Consultation

Refinements to the Proportionate Approach to Research Ethics Review in the TCPS

December 2005

Interagency Advisory Panel on Research Ethics

Working Committee on Procedural Issues for the TCPS (ProGroup)

Government of Canada | Gouvernement du Canada

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Government of Canada
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Interagency Advisory Panel on Research Ethics
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December 2005

Dear Colleagues:

Re: A Season of Consultations: Engaging Your Voice in the Evolution of the TCPS

The Interagency Advisory Panel on Research Ethics (PRE) and Secretariat on Research Ethics are pleased to announce a call for comments on the first of three documents on which we seek community input for potential amendments to the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (*TCPS).

This letter reproduces key information from PRE's website about its Season of Consultations http://www.pre.ethics.gc.ca/english/consultations.cfm .

What: PRE invites you to help shape the future of the TCPS by taking part in a Season of Consultations. The consultations feature analysis, proposals and questions from PRE's interdisciplinary Working Committees on three documents concerning potential changes to the TCPS.

When: Though other PRE consultations will follow, the consultations on these documents run from late 2005 through the spring of 2006. PRE is sequencing input on the three documents to afford the community an opportunity to participate in each or all of the consultation periods. Target dates are noted below, including a consultation that has just opened.

Who: This is an open public consultation. Research ethics boards members, universities and research institutions, administrators, researchers, research participants, ethicists, analysts, policy makers, TCPS users and other colleagues are all encouraged to participate.

How: Each consultation includes:

- ✓ a call for the submission of written comments on
- ✓ a 30 page consultation document during
- ✓ a 60-90 day period for commentary, and
- ✓ instructions on how to forward comments.

Why: The Canadian Institutes for Health Research, the Natural Sciences and Engineering Research Council of Canada, and the Social Sciences and Humanities Research Council of Canada, have created PRE to provide them with independent and interdisciplinary advice on the evolution of the TCPS. PRE and the TCPS need the diverse expertise, experience, views, and voices of the TCPS user community. PRE committed itself early in its existence to a set of First Principles—implemented by public process mechanisms—to develop its advice based on inclusive, interactive, multidisciplinary, consultative and transparent process.

Engaging voices of a diverse community will not always ensure consensus on leading challenges to the TCPS. Democracy makes no such guarantees. Still, PRE is convinced that such engagement affords TCPS users an important opportunity to contribute—by analysis, debate and written commentary—to issues and answers for strengthening the TCPS.

Consultation Documents and Periods: Current and Forthcoming

PRE has asked its Working Committees to explore leading TCPS issues through community consultations, as part of the process of developing and refining recommendations for PRE's advice to the Agencies.

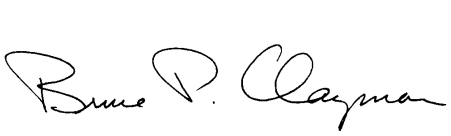
> **Refining the Proportionate Approach to Research Ethics Review in the TCPS**: Calling for comments, from 22 December 2005 – 6 March 2006, on a discussion document for shaping working recommendations for potential changes related to definitional and procedural issues in the TCPS. Conducted by PRE's Working Committee on Procedural Issues for the TCPS (ProGroup). http://www.pre.ethics.gc.ca/english/workgroups/progroup/Consultation_instructions.cfm
>
> **Privacy and Confidentiality in TCPS Social Sciences and Humanities Research:** Beginning in the winter of 2006**,** a 60-day consultation to seek community input on a consultation document that will shape working recommendations for potential changes to the TCPS. Conducted by PRE's Social Sciences and Humanities Research Ethics Special Working Committee (SSHWC).
>
> **The Duty to Share Information in Clinical Trials: Working Recommendations for the TCPS:** Beginning in the winter of 2006, a 90-day consultation on draft recommendations for textual changes to the TCPS. Conducted by PRE's Clinical Trial Information Working Committee (CTI).

Contact: For questions on the consultation process or to order copies of a consultation document, please contact PRE's supporting Secretariat on Research Ethics: secretariat@pre.ethics.gc.ca; 613.996.0072; visit PRE on the web at www.pre.ethics.gc.ca.

To subscribe to information on consultations, publications, TCPS amendments, etc., visit our updated subscription page, and ensure that we have your name and contact information.

We thank you in advance for considering this opportunity to comment, and look forward to receiving your feedback over the next months. In the meantime, we wish you the best for the upcoming season.

