IRB SOP 12.0 Social and Behavioral Research, 2018 requirements

Purpose:
Outline the regulatory and institutional standards related to the review of social and behavioral research

Responsible Personnel:

Background:
Social and behavioral research at KUMC involving human subjects most commonly produces data through the use of questionnaires, surveys, observation, behavioral interventions and retrospective data reviews. Standard requirements for IRB review and informed consent apply to social behavioral research.

Regulation and Guideline Reference(s):

References:
45 CFR 46.111
45 CFR 46.116
45 CFR 46.117

KUMC References:

Attachment(s):

Definitions:

Procedure:
Social and behavioral research at KUMC involving human subjects most commonly produces data through the use of questionnaires, surveys, interviews, focus groups, observation, and behavioral interventions. This standard operating procedure outlines the regulatory and institutional standards related to the review of social
When reviewing behavioral research, the IRB takes into account the full range of potential risks, including physical, psychological, social, economic or legal risks.

A. The IRB 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 IRB also considers the potential for participants to experience embarrassment and other social risks.

C. The IRB 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.

When formulating a behavioral research study, investigators should consider how to minimize all sources of risks. If individual benefit may be low, an acceptable risk/benefit ratio will require evidence of important benefit to science and society as a whole.

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.

Deception is permitted under certain established limits. In order for the IRB 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.

III. Provisions in the Revised Common Rule specify additional limitations on deception when the research qualifies for IRB exemption as a benign behavioral intervention. These limitations are discussed in SOP 2.5.

12.3 Debriefing

I. The IRB 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 IRB for review as part of the initial application submission.

References:
45 CFR 46.111
45 CFR 46.116
45 CFR 46.117

Approved By:
Vice Chancellor for Administration

Attachments:

Approval Signatures

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Applicability

KU Medical Center, KU SoM Wichita