



Number:	Date:	Author:	Approved By:	Page(s):
UGAHRP-097-1	09/16/2016	HSO	IRB	Page 1 of 5

1. PURPOSE

- 1.1. The University of Georgia Institutional Review Board (UGA IRB) recognizes that the use of deception and incomplete disclosure may be necessary in some **human subjects research**. While these are accepted research techniques, their use raise ethical concerns because they primarily interfere with the ability of the potential participant to give **informed consent**. This **policy** describes the responsibilities of the **investigator** and special considerations when the IRB reviews research involving deception or incomplete disclosure.

2. DEFINITIONS

- 2.1. **Deception**: the intentional misleading of research participants by providing false or misleading information about some aspects of the research. False or misleading information might relate to the purpose of the research, the role of the researcher or other participants, the true nature of the procedures to be followed, or other parts of the study.
- 2.2. **Incomplete Disclosure**: occurs when investigators withhold information to participants about some aspects of the research (typically, about the real purpose or nature of the study).

3. POLICY

- 3.1. The use of deception/incomplete disclosure must be justified in the IRB submission to show that the research cannot be performed in its absence.
- 3.2. The research participants cannot be deceived about significant aspects of the research that would affect their willingness to participate.
- 3.3. These techniques cannot be used to entice or lure a **human subject** to participate.
- 3.4. The research participants cannot be deceived or not be fully informed about aspects of the research that are anticipated to cause physical or emotional harm, or which pose greater than **minimal risk** to the participants.
- 3.5. The benefits of the research will sufficiently outweigh any risks that deception or incomplete disclosure may create.
- 3.6. For non-exempt studies, deception/incomplete disclosure will be explained to participants (through debriefing) as early as feasible unless a waiver or delayed debriefing is justified.
- 3.7. For **exempt studies** regardless of funding and funding source, debriefing will not be required.
- 3.8. A truly "informed consent" cannot be given if there is deception/incomplete disclosure so a waiver of or alteration of some informed consent elements must be approved by the IRB.
- 3.9. Human research using deception or incomplete disclosure regarding the nature or purpose of the research is eligible for exempt determination if it meets the exempt criteria and only if the subject authorizes the deception or incomplete disclosure. Authorized deception or incomplete disclosure would be the prospective agreement by the subject to participate in



Number:	Date:	Author:	Approved By:	Page(s):
UGAHRP-097-0	09/16/2016	HSO	IRB	Page 2 of 5

research where the subject (or subject’s **legally authorized representative**) is informed that he or she will be unaware of (or misled) regarding the nature or purpose of the research. See *Policy and Procedure: Exempt Review*.

4. PROCEDURES: Researchers

4.1. IRB Submission

- 4.1.1. Describe in detail the deception/incomplete disclosure, and provide a scientific justification for why this is necessary to achieve the goals of the study (i.e., how it relates to the study aims and study design). Including if alternative methods not involving use of deception/incomplete disclosure were considered and why these methods are not applicable will be helpful.
- 4.1.2. Explain the procedure to debrief participants (i.e., when and how participants will be debriefed). A debriefing form or script that will be given or read to participants will be submitted with the IRB application. See below for additional information.
- 4.1.3. Any description of risks/discomforts should address the use of deception/incomplete disclosure and if this is anticipated to cause any additional or increased physical, psychological, social, or economic harm to the participants (e.g., psychological distress, loss of self-esteem, embarrassment). Explain how any risks/discomforts will be mitigated during the experiment and after the experiment is complete (e.g., through debriefing).

4.2. Informed Consent Requirements

- 4.2.1. When investigators plan to withhold information or give subjects false information about some aspects of the research, the subject's consent may not be fully informed. For non-exempt research, the IRB must then approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent based on the following [45 CFR 46.116(d)]:
 - 4.2.1.1. The research involves no more than minimal risk to the subjects;
 - 4.2.1.2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
 - 4.2.1.3. The research could not practicably be carried out without the waiver or alteration; and,
 - 4.2.1.4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation. This requirement is met via a debriefing process (see Section 4.4).
- 4.2.2. Investigators may be vague or omit information in the consent process in order to maintain the deception or incomplete disclosure necessary for the study.
 - 4.2.2.1. For non-exempt research, the following or a similar statement will be



Number:	Date:	Author:	Approved By:	Page(s):
UGAHRP-097-0	09/16/2016	HSO	IRB	Page 3 of 5

included in the consent document(s): “In order to make this study a valid one, some information about [your participation or the study] will be withheld until completion of the study.”

4.2.2.2. For exempt research, the following or a similar statement will be included in the consent document(s): “In order to make this study a valid one, you will [not be made fully aware of or be misled about] the nature or purpose of the study.

4.3. Debriefing Requirements

4.3.1. The researcher is responsible for ensuring that the subject leaves the research setting with an accurate understanding of the deception/incomplete disclosure and why it was necessary (unless a waiver or delayed debriefing has been approved by the IRB). This is accomplished through a debriefing process where:

4.3.1.1. The debriefing is conducted as soon as practical after the subject’s participation.

4.3.1.2. Participants have the opportunity to ask questions and to withdraw from the study and/or have data that can be identified as theirs removed after the debriefing.

