
**Proportionate Approach to Research Ethics Review in
the TCPS:
Proposed Textual Changes
for Delegated Ethics Review**

Prepared by

**The Subgroup on Procedural Issues for the TCPS (ProGroup):
A Working Committee of
The Interagency Advisory Panel on Research Ethics (PRE)**

Members

Judith Abbott
Michel Bergeron (*Co-Chair*)
Susan Hoddinott
Dr. Patrick O'Neill
Heather Sampson
Dr. Janice Singer
Dr. Susan Sykes (*Co-Chair*)

Secretariat on Research Ethics

Hanan Abdel-Akher



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**Interagency Advisory Panel and
Secretariat on Research Ethics**

350 Albert Street

Ottawa Canada K1A 1H5

Tel.: 613-996-0072

Fax: 613-996-7117

E-mail: secretariat@pre.ethics.gc.ca

www.pre.ethics.gc.ca

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*The Panel and Secretariat welcome your comments:
reports@pre.ethics.gc.ca*

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1. Introduction

In the first public consultation¹ (Dec. 05 – March 06), ProGroup², a working committee of the Interagency Advisory Panel on Research Ethics (PRE) proposed a delegated authority framework and delegated review process as a replacement for the current terminology and departmental and expedited review processes in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS). A large majority of respondents from the consultation supported the proposed new terminology and process. In fact, a number indicated that a similar process was already in place at their institutions. Among the supportive comments there was recognition that the proposed delegated review process would:

- Recognize existing REB practices.
- Permit more efficient ethics review of minimal risk research.
- Ensure more effective use of resources.
- Improve accountability to the REB.
- Reduce the need for an increase in numbers of REBs.
- Offer consistency within an institution because of the direct link to the REB.
- Ensure institution-wide compliance with Tri-agency Memorandum of Understanding (MOU)³.

Very few respondents to the consultation opposed the proposed changes in terminology and procedure in total. However, many respondents who provided support for the proposed changes, also offered constructive advice and suggestions on elements that should be included in written guidance documents for delegated ethics review.

In developing the proposed textual changes, the authors were mindful of the following considerations:

- Full REB review must remain the default for research deemed to be more than minimal risk.
- Delegation of ethics review⁴ by the REB should be based on a priori guidelines and procedures.
- Delegated ethics review should apply the same level of care and consideration of ethical issues as full board review.
- The REB is responsible for all ethics review within its jurisdiction and delegated reviewer(s) are accountable to the full REB.

¹ http://www.pre.ethics.gc.ca/english/workgroups/progroup/Consultation_instructions.cfm

² ProGroup was created by PRE in 2003 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.

³ The Memorandum of Understanding on the roles and responsibilities in the management of federal grants and awards (MOU) found at http://www.nserc.gc.ca/institution/mou_e.htm

⁴ For the purposes of this document, the terms “ethics review” includes the assessment of the ethics of the proposed research and its subsequent approval or non-approval.

- Delegated review must comply with all applicable laws, regulations and other requirements.
- The process of delegated review may vary from institution to institution depending upon the experience and expertise available.

2. Summary of Proposed Textual Changes

Based on the community input and feedback in the first consultation, this paper proposes changes to relevant text in the TCPS. A summary overview of the implementation of the proportionate approach to ethics review is provided below followed by a table that outlines the proposed textual changes to the TCPS (second column) compared to the current text in the TCPS (first column).

Summary of proposed textual changes:

Principle: Proportionate Approach

TCPS Article 1.6: The REB should adopt a proportionate approach to ethics review based on the general principle that as the risk to participants increases, so should the care and breadth of expertise involved in assessing the research.

Framework: Delegated Ethics Review

The organizational policies, guidelines and procedures relating to delegated ethics review may include, but need not be limited to, the following:

- Delegation of ethics review by the REB which otherwise is the default.
- Process by which the delegated reviewer(s) is accountable and reports to the REB.
- Criteria for types of research eligible for ethics review by delegated review.
- Process for REB maintaining oversight and consistency in delegated ethics review.
- Roles and responsibilities of the REB, delegated reviewer(s) and research ethics administration professionals.
- Credentials of delegated reviewer(s).

Process: Delegated Review

The ethics review of research involving humans delegated by the full REB to an individual or individuals

D. Review Procedures – Pages 1.7/1.8 of the TCPS

Column 1 Current Text in the TCPS	Column 2 Proposed New Text
D1. A Proportionate Approach to Ethics Assessment	D1. A Proportionate Approach to Ethics Assessment
Article 1.6 The REB should adopt a proportionate approach based on the general principle that the more invasive the research, the greater should be the care in assessing the research.	Article 1.6 The REB should adopt a proportionate approach <u>to ethics review</u> based on the general principle that <u>the more invasive the research, as the risk to participants increases, so should the greater should be the care the scrutiny in assessing the</u>