Cordially,



Bruce P. Clayman
Chair
Interagency Advisory Panel on Research Ethics

Derek J. Jones
Executive Director
Interagency Secretariat on Research Ethics

An Open Invitation For Comments on a Discussion Paper:

"Refinements to the Proportionate Approach to Research Ethics Review in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS)"

Consultation Open from 22 December 2005 to 6 March 2006

ProGroup, a working committee of the Interagency Advisory Panel on Research Ethics (PRE)[1], addresses procedural and related definitional issues in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS). Further to PRE's invitation of 22 December 2005, ProGroup welcomes comments on its Discussion Paper entitled *Refinements to the Proportionate Approach to Research Ethics Review in the TCPS*. The Paper presents suggestions for changes and areas of development in the TCPS related to the definition of "research" involving humans, proportionate approach to research ethics review and related issues. It also addresses the use of other elements beyond "risk" in making decisions on the level of research ethics review. These were identified in 2003 public consultations as priority areas of concern to the research ethics community.

The results of the consultation on this Discussion Paper will lead to proposed textual recommendations for the TCPS, which will be shared for community input later in 2006.

How to Submit Your Comments

To facilitate the processing of community input, an on-line form for responses has been created. It provides ample space for both specific responses and general comments on areas addressed in the Discussion Paper. Comments may also be submitted via fax or regular mail. The links to the Discussion Paper and the on-line consultation tool, as well as the contact information are provided below. Paper copies of the Discussion Paper are available upon request through Secretariat@pre.ethics.gc.ca.

Please make your comments and suggestions as specific as possible. Examples and evidence supporting the point(s) being made should be referenced in your comments and/or copies of supporting documentation provided if possible.

Finally, we wish to engage as many members of the community as possible in this consultation process, and as such, we encourage you to share these documents with others who may be interested in responding.

Please remember that the closing date for the submission of comments is Monday 6 March 2006.

ProGroup and PRE would like to thank you in advance for taking the time to respond to this consultation.

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[1] The Interagency Advisory Panel and Secretariat on Research Ethics (PRE/SRE) was created by 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 provide independent and interdisciplinary advice to these three agencies on the interpretation, evolution and use of the TCPS.

Refinements to
the Proportionate Approach to Research Ethics Review in the TCPS
A Discussion Paper

Prepared by:

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

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Hanan Abdel-Akher

December 2005

For Consultation Purposes:
(22 December 2005 to 6 March 2006)
Comments to be submitted on-line at
https://media6.magma.ca/www.pre.ethics.gc.ca/english/consultation/consultation.cfm

Comments can also be submitted to:
Secretariat on Research Ethics
350 Albert Street Ottawa ON Canada K1A 1H5
Fax: (613)996-7117 OR ProGroup@pre.ethics.gc.ca

The content of and views expressed in this discussion paper are those of members of ProGroup, and do not necessarily reflect those of the Interagency Advisory Panel or Secretariat on Research Ethics. This document is a work in progress, developed for the purpose of consulting on the working recommendations regarding some of the priority procedural and definitional issues in the TCPS.

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Executive Summary

The defining features of research are often considered to be the use of accepted scientific methods that assure the validity and generalizability of results. It has been observed that the **definition of research in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS)** is not fully inclusive of research in the social sciences and humanities and does not address emerging fields and new methodologies. Thus, the definition of research remains in need of attention and clarification. Yet it remains difficult to find an agreed-upon definition. This discussion paper proposes approaches to a definition of research that are inclusive of new and emerging research methodologies. It proposes that a definition of research should be more encompassing of other elements and terms that are thought to be more inclusive of the range of disciplines and their accepted techniques.

Every institution, community and organization has its own hierarchy of authority and set of processes for research ethics review. The premise that the research ethics board (REB) is the body ultimately responsible for research ethics oversight is maintained by a proposed **"Delegated Review Framework"** that subsumes the more controversial and misunderstood "expedited review." This proposed approach to proportionate review is more than a name change. It offers the opportunity for more mechanisms for ethics review, and it allows entities to facilitate reviews as warranted. Rather than impose a one-size-fits-all dictum on entities, ProGroup, a working committee of the Interagency Advisory Panel on Research Ethics, recommends adoption of a system that accepts the concept of a continuum of both **risk of harm** and **vulnerability** and that lends itself to the same application with regard to the intensity of scrutiny or review.

The current TCPS terminology is often not amenable or sensitive to cultural or institutional variations. The proposed process will consider more variables than just the "risk" of the research and "vulnerable participants". Because those concepts are intertwined, the model provides options for **proportionate review** along a dual continuum. The model is applicable to the social sciences, humanities, natural sciences, engineering and health sciences disciplines and is adaptable to a range of situations, including those in which no direct interaction with subjects occurs (for example, secondary use of identifiable data or observational recordings). This concept is not new, and in fact it reflects the day-to-day practice of many REBs, especially those with large numbers of applications covering a spectrum of research disciplines.

