
**Proportionate Approach to Research Ethics Review
in the TCPS:
Proposed Textual Changes for
Concept of Risk in the TCPS**

Prepared by the
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1. Identifying a Need for Procedural and Definitional Change in the TCPS

1.1 Background

The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*¹ (TCPS) was released in 1998 by Canada's three federal granting agencies: the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC) to govern the ethical conduct of research involving humans within institutions receiving Tri-agency funds. In 2001, the Tri-agencies created the Interagency Advisory Panel on Research Ethics (PRE) to steward the evolution of the TCPS, especially with respect to new research developments and identified² gaps in the original policy statement.

In March 2003, in response to the recognized need to address procedural and definitional issues in the TCPS, PRE created the Sub-group on Procedural Issues for the TCPS (ProGroup). ProGroup's mandate is to provide advice about priorities, methods and mechanisms for identifying gaps and procedural and definitional issues within the TCPS, and to coordinate a response to those issues. ProGroup's approach to its work is consistent with PRE's first principles, which include transparency, community engagement and consultation. Public consultations by ProGroup in 2003 identified the clarification of a definition of risk as one of the research ethics community's top priorities for potential procedural and definitional amendments in the TCPS.

1.2 Introduction

ProGroup's first public consultation took place between December 2005 and March 2006, on its four-part document entitled "Proportionate Approach to Research Ethics Review in the TCPS"³. One section of the consultation report focused on the Concept of Risk in the TCPS. In its report, ProGroup recommended a reconsideration of the terminology of risk as currently discussed in the TCPS. It proposed replacing "risk" by "risk of harm" in order to recognize the varying terminologies used by different research disciplines. ProGroup also proposed taking into account, and provided an illustrative list of, other elements to be considered in the assessment of risk.

2. Purpose of this Paper

The present paper follows from ProGroup's 2006 consultation on the concept of risk in the TCPS, and reflects feedback received from the research ethics community.

In its review of feedback received in response to the public consultation process, ProGroup found there was very little support for a change in terminology from the term "risk" to "risk of harm". Among the reasons given by the large majority of respondents who did not favour a change, the following were cited:

- No obvious value in changing to the new term; nothing to be gained.
- Existing literature uses the term "risk" to encompass probability and magnitude of harm.

¹ <http://pre.ethics.gc.ca/english/policystatement/policystatement.cfm>

² <http://www.pre.ethics.gc.ca/english/workgroups/progroup.cfm>

³ http://www.pre.ethics.gc.ca/english/workgroups/progroup/Consultation_instructions.cfm

- Use of the phrase “risk of harm” does not incorporate it into a discussion of the probability and magnitude of harm i.e. this becomes harm.
- “Risk” is a value laden and normative term and use of “risk of harm’ does not resolve this.
- “Risk” and “harm” are separate issues and should not be combined or used as synonyms.

Respondents who supported the proposed change from “risk” to “risk of harms” indicated this was because the term “risk of harm” appears to have application to a broader range of disciplines. These views however, were in the minority.

Feedback related to proposed elements for consideration in the assessment of risk suggest that some respondents were concerned that the list may be taken as prescriptive rather than illustrative. Others expressed concern about some of the elements proposed in the list such as the scientific rigour, integrity, conflict of interest, privacy and confidentiality.

Some respondents suggested other types of harms to be added to the list of examples proposed by ProGroup. These included reputational risk, negative consequences for third parties (e.g. community well-being, reputation and livelihood), discomforts and inconveniences, social, family and community relationship, personal and cultural identity, feeling of self worth, fear, humiliation, interpersonal trust, and cynicism, self-knowledge and general knowledge, and moral harm.

This paper includes three recommendations: one related to the terminology of risk; one related to a list of elements to be considered when determining risk; and a third that proposes textual additions to the section of the TCPS that specifically deals with minimal risk (Section C).

3. Recommendation 1: Related to Terminology

Based on community response to the first consultation, ProGroup recommends remaining with the term “risk” in the TCPS.