4.3.1.3. If an investigator becomes aware during the debriefing that research procedures have caused harm to a participant, the investigator will take reasonable steps to ameliorate the harm and report the event to the IRB. Report is submitted via Click IRB’s Report New Information form.

4.3.1.4. Investigators describe the process in a Debriefing Form or Script that is submitted with the IRB application. See [Template for the Debriefing Form or Script](#).

4.3.2. There are certain circumstances under which the investigators may request a *waiver of the debriefing requirement*.

4.3.2.1. The IRB may waive the requirement for debriefing if the investigators can provide a rationale for this request.

4.3.2.2. Examples of circumstances in which debriefing may not be appropriate include:

4.3.2.2.1. When the debriefing may cause more harm than the deception/incomplete disclosure itself.

4.3.2.2.2. When study involves a specialized or unique population and the debriefing may make it impracticable to conduct future research that targets the same population.

4.3.3. There are certain circumstances under which the investigators may request a delayed debriefing.

4.3.3.1. The IRB may approve a delayed debriefing if the investigators can provide a rationale, the timing for subsequent debriefing, and submit the Debriefing Form or Script.

4.3.3.2. Example of a circumstance in which delayed debriefing may be appropriate: If a



Number:	Date:	Author:	Approved By:	Page(s):
UGAHRP-097-0	09/16/2016	HSO	IRB	Page 4 of 5

study requiring debriefing will run over several days or weeks, subjects who have completed the study might tell others about it. If they have been debriefed and thus know the aspects of the research that involved deception or incomplete disclosure, they might share that information with prospective subjects, thus compromising the scientific validity of the study.

4.3.3.3. There are several strategies to provide subjects with a delayed debriefing. If names, e-mail addresses, and or addresses are collected as part of the study, debriefing information can be sent via e-mail or mail when the study is complete. Options include:

4.3.3.3.1. Give subjects a URL where they can get debriefing information after a particular date upon which the information will be available.

4.3.3.3.2. Have each participant address an envelope to self before leaving the study session and send the debriefing information when the study is completed.

4.4. FDA Regulations and Placebos

4.4.1.A study subject to FDA regulations cannot be conducted with deception or incomplete disclosure because the required waivers of consent can only be granted under limited conditions involving emergency, life threatening situations for participants under 21 CFR 50.23.

4.4.2.However, placebo use during the course of a clinical investigation (e.g., in the control arm of a randomized clinical trial) is not considered deception or incomplete disclosure as long as subjects are informed that they may/will receive a placebo. Suggested language may include, "You may receive placebo at some point during this trial," or "Some subjects will receive active drug and some subjects will receive placebo," or "Every subject will receive placebo at some point during the study." Placebo use in a clinical trial would, therefore, not require a waiver of or alteration of informed consent.

5. PROCEDURES: Institutional Review Board

5.1. The IRB reviewing research involving deception or incomplete disclosure must be sensitive to possible harms, and use good judgment, evaluating the potential risks on a case-by-case basis.

5.2. Where deception or incomplete disclosure is involved, the IRB needs to be satisfied that the deception/incomplete disclosure is scientifically justified.

5.3. IRB must determine whether the false/misleading information or information to be withheld would influence the decision of majority of the prospective participants about participating in the research. In general, deception/ incomplete disclosure is not acceptable if, in the judgment of the IRB, the participants may have declined to participate had they been informed of the true purpose of the research.

5.4. Deception or incomplete disclosure cannot be used to entice or lure a subject to participate.



Number:	Date:	Author:	Approved By:	Page(s):
UGAHRP-097-0	09/16/2016	HSO	IRB	Page 5 of 5

- 5.5. Research should not be permitted if the risk to subjects is more than minimal and the subjects are not being informed of things they would consider material to a decision to participate.
- 5.6. When appropriate, a debriefing process will be conducted as soon as practical after the subject's participation.
 - 5.6.1.A Debriefing Form or Script that details the debriefing information will be provided to participants.
 - 5.6.2. Participants must have the opportunity to withdraw from the study and/or have data that can be identified as theirs removed after the debriefing.
- 5.7. For non-exempt research, the IRB must document that an alteration of the informed consent requirements is justified under the waiver criteria described above [45 CFR 46.116(d)].

6. MATERIALS

- 6.1. Template for Debriefing Form or Script (The template is available [here.](#))

7. REFERENCES

- 7.1. 45 CFR 46 Code of Federal Regulations for the Protection of Human Subjects -- <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>
- 7.2. American Psychological Association Ethical Principles and Code of Conduct: Deception in Research.
- 7.3. IRB Guidebook. http://www.hhs.gov/ohrp/archive/irb/irb_chapter3.htm
- 7.4. Sloan, L and Hull, J. 2006. Deception of Research Subjects 2nd Edition. In *E. A Bankert and R. J. Amdur (Eds.), Institutional Review Board Management and Function* (210-215). Sudbury, Massachusetts: Jones and Bartlett Publishers.
- 7.5. Policy and Procedure: Exempt Review