1.0 Identifying a Need for Procedural and Definitional Change to the TCPS

1.1 Introduction

Soon after the 1998 release of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS), individuals and groups responsible for the application of the TCPS at the institutional level identified substantive, procedural and definitional issues that required attention. These issues have contributed to confusion and uncertainty for Research Ethics Boards (REBs) as they interpret and apply the TCPS during the research ethics review process. A similar experience has been reported by many researchers from various disciplines who also need to work within, and apply, the TCPS in the course of their research ethics applications to REBs.

Moreover, the application of the TCPS has been expanded beyond the traditional academic and scholarly spheres—that is, beyond research traditionally undertaken by researchers in universities and academic teaching hospitals. Since 1998, the TCPS has applied to institutions funded by the Natural Sciences and Engineering Research Council (NSERC), the Social Sciences and Humanities Research Council of Canada (SSHRC), and the Canadian Institutes of Health Research (CIHR), hereinafter referred to as "the Agencies." This means that the TCPS extends to **all** research involving humans in institutions that receive funding from the Agencies. The TCPS has since been accepted internationally as the Canadian standard for ethical review of research involving humans and by many Canadian institutions and organizations not obligated to use it. Although these latter organizations are not within the jurisdiction of the Agencies, it is important to recognize the far-reaching and standard-setting impact of the TCPS. As a result, the document no longer has only a strict academic or scholarly application.

Since its creation in 2001 by the Agencies, the Interagency Advisory Panel on Research Ethics (PRE) has had a mandate to steward the evolution of the TCPS. In March 2003, in response to the recognized need to address procedural and definitional issues, PRE created the Sub-group on Procedural Issues for the TCPS (ProGroup). ProGroup was mandated 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 work is based on PRE's first principles, which include transparency, community engagement and consultation. This discussion paper represents the culmination of ProGroup's work on one of the areas that a public consultation process identified as requiring its immediate attention: Proportionate Review of the Ethics of Research Involving Humans. This discussion paper was

produced, in part, with the assistance of a Virtual Scholar (VS)[1] and includes a review of national and international academic and policy literature (see Appendix 1 of this discussion paper for a list of sentinel resources).

1.2 Objectives, Intent and Focus

The TCPS is intended to assist members of REBs, researchers, research ethics administrators and research subjects[2] to understand and apply definitions and procedures that relate to the ethics review process.

This discussion paper (also referred to as "paper" in this document) serves a number of objectives:

1) It provides a broader understanding of, and use for, the term "research," recognizing that this term is imprecise and that its definition and the activities that fall under "research" vary across disciplines and institutions.
2) It examines key definitional and procedural issues concerning the proportionate approach in research ethics review and related elements:

    a. Does the activity require research ethics review?
    b. Which level of research ethics review should be used?

3) It directs the focus of the decision on the level and mechanics of the review process away from the dichotomy of less-than-minimal risk versus greater-than-minimal risk to a continuum of risk of harms encompassing many factors. This shift introduces the concept of the relationship between risk of harm and vulnerability of subjects as a key determinant in the level and mechanics of the research ethics review process.

[1] ProGroup recognizes the work of the Virtual Scholar, Dr. Michael Yeo of Laurentian University, conducted in support of ProGroup's work in the area of proportionate review.

[2] For the purposes of this document, the authors have opted to use the term "subject" rather than "participant," to be consistent with the TCPS.

2.0 Toward an Understanding of Research Involving Humans

The term "research," with regard to research involving humans, has been found to be neither precise nor inclusive. It is, in fact, open to significant interpretive variation regarding the activities that require research ethics review. Such uncertainty is problematic, in that it leads to variations in the application of the definition by those involved in the ethics review process, including REBs.

And not just the definition of research involving humans is at issue. The flexibility provided in the TCPS can be regarded as useful because the definition can be applied to a spectrum of disciplines and research methodologies. At the same time, the flexibility can create ambiguity and, as such, has been identified as a source of tension between REBs and researchers. This ambiguity could be reduced in some measure, but it will likely never be eliminated entirely. Moreover, any move to extend the definition of research involving humans to include activities that are currently excluded from research ethics review under the TCPS must be avoided. [See Article 1.1(d).]

Other data-gathering activities involve humans or their records, but do not fit the definition of research on human subjects, and thus do not fall under the requirements for ethics review as defined by the TCPS. In these circumstances, confusion often arises as to whether a requirement for research ethics review should be applied. However, care must be taken to ensure that the mandate of the REB is not inappropriately extended to areas in which the REB would not normally be seen to have jurisdiction (called "research ethics drift").

