

Guideline #: 001 13-14

Title: Eligibility for Delegated Review: Minimal Risk Criteria

The REB process used to review new applications varies according to the level of risk that research participants could experience as a result of the particular type of research procedures used. TCPS2 Article 2.9 states “The REB shall adopt a proportionate approach to research ethics review such that, as a preliminary step, the level of review is determined by the level of risk presented by the research: the lower the level of risk, the lower the level of scrutiny; the higher the level of risk, the higher the level of scrutiny”.

The concept of ‘minimal risk’ provides a foundation for proportionate review. Minimal Risk is defined in TCPS2 as follows: “*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*”. Applications that meet minimal risk criteria are eligible for delegated review and it is expected that the majority of research submitted to the REB will fall into the minimal risk category. However, the REB retains the right to decide to put any application submitted for delegated review forward for full board review. In such cases, the applicant will be notified of the change in the status of the application.

It is now widely accepted that the majority of research in the social sciences, behavioural sciences and humanities involves no more than minimal risk to participants. However, in determining whether a study meets the minimal risk criteria, the level of risk the study entails and the vulnerability of the research participants must be considered.

This document is intended as a guideline rather than a procedural directive as each project will need to be judged based on its unique context.

Research Risk

Types of risk include: physical risks, psychological or emotional risks, and social risks. Physical risks are risks of harm through bodily contact or administration of any substance – this is not a common risk in social science, behavioural and humanities research. Psychological or emotional risks are risks of harm due to feeling embarrassed, uncomfortable, anxious or upset. Psychological harms vary tremendously from study to study, from a temporary emotional reaction to a survey question to the possibility of trauma in rare cases. Social risks are risks of harm due to loss of status, privacy, reputation, legal or financial risk as a result of confidentiality breaches.

Beyond the character of the risk itself, researchers and Research Ethics Board members should consider the magnitude or seriousness of the harm. There is a difference between transient harms equivalent to those people regularly experience on a daily basis (e.g., an emotional but temporary reaction to survey questions) and ones that are longer lasting (reputation loss following breach of confidentiality). The probability of occurrence of the harm should also be considered. Are the foreseeable harms likely, possible but unlikely, or extremely remote?

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*” (p. 197). 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
- Setting and recruitment
- Dependency
- Socio-economic status.

The TCPS2 states that individuals or groups whose circumstances make them vulnerable should not be inappropriately included or automatically excluded from participation in research on the basis of their circumstances; however, it recognizes that vulnerability is 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*”.

An initial assessment of the level of risk that projects may entail can be done using the following matrix. You should tick one box corresponding to the overall level of risk that the study poses after considering where the study lies on both axes: participant vulnerability and research risk.

| | Research risk | |
|---------------------------|-------------------|------------------------|
| Participant Vulnerability | MINIMAL RISK | MORE THAN MINIMAL RISK |
| HIGH | Full board review | Full board review |
| LOW | Delegated review | Full board review |

Types of studies that would not qualify for minimal risk review include but are not limited to:

- Research that involves BOTH vulnerable populations AND highly personal, sensitive or incriminating topics or questions; e.g. studying people engaged in illegal activities (e.g. heroin use or euthanasia) about these activities, discussing experiences of bullying amongst school-aged children who have been bullied, talking to people who are currently suicidal about their experiences of depression. This does not mean, however, that studies are about the topic of drug use, bullying or suicide must always be reviewed at the full board, it depends on the population being studied and the type of research methodology involved.
- Research that uses deception unless the researcher has convincingly argued that the deception is of a minor nature and the possibility of harm is remote.
- Research that involves the generation of databases of populations where potential future research is unknown, and where the data could possibly be linked or traced to personally identifiable information.

The REB application under the “Preliminary Checklist” tab gives researchers the opportunity to elaborate on the risks that may be involved with the study. This tab provides an important way of justifying risk assessment, especially if the study might be considered sensitive and risky to an outsider, but the researcher has evidence to suggest that it’s not.

If a study falls into the minimal risk categories on the above matrix it is eligible for delegated review.

References:

-TCPS2

-UBC Behavioural REB Guidance Notes

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Date of approval: ___November 26, 2013_____