate, they should be given the opportunity to withdraw from the study and have their data removed.

Use of Deception during the Consent Process
Since voluntary informed consent cannot truly occur if the participant is not told that they will be deceived, justification must be provided for procedures necessitating deception. Also participants should be fully informed at the conclusion of the activities in most cases.

Deception research should include a request from the researcher to waive certain elements of informed consent, which can be documented in addendum F of the IRB application. According to the federal regulations, the IRB may approve a consent procedure which does not include or which alters some or all of the elements of informed consent if it finds and documents that:

(1) The research involves no more than minimal risk to the subjects;
(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; and
(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
(5) The research is not FDA-regulated.

The IRB cannot approve research involving deception if it entails more than minimal risk and withholds information that is essential to the subject's decision to participate in the study**.** The IRB should consider whether the withheld information would influence the decision of potential subjects to participate in the research.

Debriefing

A debriefing procedure should be utilized for research involving deceptive practices in most cases. Debriefing ensures that participants are informed of all deceptive elements of a study and understand the need for deception in the research. The debriefing provides participants with a full explanation of the hypothesis being tested, procedures to deceive participants and the reason(s) why it was necessary to deceive them. It should also include other relevant background information pertaining to the study. The IRB should receive a debriefing script or statement that describes the information subjects will receive regarding the deception and their participation in the research. If the researcher feels that a debriefing of participants is not appropriate for his/her research, justification for that request must be included in Addendum F of the application and the request will be considered by the IRB.

Withdrawal of Data

The American Psychological Association's Ethical Principles of Psychologists and Code of Conduct, standard 8.07, requires that "Psychologists explain any deception that is an integral feature of the design and conduct of an experiment to participants as early as is feasible, preferably at the conclusion of their participation, but no later than at the conclusion of the data collection, and permit participants to withdraw their data." When feasible, all investigators should follow this standard. If the offer to withdraw data is not appropriate for a proposed study, the investigator should explain why in the application.

Procedures:

1. **Submission to the IRB through IRBNet.** Along with a fully completed protocol application, the IRB must receive a completed Addendum F on Deception. The addendum must include a justification of the deception and plan for debriefing. Additionally, the IRB should review all debriefing information in the form of scripts or statements that will be read to subjects.

2. **IRB Review.** In cases where the researcher wishes to withhold or partially disclose pertinent information or deceive participants, the IRB must receive and review the following information as either part of the IRB application or part of the deception Addendum:
    a. Request for a waiver or alteration of consent
    b. Description of the nature of the information to be withheld
    c. Plan and script for debriefing participants
    d. Procedures or limitations on withdrawal of subject's data.
    e. Who will debrief subjects
    f. When participants will be debriefed

3. **Filing.** All determinations will be kept on file per standard procedures.

Related Forms, Guidance, and SOPs:

- Waiver of Consent; 45 CFR 46.116(f)
- FDA; 21 CFR 50.20
- Based on University of Alabama Guidance on Use of Deception/Concealment in Research

Responsibility:

Execution of SOP:
Principal Investigator
Study Team Members
IRB Staff
Institutional Review Board

Approval and Version History:

Please contact irb@gmu.edu if you have any questions about this policy or the version and approval history.

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Approved By	Title and Division	Date Approved
Aurali Dade	Associate Vice President, Research Development, Integrity and Assurance	March 22, 2016
Greg Guagnano	IRB Chairperson	March 22, 2016