Research involving deception or withholding of information

Some research designs may require the withholding of information from human subjects. Research involving deception or withholding of information must be reviewed by the IRB with common sense and sensitivity. The withholding of information by researchers is different from the practice of deception, in which researchers provide false or misleading information to subjects. Studies involving deception need to be carefully reviewed by the IRB to ensure that the deception is justified through an examination of the risks and benefits of that deception. Furthermore, the IRB should ensure that, when appropriate, the subjects will be debriefed. Before approving a study that involves deception, the IRB should determine that the subject population is suitable and that the deception involved in the study would not alter a subject’s assessment of risk to himself/herself if he/she was aware of the deception at the time he/she agreed to participate.

Deception can only be permitted where the IRB finds and documents that waiver or alteration of the informed consent requirements is justified according to 45 CFR 46.116(d). The IRB must document that the following criteria have been satisfied:

- The research involves no more than minimal risk to the subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.