	<p><u>research and the breadth of expertise involved in the review process.</u></p>
<p>The concept of proportionate review gives practical expression to the general principle that, especially in the context of limited resources, the more potentially invasive or harmful is the proposed and ongoing research, the greater should be the care in its review. While all research must be reviewed adequately, proportionate review is intended to reserve most intensive scrutiny, and correspondingly more protection, for the most ethically challenging research.</p>	<p>The concept of proportionate review gives practical expression to the general principle that, especially in the context of limited resources, the more potentially invasive or harmful the proposed and ongoing research, the greater should be the care in its review <u>the more scrutiny and expertise should be applied to the ethics review process.</u> While all research must be reviewed adequately, proportionate review is intended to reserve <u>direct the most</u> intensive scrutiny, and correspondingly more <u>the most</u> protection, for the most ethically challenging <u>or high risk</u> research.</p>
<p>Potential harms are usually understood in relation to risks, which are defined in terms of the magnitude of a harm and the probability of its occurrence. Both potential harms and benefits may span the spectrum from minimal through significant to substantial. A proportionate approach to ethics review thus starts with an assessment, primarily from the viewpoint of the potential subjects, of the character, magnitude and probability of potential harms inherent in the research. The concept of minimum risk provides a foundation for proportionate review.</p>	<p>Potential harms are usually understood in relation to risks, which are defined in terms of the magnitude of a harm and the probability of its occurrence. Both potential harms and benefits may span the spectrum from minimal through significant to substantial. <u>Risks can be unknown in some cases such as the application of new research methods.</u> A proportionate approach to ethics review thus starts with an assessment, primarily from the viewpoint of the potential subjects <u>research participants</u>, of the character, magnitude and probability of potential harms inherent in the research. The concept of minimum risk provides a foundation for proportionate review.</p>
<p>In practice, proportionate review implies different levels of REB review for different research proposals. The following approach to proportionate review is offered for the consideration of research institutions and universities. It envisages three levels of review, each linked to the other through formal authorization by the institution, as well as by accountability through the REB to the institution's authorities. The three levels proposed are:</p> <ul style="list-style-type: none"> • Full REB review; • Expedited REB review by an individual or subgroup of the REB; and • Departmental-level review of undergraduate projects carried out within formal course requirements. 	<p>In practice, proportionate review implies different levels of approaches to REB review <u>for different research proposals depending upon the level of risk.</u> It supports two levels of review, each linked through formal <u>accountability to the REB.</u> The following approach to proportionate review is offered for the consideration of research institutions and universities. It envisages three levels of review, each linked to the other through formal authorization by the institution, as well as by accountability through the REB to the institution's authorities. The three levels proposed are:-</p> <p><u>The two levels proposed are:</u></p> <ul style="list-style-type: none"> • <u>Full REB review; and</u> • <u>Expedited REB review by an individual or subgroup of the REB; and</u> • <u>Departmental level review of</u>

	<p><u>undergraduate projects carried out within formal course requirements, Delegated REB review in which the (full) REB delegates ethics review to an individual or individuals.</u></p>
<p>Full review by an REB should be the default requirement for all research involving human subjects unless the institution decides to authorize expedited review based primarily on the harms that are expected to arise from the research. For example, the institution may decide that categories of research that are confidently expected to involve minimal risk may be approved by the chair or another designated member or a subcommittee of the REB. Examples of such categories of expedited REB review might include:</p> <ul style="list-style-type: none"> • Research protocols that involve no more than minimal risk; • Annual renewals of approved projects in which there has been little or no change in the ongoing research; • Research involving review of patient records by hospital personnel; or • Affirmations that conditions laid down by the REB as a condition of approval have been met. <p>The possibility of departmental level review for projects that are carried out by undergraduate students as part of their course work has been discussed above (see Section 1, B3).</p>	<p>Full review by an REB <u>Ethics review by the full REB</u> should be the default requirement for all research involving humans subjects unless the institution decides to authorize expedite review <u>However, an REB may authorize, with the support of its institution, delegated ethics review</u> based primarily on the harms that are expected to arise from the research. <u>In delegating its review process, the REB should carefully select delegated reviewer(s).</u> For example, the institution <u>the REB</u> may decide that its chair or another individual or individuals (i.e., delegated reviewer) may review and approve categories of research that are confidently expected to involve minimal risk may be approved by the chair or another designated member or a subcommittee of the REB. Examples of such categories of expedited <u>delegated</u> REB review might include:</p> <ul style="list-style-type: none"> • research protocols that involves no more than minimal risk, • <u>minimal risk changes to approved research,</u> • <u>annual renewals of approved research, projects in which there has been little or no change in the ongoing research</u> • <u>evidence that requirements laid down by the REB have been met.</u> • Research involving review of patient records by hospital personnel; or • Affirmations that conditions laid down by the REB as a condition of approval have been met. <p>The possibility of departmental level review for projects that are carried out by undergraduate students as part of their course work has been discussed above (see Section 1, B3).</p>
<p>An institution that decides to authorize expedited REB review mechanisms, either within the REB structure or through departments (see Section 1, B3), must require that such approvals be reported in appropriate</p>	<p>An institution that <u>An REB</u> that decides to authorize expedited REB review mechanisms either within the REB structure, or through departments (see Section 1, B3); <u>a delegated review process</u> must require that <u>such</u></p>

<p>ways to the full REB, permitting the REB to maintain surveillance over the decisions made on its behalf. Principles of accountability require that, regardless of the review strategy, the REB continue to be responsible for the ethics of all research involving human subjects that is carried out within the institution.</p>	<p>approvals <u>the actions and decisions of the delegated reviewer(s) be formally reported in appropriate ways to the full REB in a timely and appropriate manner, thus, permitting the REB to maintain surveillance over the decisions made on its behalf. REBs retain the authority to accept the report as presented or to request a more rigorous review process. It is imperative that delegated reviewer(s) be accountable to the full REB. With the support of their institutions, REBs may develop their own mechanisms under which delegation of ethics review and the associated reporting process will occur.</u></p> <p>Principles of accountability require that, regardless of the review strategy, the REB continue to be, <u>The REB is ultimately responsible for the ethics approval of all research involving humans subjects that is carried out within the institution under its jurisdiction.</u></p>
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