4. Recommendation 2: Related to a List of Elements

Based on community response to the first consultation, and the possibility that a list of elements may be considered as prescriptive rather than as illustrative, ProGroup recommends that a list of elements not be included in the text of the TCPS. ProGroup notes that this would not preclude inclusion of a list as an appendix to the document.

5. Recommendation 3: Related to Proposed Textual Additions

ProGroup feels that the research ethics community could benefit from greater guidance around assessing and categorizing risk. To this end, this paper proposes the addition of new text as a first section to Section C of the TCPS on “Analysis, Balance and Distribution of Harms and Benefits”. As well, an expansion of the current discussion under minimal risk is proposed. It is felt that these modifications will assist in clarifying differences between the terms “risk” and “harm” and in understanding the concept of risk. ProGroup also notes the need to raise awareness related to the identification of risk in some disciplines and methodologies, and therefore, proposes new text to this effect.

Currently the TCPS defines minimal risk in Section C1 on minimal risk in the following manner: “if potential subjects can reasonably be expected to regard the probability and magnitude of

possible harms implied by participation in the research to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research, then the research can be regarded as within the range of minimal risk. Above the threshold of minimal risk, the research warrants a higher degree of scrutiny and greater provision for the protection of the interests of prospective subjects. There is a similar threshold regarding undue or excessive offers of benefit. As an offer of payment in relation to research participation exceeds the normal range of benefits open to the research subject, it is increasingly likely to amount to an undue incentive for participation (see Section 2B).”

The concept of “minimal risk” is generally used to determine whether research is eligible for delegated (expedited) review. A variety of jurisdictions have proposed a number of categorizations of “risk.” Most of these categorizations centre on the determination of **minimal** risk.

No jurisdiction specifies eligibility criteria for proportionate review in a way that is free of ambiguity and uncertainty. Such ambiguity or uncertainty can be a problem in that it leads to variation in the answers that various groups, including various REBs, give to the question. Depending on how the relevant terms and procedures are interpreted, the answers may be different. Moreover, factors other than formal definitions and criteria may influence the willingness of REBs to approve an assessment by less than the full REB.

On the surface, the meaning of “minimal risk” is clear. The exposure of research subjects⁴ to a degree of harm roughly equivalent to what they might expect in the course of daily life is described as “minimal risk.” The term “risk” is used to mean some combination of degree of harm and probability of experiencing it. REBs should have the flexibility to exercise their good judgment as to the particular circumstance of research so that appropriate mitigating measures are taken, ensuring full and informed consent...etc. REBs should also monitor ongoing research for potential changes in risks as part of the continuing ethics review of research.

The attempt to define “risk” combines the probability of harm and the magnitude of harm, and applies the word “minimal” to both. It implies, that **by definition**, harms “ordinarily encountered in daily life” are normally encountered by everyone. Finally, it does not distinguish between harm that is transient, such as an emotional but temporary reaction to survey questions, and harm that is longer lasting, such as the loss of reputation following a breach of confidentiality.

REBs and researchers are encouraged to adopt and maintain a subject-centered perspective in their respective discussions and considerations of risk associated with research. Doing so enables the estimation of level of risk to reflect the manner in which the risk is perceived by the research participant and/or broader society. This perspective is also a crucial element related to the manner in which participants are informed of risks as part of the informed consent process.

REBs assessment of risks for specific populations necessitates that the REB understands the role of the culture, values and beliefs of the populations to be studied as well as any guidelines that exist for conducting research with these populations. Furthermore, risk may be perceived differently by different groups in the population and as a consequence, this needs to be taken into account by REBs.

5.1 Proposed Textual Addition to Section C: Analysis, Balance and Distribution of Harms and Benefits (page 1.5 of the TCPS)

The following underlined text is proposed as a preamble to the existing text under the current title “Analysis, Balance and Distribution of Harms and Benefits.” This is followed by other new text added to raise awareness of the concept of risk in certain disciplines and methodologies.

⁴ For the purpose of this paper, and while recognizing that some disciplines refer to research “subject” rather than research “participant,” the authors have opted to use the term “subject,” to be consistent with its current use in the TCPS.

