

EXAMPLES OF RISK

Physical Risk

Physical discomfort, pain, injury, illness or disease brought about by the methods and procedures of the research.

Psychological Risk

May be experienced during the research situation and/or later, as a result of participating. Includes anxiety, stress, fear, confusion, embarrassment, depression, guilt, shock, loss of self-esteem, altered behavior.

Social/Economic Risk

Alterations in relationships with others that are to the disadvantage of the subject, including embarrassment, loss of respect of others, labeling with negative consequences, or diminishing the subject's opportunities and status in relation to others. Economic risks include payment by subjects for procedures, loss of wages or income, and damage to employability.

Legal Risk

Risk of criminal prosecution or civil lawsuit when research methods reveal that the subject has or will engage in conduct for which the subject or others may be criminally or civilly liable.

Loss of Confidentiality

Confidentiality is presumed and must be maintained unless the investigator obtains the express permission of the subject to do otherwise. Risks include invasion of privacy, as well as the social, economic and legal risks outlined above.

MINIMAL RISK

Federal regulations define "minimal risk" as follows: "The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." In broad terms, a project involves minimal risk if:

1. The participant experiences no pain or physical danger;
2. The participant experiences no emotional arousal or psychological stress beyond the levels normally to be expected in everyday life;
3. The project neither induces nor attempts to induce long-term significant change in the participant's behaviors (including attitudes toward self and others);
4. The data would not embarrass or socially disadvantage the participant, were confidentiality to be violated; and
5. If the investigator conceals information about the specific purpose of the project, there is no reason to believe the subject would choose not to participate if s/he had known that information initially.