2.1 How the TCPS Addresses the Definition of "Research"

The TCPS defines research as involving "a systematic investigation to establish facts, principles or generalizable knowledge" (TCPS page 1.1). Article 1.1(a) of the TCPS says

> all research that involves living human subjects requires review and approval by an REB in accordance with this Policy Statement, before the research is started. . . .

For research involving secondary use of data, Article 3.3 indicates that REB approval is required for the use of identifiable information from a person's records. However, in some disciplines this does not restrict the need for approval only to records of living persons e.g. use of medical records. In some jurisdictions, the requirement for REB approval for the use of identifiable secondary data is embedded in privacy legislation. Article 1.1 excludes some specific information from review:

- research about a living individual involved in the public arena, or about an artist, based exclusively on publicly available information, documents, records, works, performances, archival materials or third-party interviews, is not required to undergo ethics review. Such research only requires ethics review if the subject is approached directly for interviews or for access to private papers, and then only to ensure that such approaches are conducted according to professional protocols and to Article 2.3 of this policy [TCPS Article 1.1(c)]

and

- quality assurance studies, performance reviews or testing within normal educational requirements should also not be subject to REB review. [TCPS Article 1.1(d)].

The TCPS does not define the activities in Article 1.1(d), but it does elaborate as follows:

> Article 1.1(d) indicates that studies related directly to assessing the performance of an organization or its employees or students, within the mandate of the organization or according to the terms and conditions of employment or training, should also not be subject to REB review. However, performance review or studies that contain an element of research in addition to assessment may need ethics review. (TCPS, page 1.2).

The TCPS also indicates that "the opinion of the REB should be sought whenever there is any doubt about the applicability of this Policy to a particular research project" (TCPS page 1.2) and provides, in Appendix 1, areas of research in which the REB should at least be consulted. In anticipation of these enquiries, to facilitate communication and to reduce arbitrary and ad hoc decision-making, this discussion paper reinforces the expectation that REBs publish guidelines applicable to their institution.

2.2 A Closer Look at Other Definitions of Research Involving Humans

The research community (research subjects, researchers, REBs and institutions) may be better served by revising the current definition provided in the TCPS to recognize various disciplines and their existing

and emerging research modalities (TCPS Section C, page i.5). To protect research subjects, institutions through their REBs must require ethics review of activities involving humans or their data when those activities have a component of research. Section 2.1 of this paper addressed the definition of research from the perspective of the TCPS mandate. However, a consideration of definitions of research from other authorities is informative, as is a consideration of such definitions from a variety of disciplines. To that end, this paper provides a set of definitions of research that may be considered representative of definitions from both the social sciences and humanities disciplines, as well as from the biomedical disciplines. These definitions are presented in Appendix 1 of this paper.

It should be noted that, although most published definitions of research come from the biomedical field or from other positivist-based research paradigms, even the pertinent research ethics literature lacks agreement about the elements that characterize "research." A consideration of the social sciences, humanities and engineering literature on research ethics indicates that, although the disciplines all use the term, few examples of a definition of research are available. Moreover, although professional organizations in the social sciences include the term "research" within their codes of ethical conduct, they do not provide a definition.

2.3 Putting Definitions into Practice

Definitions of research vary in interpretation and breadth of application. Further, a number of common elements can be identified in the definitions presented in Appendix 1. Specifically:

- information is collected by means of accepted scientific methods, and
- information collected will develop or contribute to generalizable knowledge.

Rather than clarify what is meant by "research," these elements provide additional challenges. The reliance on the term "accepted scientific methods" is both limited and limiting, because it suggests a lack of recognition of other available research methodologies and of new and emergent techniques. The absence of recognition of other methods risks the marginalization of those methods by REBs that believe they must rely on and adhere to rigid and historic definitions of research.

Similarly, the terms "generalizability" and "generalizable" more often have utility and meaning in research that tends to be hypothesis-driven and uses a traditional statistical perspective. These terms may not be sufficiently flexible when transferred to a broader context that includes humanities and

social sciences activities in which research does not necessarily rely on hypothesis testing. Moreover, the terms may not be a good fit for activities and methodologies that use the data collected to inform or direct changes in policy or professional practice (for example, program evaluation, participatory action research), or to test a hypothesis or procedure that may eventually lead to further research that may answer a specific question related to an existing body of knowledge (for example, pilot research).