Three main considerations are relevant to the assessment and categorization of risks to research subjects (and also possible risks to third parties, collectivities and institutions or organizations):

- The nature of the harm
- The magnitude or seriousness of the harm or detriment
- The probability of occurrence of the harm

An explanation of “risk” should clarify the distinction between risk as a probability of harm and risk as a magnitude of harm. For example, the various kinds of harms that a subject might incur, the likelihood of subjects actually incurring harms, and the available methods of ameliorating the harms all need to be considered. Research in certain disciplines, such as epidemiology, genetics or sociology or cultural anthropology may present risks that go beyond the individual and may involve the interests of communities, societies or other defined groups.

The standard of minimal risk is commonly defined as follows: if potential subjects can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research, then the research can be regarded as within the range of minimal risk. Above the threshold of minimal risk, the research warrants a higher degree of scrutiny and greater provision for the protection of the interests of prospective subjects. There is a similar threshold regarding undue or excessive offers of benefit. As an offer of payment in relation to research participation exceeds the normal range of benefits open to the research subject, it is increasingly likely to amount to an undue incentive for participation (see Section 2B).

Certain accepted research paradigms bring inherent limitations to the prior identification of risk. For example, in research in the social sciences in which emergent design is employed, the manner in which the study will proceed will be known only as the study unfolds. As a consequence, the researchers cannot describe all aspects of the study to subjects at the outset as part of the informed consent process, because the researchers cannot know with certainty how the research will proceed. The nature and extent of risks associated with the study is one aspect that may not yet be known. However, it would be incumbent upon a researcher using this paradigm to present to the subject, as soon as it becomes known, any information that could affect the subject’s decision to continue his/her participation in the study.

In addition, the practice of withholding full information about the study purpose at the outset is common in certain disciplines (e.g. social psychology), and is known as deception or non-disclosure. This practice can make it difficult—or even impossible—for subjects to make a personal determination of risk. Researchers explain this practice by saying that, if research subjects were to be fully informed about all aspects of the study at the outset, their behaviour would be influenced. The validity of the data could be suspect, but in undetermined ways, and thus the data found to be unusable. In these cases, the REB is responsible for making the risk determination on behalf of the research subject, and the researchers are obligated to provide a full debriefing after the fact, and to give subjects the opportunity to withdraw their data.

5.2 Further Textual Additions to Section C1. on Minimal risk; relating to risk in clinical research (Paragraphs 2-4)

ProGroup also holds the view that more interpretive guidance could be beneficial to REBs and researchers in the discussion related to the special issues raised by the concept of minimal risk in clinical research (i.e. Section C1, paragraphs 3-4). The additional text proposed for this section is underlined.

In some areas of treatment (for example, surgery, chemotherapy or radiation therapy), the treatments themselves are known to pose considerable risks of harm. This allows research on therapeutic options to proceed for person for whom there are no other treatment options available. Such therapeutic risks may be regarded as within the range of minimal risks for patient-subjects, since they are inherent in the treatment that the patient will be undergoing as a part of his or her current everyday life...Hence, the idea that considerable anticipated therapeutic risks might also be within the range of minimal risks extends to the therapies in the trial.

This consideration does not apply to non-therapeutic risks, which arise from actions that go beyond the needs of the subject as a patient, and that are incurred only for the needs of the research. REBs should be sensitive to this distinction for all research projects. They should recognize the need to minimize harms, and to ensure that these harms are proportionate to the benefits that might be expected from the knowledge gained from the study. For projects that involve both therapeutic and non-therapeutic risks, the risks that are required for therapy as opposed to research need to be delineated. For these reasons, REBs should be alert to the potential for confusion of therapy and research, and to be mindful of their responsibility to ensure that therapeutic risks and benefits are separated from non-therapeutic risks and benefits to subjects. Consistent with their commitment to research ethics education, REBs should assist clinician-researchers wherever possible, in clarifying this distinction in their application, protocol and materials for the subjects.