Section 13: Research Using Deceptive or Incomplete Disclosure

13.1 Background and Rationale
Research involving deception and incomplete disclosure involves intentionally communicating information to research subjects in a way that produces false beliefs. Obfuscation or withholding information at the outset of a study is also considered deception. Any research in which information is withheld until subjects have participated to some degree should be considered as a deception study. This type of research methodology is sometimes used to:

1. Improve study validity,
2. Assure study integrity, or
3. Allow data collection that would otherwise be unobtainable because of defensiveness, shame, etc.
4. To test or assess specific hypothesis that relate to psychological, economic, or communication processes related to deception.

13.2 General Guidelines
The following are general guidelines regarding the design, review and conduct of studies involving deception and incomplete disclosure:

1. Use of deception and incomplete disclosure is usually only acceptable for studies that are minimal risk.
2. The use of deception/incomplete disclosure should have no adverse effects on the well-being of subjects.
3. The IRB must be supplied with sufficient information to determine that the value of the research outweighs the risk of waiving some aspects of the requirement for full disclosure in the informed consent process. (See Section 6.7 Waiver of Informed Consent and Waiver of Documentation of Consent)
4. There is no reasonable alternative to scientifically and effectively address the research question without the use of deception/incomplete disclosure.
5. Subjects are not deceived about any aspect of the study that would alter their willingness to participate.
6. As soon as it is appropriate, debriefing should be accomplished and the deception/incomplete disclosure explained to subjects.
7. When appropriate, subjects should be informed prospectively of the use of deception/incomplete disclosure and consent to its use.
8. During debriefing inform subjects of their right to withdraw their data, if they wish,
and how that will be accomplished.

13.3 Principal Investigator Requirements
To assist the IRB in its review and determination of the appropriateness of the research study, Principal Investigator(s) should address the following items in the relevant documents:

1. Explain the reason(s) for use of deception/incomplete disclosure in the study design. Specifically, address why complete disclosure would compromise the scientific validity of the study.
2. Describe the extent of the deception/incomplete disclosure in detail and how it relates to the study aims and design.
3. Justify and discuss how the proposed research, involving deception/incomplete disclosure involves no more than minimal risk to subjects. Consider all levels of increased risk subjects could experience as a result of the deception/incomplete disclosure methodology.
4. Justify and discuss why there are no feasible or scientifically valid alternative methods, which do not involve deception/incomplete disclosure, to conduct the research.
5. Describe the methods for prompt disclosure to debrief subjects. This should be accomplished as soon as possible after subjects complete research related activities. Also describe how you will assure that subjects leave the study setting with a clear and accurate understanding of the deception/incomplete disclosure and the reasons for using this methodology. If debriefing is not planned, justify why.

13.4 Potential Risks
There are several potential risks associated with use of deception/incomplete disclosure and these should be considered when designing the study:

1. Subjects may feel that they were coerced to act against their will. If so and if they had been completely informed, they may have chosen not to participate.
2. Subjects may feel ashamed, guilty, stressed, or embarrassed because they now have knowledge about themselves that they otherwise would not have known or would not want to know.
3. Subjects may feel a loss of control that will cause distrust and suspicion regarding human subjects research in general.
4. The research may undermine the trust in professional standards governing human subjects research.