

Risk Level and Vulnerable Populations

Managing risk for research participants

Proportionate review: higher-risk studies receive more scrutiny. Your protocol should present information in a way that enables appropriate risk assessment.

Describe the study's procedures:

Provide a step-by-step description of what participants will do, how long it will take, and where activities will take place.

When recruiting multiple participant groups, provide a clear outline of the procedures for each group separately as different groups will often require different approaches and mitigation strategies.

Identify/explain risks likelihood and magnitude

Risks to be identified include economic, professional, legal, social, psychological, and physical risks.

Describe risk-mitigation strategies, including safety procedures, data security protections, support resources provided to participants, etc.

Minimal-risk studies: proportionate review requires determining whether a study is minimal risk.

Minimal Risk: the likelihood and magnitude of possible harm *is no greater than those encountered in everyday life*. Types of harm include physical, psychological/emotional, legal, social (e.g., privacy, reputation). Potential harm may increase when viewed in relation to participant vulnerabilities.

Additional risk: your protocol should detail the additional risk the study brings into the participant's daily life or explain why your intervention does not bring in additional risks into the participant's everyday life.

Example: interviewing a lawyer about the law would be considered part of their everyday life. However, interviewing them to ask about their employer or employment conditions would bring in an additional risk that is not part of their day-to-day life.

Profile of research participants: proportionate review requires considering who the participants are when determining the risk level.

Vulnerable populations are participants with reduced ability to give free and informed consent.

Examples: children, persons with dementia, marginalized groups, etc.

Context matters: being a member of a particular group does not inherently make a participant vulnerable.

Example: if your study involves Indigenous business owners, and you are asking them about the strategies they use to promote their business, the Indigenous participants in this context would not be considered vulnerable.

Some groups **may not seem vulnerable** but are so within a particular context.

Example: student participants might perceive that participation in the research could affect their grades, especially if the research is conducted by their instructor