Chapter 13

Social and Behavioral Research

Social and behavioral research often involves surveys, observational studies, personal interviews, or experimental designs involving exposure to some type of stimulus or intervention. Such research in most instances is approved through expedited review or determined exempt, however there are instances when such research requires full board review. The IRB, in its review process, must consider that the probability of such risks may in fact be considered greater than minimal risk. These considerations are discussed in this chapter.

Social and Psychological Harms

As reflected in the mission of the IRB and the basis of ethical review of research, the IRB must examine the risk of harm, not only those presented as physical harms, but psychological, social, and financial. The IRB should consider the potential for participants to experience stress, anxiety, guilt, or trauma that can result in genuine psychological harm. The IRB should also consider 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.

To mitigate such risks, the IRB should review the proposal for appropriate preventative protections and debriefings, adequate disclosure of risks in the informed consent information, and mechanisms to protect the confidentiality and privacy of persons in or affected by the research. The IRB should also determine the availability of behavioral health resources and support systems to aid participants should participation result in untoward effects on the individuals that may experience any of these unintended harms.

Privacy and Confidentiality Concerns.

The IRB must also determine that the research protocol or plan contains adequate provisions to protect the privacy of participants and the confidentiality of data. Methods used to identify potential research participants or to gather information about participants do not invade the privacy of the individuals. Identifiable information may not be obtained from private (non-public) records without the approval of the IRB and informed consent of the participant. This also applies to those situations when information is sought to identify potential participants. However, there are circumstances in which the IRB may approve a waiver of usual informed consent requirements.
The requirements for informed consent waiver can be found in Chapter 11.

i. In all instances, the IRB will require a plan that details the processes that will be utilized to collect data, the systems to be utilized for data storage, what data elements will be retained, and if and how any of the collected data will be shared.

ii. When reviewing survey and interview research, the IRB must be aware of the regulatory provisions at 45 CFR 46.117(c)(1) for waiving documentation of consent when a signed consent form constitutes the only link between the research and the participants and would itself be a risk to the participants.

iii. DHHS regulations at 45 CFR 46.116(b)(5), FDA regulations, and the Common Rule require that subjects be informed of the extent to which confidentiality of research records will be maintained.

iv. The IRB may require that an investigator obtain a DHHS Certificate of Confidentiality (CoC). The CoC protects against the involuntary release of sensitive information about individual participants for use in Federal, State, or local civil, criminal, administrative, legislative, or other legal proceedings.

Research Involving Deception or Withholding of Information

i. IRBs reviewing research involving incomplete disclosure or outright deception must apply thoughtful consideration and sensitivity to the review. Deception research involves psychology research in which the participant is not told, or is misled, about the true purpose of the research.

ii. Where deception is involved, the IRB needs to be satisfied that the deception is necessary and that, when appropriate participants shall be debriefed. Debriefing may be inappropriate when the debriefing itself would present an unreasonable risk of harm without a corresponding benefit.

iii. Deception can only be permitted where the IRB documents that a waiver of the usual informed consent requirements is justified under the criteria present in Federal regulation and the Common Rule at 45 CFR 46.116(f). Specifically, the IRB must find and document that all four of the following criteria have been satisfied:

- The research presents no more than minimal risk to subjects,
- The waiver or alteration shall not adversely affect the rights and waiver or alteration,
- If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format, and
- Where appropriate, the subjects shall be provided with additional pertinent information after participation.

iv. The IRB reviewer will document how the proposed research satisfies the above criterion to support approval of the research.

Regulations make no provisions for the use of deception in research that poses greater than minimal risks to participants.