



GUIDELINES FOR DETERMINING RESEARCH RISK CATEGORIES

(A) DEFINITION OF RESEARCH RISK

i. Minimal Risk Research

Research in which there is no foreseeable risk of harm or discomfort and any foreseeable risk is no more than inconvenience.

Examples: inconvenience may include filling in a form, participating in a street survey, or giving up time to participate in research.

ii. Above Minimal Risk Research

Research in which the only foreseeable risk is one of discomfort, risk for participants is more serious than discomfort and/or any possibility of harms greater than discomfort.

Examples: interviewed regarding personal/sensitive topics, power relationships (employer-employee, coach-athletes etc) that may influence the abusive of power over the participant, most clinical interventional research involving drugs or devices.

(B) RISK FACTORS

i. Types of Risk

Physical risk: risk of harm through bodily contact or administration of any substance, device or other intervention.

Psychological or emotional risk: risk of harm due to feeling worthlessness, distress, guilt, anger or fear, religious related, for example, to disclosure of sensitive or embarrassing information, or learning about a genetic possibility of developing an untreatable disease, manipulated or in other ways treated disrespectfully or unjustly.

Social risk: risk of harm including damage to social networks or relationships with others, loss of privacy or reputation; discrimination in access to benefits, services, employment or insurance; social stigmatisation; and findings of previously unknown paternity status

Economic risk: including the imposition of direct or indirect costs on participants

Legal risk: including discovery and prosecution of criminal conduct

ii. Group Vulnerability

Vulnerability exists along a continuum and is influenced by many factors. The combination with the research design can influence the level of risk and ultimately the designation of risk for the research study:

- a) Participant capacity (mental, emotional, cognitive)
- b) Age
- c) Wellness or health status
- d) Dependency
- e) Power relationships
- f) Setting and recruitment
- g) Socio-economic status

iii. Funding Source

Study funding by for-profit sponsor /organization – could require Research Ethics Committee (REC) full review if issues such as privacy, confidentiality and consent, or intellectual property are involved.

(C) CATEGORIES OF RESEARCH

i. Expedited Review

This category involve collection of samples and data that involves no more than minimal risk to subjects. Expedited review allows the REC chairperson or one or more experienced reviewers designated by the chairperson from among members of the REC to evaluate and approve specific types of research. Reviewers conducting an expedited review may exercise all of the authority of the REC except that they may not disapprove a study. When the reviewer(s) cannot approve the research under expedited review, the study will be referred to REC for full review.

ii. REC Full Review

Proposed human subject research which does not fall into the expedited review category must be submitted for full REC full review.

