

12.0 Social and Behavioral Research

Social and behavioral research at KUMC involving human subjects most commonly produces data through the use questionnaires, surveys, observation, and retrospective data reviews. It is possible for some behavioral research studies to include physical interventions. These interventions often contain very minimal risk and aim to help examine social behaviors in a hospital setting as opposed to medical treatment itself.

12.1 Special Considerations

- I. Most behavioral research does not involve any type of physical intervention and therefore does not contain any physical risks. When reviewing behavioral research, the Human Subjects Committee takes into account a wide range of other types of potential risks such as psychological, social, economic or legal risks.
 - A. The HSC considers the potential for participants to experience stress, anxiety, guilt, or trauma that can result in the onset or relapse of a behavioral disorder or other psychological harm.
 - B. The HSC also considers the potential for to experience embarrassment and other social risks.
 - C. The HSC also considers the risks of criminal or civil liability or other risks that can result in serious social harms, such as damage to financial standing, employability, insurability, or reputation; stigmatization; and damage to social or family relationships.
- II. When formulating a behavioral research study, investigators should consider how to minimize non-physical risks. Although these studies may not offer the prospect of individual benefits, individual benefits should be maximized as appropriate to the research. Because individual benefit may be low, an acceptable risk/benefit ratio will require evidence of important benefit to science and society as a whole.

12.2 Use of Deception

- I. Deception is the intentional misleading of subjects. This includes omitting or withholding information about the nature of an experiment. Using deception by withholding the purpose of the research, the role of the researcher, or what procedures in the study are experimental increases ethical concerns, because it interferes with the ability of the subject to give informed consent. However, deception may be necessary for certain types of behavioral research because subjects act differently depending on whether they are fully informed about the nature of the study.

- II. Deception is permitted under certain established limits. In order for the HSC to adequately review the risk/benefit balance of the study, the investigator must provide information to demonstrate:
 - A. The study could not practicably be done without the use of deception;
 - B. All subjects will be debriefed immediately after their participation is complete;
 - C. Subjects will be given the opportunity to ask questions about the withheld information;
 - D. Subjects will be given the opportunity to withdraw from the study and have their data removed;
 - E. Subjects will not be exposed to more than minimal risk; and
 - F. The withheld information does not increase the risk of participation in the study and is not likely to change people's decisions to participate in the study.
 - G. The deception will not adversely affect the rights and welfare of the subjects.
 - H. The research does not involve the use of drugs or medical devices and does not require reporting of data to FDA.

12.3 Debriefing

- I. The HSC requires investigators to debrief subjects who have been deceived during participation in research activities immediately following their participation. The debriefing should include a detailed description of all information that was withheld from the subject and any other ways in which deception was used.
- II. The investigator is responsible for ensuring that the subject leaves the research setting with an accurate understanding of the deception. The debriefing process, including any written materials, must be submitted to the HSC for review as part of the initial application submission.

References:

45 CFR 46.111
45 CFR 46.116
45 CFR 46.117