# Deception of Subjects

HRPP acknowledges that it is occasionally necessary to use deception in a research design in order to protect or strengthen the scientific integrity of an investigation. However, because participants are deliberately misinformed concerning the actual purposes or procedures of the research in such cases, HRPP considers such research to not meet the general requirement for informed consent as stated in the Code of Federal Regulations (45 CFR 46.116.a.1). This part of the law delineates the basic elements of informed consent, and states that in seeking informed consent, the following information shall be provided to each subject:

* *An explanation of the purposes of the research and a description of the procedures to be followed*

The Code of Federal Regulations, however, does provide for instances in which informed consent can be altered or waived. This can occur only if all of the following conditions are met:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration [of consent] 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 [of consent];
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Therefore, investigators proposing research to HSCL in which participants are misinformed concerning the study's procedures or purposes during the course of data collection must address how their applications meet these conditions. This requirement may be met in a number of ways. However, in order to address these issues and facilitate review of such applications, HSCL recommends that applications for research involving deception adhere to the guidelines listed on the following page.

*Although applications involving deception must meet the conditions for alteration of informed consent, consent procedures are still required to meet certain elements of informed consent described in 45 CFR 46.116.a.2-8. Note that the informed consent form may not contain misinformation, may not be used as part of the deception, and may not be used as a means for manipulating subjects' behavior.*

**Please use the guidelines on the following page.**

# Deception of Subjects – Application Guidelines

***Justification for the Deception and Explanation of Risk within the HRPP Application***

* Provide specific and cogent reasons why fully informed consent is not appropriate for this study, and/or the manner in which fully informed consent threatens the integrity of the research. Explain the process to debrief participants. Explain when participants will be debriefed and who will debrief them.
* Provide a statement affirming that the proposed research presents no more than minimal risk to the participants. "Minimal risk" means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

***Information pertaining to Study Procedures and Debriefing within the Informed Consent form***

* Provide a truthful and accurate explanation of the purpose of the study to the extent possible without giving too much of the study away.
* Include a statement regarding debriefing such as “Some research requires that the full purpose of the study not be explained before you participate. We will give you a full explanation at the end of the study.” OR “After completing the study you will receive detailed information regarding its nature.”

***Debriefing Statement/Script to be given or read to Participants***

* Submit a debriefing statement/script to HRPP in which participants are informed that deception took place, and are appropriately informed as to the actual purpose of the research and the role of the deception in protecting the integrity of the research. Your debriefing statement **must** contain the following elements:
	+ Label the form as “Debriefing Statement”
	+ Study title
	+ PI name and contact information for follow-up questions
	+ Thank participants for taking the time to participate in the study
	+ Explain what was being studied (i.e., purpose, hypothesis, aim).  Use lay terms and avoid use of jargon.
	+ Explain how participants were deceived
	+ Explain why deception was necessary in order to carry out the research
	+ Explain how the results of the deception will be evaluated
	+ Remind subjects of their right to withdraw from the study at this time.
	+ If the study involves use of audio or videotaping, give the participant an opportunity to withdraw his/her consent for use of the tapes as well as withdraw from the study altogether.

# *Please note that the above elements do not constitute an exclusive list. When appropriate, HRPP may request that additional elements of information be provided to each subject.*