Deception in Human Research	Effective	12.9.2015
	Revised	1.21.2019

1.0 Purpose: The purpose of this standard operating practice (SOP) is to describe the expectations the University and Medical Center Institutional Review Board (UMCIRB) has when an investigator wishes to use any form of deception in their human research proposal.

2.0 Persons Affected:

2.1 Investigators and study team members
2.2 UMCIRB Chairpersons and members
2.3 UMCIRB Office staff members

3.0 SOP: While the use of deception may be a valuable methodology to avoid bias or test a hypothesis, these techniques raise important ethical issues. The federal regulations for obtaining informed consent require full disclosure of the research to the participant and therefore, studies involving deception need to be carefully reviewed by the IRB to ensure that the deception is justified. This is achieved through an examination of the risks and benefits of that deception and there should be no reasonable alternative method that would be equally effective. To approve research involving deception, the study procedures cannot involve greater than minimal risk to participants.

Studies involving deception can be reviewed by expedited procedures or, depending on the level of deception used in the research, could be reviewed by the convened IRB. Some deception procedures may also be approved under an Exempt category of research (see Certified Exempt Research SOP for details of the limited use of deception).

Deception includes active deception or providing incomplete disclosure of study purposes or methods to carry out research.

4.0 Definitions:

4.1 Active Deception: As it applies to research, is a situation where an individual is provided false or misleading information regarding the true purpose of the study, which may include incomplete disclosure, and may be used to avoid study bias or test a hypothesis that requires the participant's misdirection. Examples of active deception include providing a "cover story" which falsely describes the purpose of the research and those that use a "confederate", a person posing as a research participant, whose behavior in the study is actually part of the research design.

4.2 Deception: Misleading participants as to the true nature of the study procedures. Deception includes both active deception and deceptive incomplete disclosure.

4.3 Deceptive Incomplete Disclosure: A situation in which an investigator withholds information about the specific purpose, nature, or other aspect of research; and 1) that information, if provided during initial consent may have affected participants decision to participate and/or 2) when participants learn of the information withheld, they would likely feel deceived. It is important to note that incomplete disclosure may or may not be considered deception. An example of non-deceptive incomplete disclosure includes providing information to the subject about the research that is true, yet not detailed enough to reveal the main aims or hypotheses of the study. An example of deceptive

incomplete disclosure includes audiotaping or videotaping subjects without their knowledge or consent.

5.0 Responsibilities:

5.1 Investigators/study team members have the responsibility to:

5.1.1 Clearly outline and justify the use of deception in the proposed research;

5.1.2 Provide sufficient information regarding the study in the informed consent document,

5.1.2.1 Justify any alterations in the consent process or document;

5.1.2.2 If possible, tell individuals they are participating in research without full knowledge of the true purpose in order to accomplish study objectives.

5.1.3 Provide a script to be used during the debriefing session after the individual's participation in the research study and utilize this to debrief participants unless the IRB determines that such debriefing would cause harm to the subject;

5.1.4 Ask participants if they would like their study information withdrawn after they have been debriefed and withdraw the study information should this be requested by the research participant.

5.2 UMCIRB Office staff are responsible for

5.2.1 Ensuring applications involving deception have complete information for the IRB to make a determination for approval;

5.2.2 Communicating any requirements for approval to the study team.

5.3 UMCIRB/UMCIRB Chairperson (or designee) will take the following into account when reviewing research involving deception:

5.3.1 The scientific value and validity of the research including justification for the use of deception;

5.3.2 Alternative procedures which could be utilized;

5.3.3 Examination of the recruitment and protocol/research plan to ensure the deception in and of itself does not influence study participation;

5.3.4 Inducement of harm and the reduction of harms through debriefing;

5.3.4.1 Debriefing may be inappropriate when it presents an unreasonable risk of harm without benefit.

5.3.5 Existence of an acceptable plan/script for debriefing and a description of plans to provide the participants with the option to have their data withdrawn from data analysis;

5.3.6 The privacy implications to subjects who participate and confidentiality of study data;

5.3.7 Whether adequate justification has been provided to approve a waiver of consent or alteration of some part of the consent according to the following criteria:

5.3.7.1 The research involves no more than minimal risk to the subjects;

5.3.7.2 The waiver or alteration will not adversely affect the rights and welfare of the subjects;

5.3.7.3 The research could not practicably be carried out without the waiver or alteration; and

5.3.7.4 Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Revision History:

Date	Change	Reference Section(s)
1.21.2019	Modified to reflect allowance of deception under Exempt category.	Section 1 and 3