

SVN PRN
Research Corner – September 2018
Defining Risks in Research

Risk is defined as the probability of harm occurring to the subject as a result of participation in a research study. All research studies submitted for approval to an Institutional Review Board (IRB) must explicitly identify and address the potential for risk to the subject as part of the process. This is a federal requirement in order to protect human subjects. There are five broad risk categories in research. They are:

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

Psychological: Include experiencing negative emotional states such as anxiety, depression, guilt, shock, loss of self-esteem or altered behavior. Deception is another psychological risk.

Social/Economic: Social risks are changes in relationships with others that include embarrassment, loss of respect. Economic risks include loss of wages or paying for procedures that are not otherwise needed.

Loss of Confidentiality: Confidentiality of identifiable information must be maintained. The more sensitive the research, the greater the care should be exercised in obtaining, handling, and storing data.

Legal: The research methods are such that the subject or others will be liable for a violation of the law, either criminal or civil liability.

The type of risk(s) varies depending upon the proposed research. In addition to identifying/addressing risks, when submitting the study, the Principal Investigator (PI) may feel that that the study may be classified as “minimal risk” to obtain expedited IRB approval. The Code of Federal Regulations (HHS-45 CFR part 46) defines a minimal risk study as the probability and magnitude of harm or discomfort anticipated in the research is not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. An example of a minimal risk study is blood samples that include specifics regarding subject weight, sample volume and blood draw frequency. Other minimal risk research includes collection of data through non-invasive means such as chart reviews, data obtained from voice, video, digital or image records made for research purposes or research on individual or group characteristics or behavior (e.g., surveys, interviews).

It is the responsibility of the IRB to carefully review and validate the proposed research provides specifics on all potential risks. If submitted under the minimal risk category, the IRB must ascertain the study meets the criteria. This assists in maintaining the highest research standards and optimal subject protection.

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