

Research Risk Assessment Guidelines

To help determine whether your research project should be classified as minimal risk or above minimal risk, please consult the following guideline. Please note that the Research Review Committee will conduct its own risk assessment on all minimal risk applications. For additional information on risk and risk determination, please consult the [Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans, Chapter 2, part B](#).

Definition of Minimal Risk

According to the TCPS2, “Minimal risk” research is defined as research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research.”

To properly assess whether any given research project meets the TCPS2 definition of minimal risk, researchers (and REBs) must consider both a) the nature of the research risks involved; and b) the vulnerability of research participants. Each of these factors is elaborated upon below.

A) Nature of the Research Risks

Because research is a step into the unknown, its undertaking can involve harms to participants and to others. Harm is anything that has a negative effect on the welfare of participants, and the risks of harm may be physical, psychological/emotional, social, or legal in nature.

Risk is a function of the magnitude or seriousness of the harm, and the probability that it will occur, whether to participants or to third parties (as outlined below). A proper ethical analysis of a research protocol should consider both the foreseeable risks and the available methods of eliminating or mitigating those risks.

The magnitude or seriousness of the harm

Potential harms in research may span the spectrum from minimal (e.g., inconvenience of participation in research) to substantial (e.g., a major physical injury or an emotional trauma). Harms may be transient, such as a temporary emotional reaction to a survey question, while other types of harm may be longer lasting, such as the loss of reputation following a breach of confidentiality, or a traumatic experience. It is important to be aware that the perspective of participants regarding harm may vary from that of researchers. Participants themselves may vary in their reaction to the research. Researchers (and REBs) should, as far as is possible, attempt to assess the harm from the perspective of the participants. It is also important to note that research in certain disciplines may present risks that go beyond the individual and may involve the interests of communities, societies or other defined groups.

The probability of occurrence of the harm

This refers to the likelihood of participants actually suffering the relevant harms. An assessment of harm probability may be based on the researcher’s past experience conducting such studies, the review of existing publications that provide rates of the relevant harms in similar issues, or on other empirical evidence.

B) Participant Vulnerability

In assessing the risk level of their research projects, researchers must also take into account participant vulnerability. According to the TCPS2, vulnerability is “A diminished ability to fully safeguard one’s own interests in the context of a specific research project. This may be caused by limited capacity or limited access to... rights, opportunities and power. Individuals or groups may experience vulnerability to different degrees and at different times, depending on their circumstances.”

Vulnerability exists along a continuum and is influenced by many factors including (but not limited to):

- Participant capacity (mental, emotional, cognitive)
- Age
- Wellness or health status
- Institutionalization
- Power relationships
- Gender and gender identity
- Ethnic, racial, or national minority status
- Setting and recruitment
- Dependency
- Socio-economic status.

The TCPS2 states that individuals or groups whose circumstances make them vulnerable should neither be inappropriately included nor automatically excluded from participation in research. Participant vulnerability should rather be viewed as contextual and relational. According to Article 4.7 of the TCPS2, “individuals should not automatically be considered vulnerable simply because of assumptions made about the vulnerability of the group to which they belong. Their particular circumstances shall be considered in the context of the proposed research project.”