Special Considerations about Risks in Behavioral and Social Sciences Research

Behavioral and social sciences research often involves surveys, observational studies, personal interviews, or experimental designs involving exposure to some type of stimulus or intervention. This guidance discusses when exemption and expedited review are appropriate for this type of research.

Social and Psychological Harms.

When evaluating behavioral and social science research, the IRBs carefully examines the research to determine the probability of risk of harm to subjects:

(1) The IRB considers the potential for participants to experience stress, anxiety, guilt, or trauma that can result in genuine psychological harm.
(2) 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.
(3) If information is being collected on living individuals other than the primary "target" subjects the IRB considers the risk of harm to those "non-target" individuals, as well.

To mitigate such risks, the IRB reviews the proposal for appropriate preventive protections and debriefings, adequate disclosure of risks in the informed consent information, and mechanisms to protect the confidentiality and privacy of persons participating in or affected by the research.

Research Involving Deception or Withholding of Information.

When reviewing research involving incomplete disclosure or outright deception, the IRB applies both common sense and sensitivity to the review. Where deception is involved, the IRB needs to be satisfied that the deception is necessary and that, when appropriate, the subjects shall be debriefed. (Debriefing may be inappropriate, for example, when the debriefing itself would present an unreasonable risk of harm without a corresponding benefit.) The IRB will also make sure that the proposed subject population is suitable.

Deception is only permitted where the IRB documents that an alteration of the usual informed consent requirements is justified under the criteria present in the Common Rule. Specifically, the IRB must find and document that all five of the following criteria have been satisfied:

(i) The research involves no more than minimal risk to the subjects;
(ii) The research could not practicably be carried out without the requested waiver or alteration;
(iii) 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;
(iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
(v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

In making the determination to approve the use of deception under an alteration of informed consent, the IRB considers each criterion in turn, and documents specifically (in the minutes of its meeting and in the Protocol file) how the proposed research satisfies that criterion.

(Note: The regulations make no provision for the use of deception in research that poses greater than minimal risks to subjects.)