SOP 6.03 - Informed Consent: Deception Research

1. Objective
In accordance with the Belmont Report ethical principle “Respect for persons,” and 45 CFR 46.116, this SOP discusses gaining informed consent during research that involves deception.

2. General Description
The basic process and documentation of informed consent often requires alteration or amendment when conducting research that involves deception.

3. Roles & Responsibilities
Execution of SOP: Principal Investigators (PI)/Study Personnel (SP), IRB Chair, IRB, Office of Research Integrity (ORI) Staff.

Investigators
In general and in addition to the basic elements of consent discussed in SOP 6.01, researchers should consider the following:

(1) It has been determined that the use of deceptive techniques is justified by the study’s prospective anticipated benefit and that equally effective non-deceptive procedures are not feasible,

(2) The research does not involve deception about procedures that are reasonably expected to cause physical pain, or severe emotional distress.

(3) The researchers seek to explain any previous deception to subjects as early as possible, preferably at the end of their participation, but no later than the conclusion of data collection, and then to permit subjects to withdraw their data.

IRB
It is the general responsibility of the IRB or reviewing entities to ensure that the basic and applicable elements of informed consent have been met satisfactorily, with the idea that Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. With exception to a claim for Exemption from the need for IRB review, consideration towards a waiver of some or all elements of informed consent must be justified and properly documented during the course of a review. However, even in the case of a claim for Exemption, the IRB-related review will consider the basic elements of informed consent as they are discussed in SOP 6.01. The IRB is responsible for reviewing the planned informed consent process
to ensure that it meets the ethical and regulatory requirements for fully informed and voluntary consent to participate in research.

4. **Procedures**

**Informed Consent in Studies Involving Deception or Incomplete Disclosure**

Studies which, at the time of informed consent, will not fully disclose the purpose, nature or other aspects of the study to potential participants; or that describe a study purpose that does not reflect the actual study purpose, may do so only when the deception is deemed necessary by the IRB for the conduct of the research and does not increase risks beyond what participants may agree to had they been fully informed.

The IRB may approve a consent process involving incomplete disclosure of the eight basic elements of consent if the requirements for a waiver or alteration of consent described in 45 CFR 46.116 (SOP 6.01) are met. Investigators must keep in mind, that when deception is used, the fourth criterion applies: Subjects are to be provided additional pertinent information about the research after participation. More specifically, participants must be debriefed after participation unless doing so would harm them. In the latter case, investigators and the IRB must weigh the harms resulting from participation in the research with the ethical concerns related to the purposeful withholding or provision of false information to research participants without rectifying the situation at the conclusion of their participation.

When participants will be debriefed, they must be told that deception or incomplete disclosure were used and must also be told what constituted the deception or incomplete disclosure and why these were necessary. After the debriefing, researchers may ask subjects to not talk to others about the deception or incomplete disclosure to minimize the possibility that results may be skewed if latter subjects knew in advance that deception or incomplete disclosure was being used in the study.

Consent forms and scripts should not include false or misleading information to further the deception. However, investigators may be vague as to the purposes of the study or omit information in consent materials in order to maintain the deception or incomplete disclosure necessary for the study. When such information would not adversely affect the research results (i.e., by influencing participant behavior), investigators should include a statement in the consent form or script advising potential participants that the information provided in the relevant consent materials is not complete and that participants will be debriefed after their participation has concluded.

The following paragraph provides sample language investigators may wish to use or adapt:

“Research designs sometimes require that the full intent of a study not be explained prior to participation. Although we have described the general nature of the tasks that you will be asked to perform, the full intent of the study will not be explained to you until after the completion of the study. At that time, we will provide you with a full debriefing which will include an explanation of the purpose of the study and other relevant background information pertaining to the study. You will also be given an opportunity to ask any questions you might have about the study and the procedures used in the study.”
Informed Consent/Assent Approval
Upon approval of the protocol, the Principal Investigator is notified that the research team is responsible for conducting the research as stated in the protocol most recently reviewed and approved by the IRB, which shall include using the most recently submitted Informed Consent/Assent forms and recruitment materials.

5. References
45 CFR 46.116, 46.117
UNLV Rules and Procedures for Conducting Human Subject Research, 2.2, 5.1.4
Institutional Review Board Management and Function, Bankert & Amdur – Chapter 6-4, 6-5