For these reasons, this paper does not recommend perpetuating the more traditional statistical perspective of the meaning of "generalizable" (for example, sufficient representation of a sample so that the results can be applied more broadly to a population). Rather, this paper advocates for a broader interpretation involving various paradigms in which all seek to develop knowledge that informs humanity beyond the specific situation in which the work was conducted. For example, interviewing a group of first-time mothers about their experiences during a time of crisis can expand our understanding of what it is to be human.

This discussion paper therefore recommends an expansion to the definition of research, from sole reliance on "accepted scientific methods" and "generalizable" to more encompassing statements including this terminology:

- traditional or emergent methodologies and techniques that are accepted as characteristic of the specific discipline, and

- contribution or addition to a body of knowledge, or obtaining or confirming knowledge, which includes the expectation that the knowledge will be disseminated.

2.4 Ambiguity in Requirements for Research Ethics Review

In most instances, determining whether an activity is research involving human subjects will not be problematic, and general agreement among REBs is likely (for example, interviews with new mothers about their childbirth experiences; focus groups to assess the impact on sibling relationships of participation in team sports; clinical trials to test the efficacy of new drugs; interviews with elderly people regarding their social interactions). However, in other instances in which the purpose of the activity or research is less clear, REBs may differ in their opinions and decisions. This variability may be influenced by their interpretations of the two main components of the definition: "research" and "involving human subjects."

The boundary between certain non-research activities and activities requiring research ethics review is becoming increasingly difficult to distinguish because they both

- employ or include research tools, methods and data collection practices.
- are funded by agencies that traditionally fund research.
- are undertaken by persons or organizations primarily concerned with research.
- are of interest to the broader community, and are published in journals or are presented at conferences.

Examples of activities where boundaries may overlap or appear blurred, ambiguous or contestable with research requiring REB review include these:

a. Interviews with experts or public figures
b. Observational activities
c. Evaluation of therapy and non-validated practices
d. Public health practice, surveillance
e. Audits
f. Monitoring of quality of service
g. Program evaluation
h. Records review
i. Quality assurance, assessment or improvement
j. Resource utilization and cost–benefit analyses

The volume and magnitude of many of these activities are increasing largely because of an increased emphasis on accountability, quality and cost effectiveness. In many instances, these activities are becoming legislatively, organizationally, institutionally or professionally mandated.

The underlying problem is that disagreement arises about which activities should be subject to research ethics review. Also, confusion exists about how to make effective and accurate determinations about which activities should be subject to research ethics review.

The rationale for the exclusion of certain activities appears to be that the activities in question are inherent in the mandate of an organization or are required by law (for example, quality assurance). It is reasonable to make the interpretation that the intended **purpose** of such activities, as distinct from the

potentially similar **methods** that they employ (for example, interviews or surveys), differentiates them from activities that require research ethics review. Many activities involving humans should not be subject to review by an REB even though the ethical issues they pose and the methods they use are similar to those considered by REBs in their review of research activities.

This paper recognizes the value of REBs and researchers working together to develop and publish *a priori* guidelines. These guidelines can build on the TCPS and assist researchers in differentiating between activities that require REB review and those that do not. Guidelines would facilitate consistency and reduce *ad hoc* decision-making on the part of REBs.

3.0 Toward an Understanding of Risk and Vulnerability

This section seeks to clarify issues concerning the determination of processes and guidelines that should apply to **research deemed subject to research ethics review.** In particular, it focuses on issues related to determining the appropriate level of review and on the definition of risk as it relates to that determination.

The concept of "minimal risk" plays several roles in the TCPS beyond determining whether a given activity is eligible for delegated (expedited) review. If the sole focus is on defining minimal risk, then the relationship between the definition of minimal risk and the answer to the question "Is this activity eligible for delegated (expedited) review?" will be missed.

Eligibility criteria for proportionate review are not free of ambiguity and uncertainty. Both can be a problem in that they lead 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.

Although the intent of the TCPS is to provide flexibility in the application of the guidelines to a spectrum of research methods and disciplines, it would be futile to place the burden entirely on the definition of minimal risk. Thus, it may be more promising to move away from minimal risk as the sole determinant of level of ethics review and to instead specify additional criteria for risk or vulnerability, or both, or to describe representative types of activities.

3.1 Considering the Term "Risk"

A number of definitions or categorizations of "risk" have been proposed. Most of these definitions or categorizations centre on the determination of **minimal** risk.

Review of the literature reveals no universally agreed-upon definition for risk; however, most sources refer to a variety of risks, including physical, psychological, social, economic and legal. But these concepts are also subjectively defined. Standards and procedures for ethics review currently distinguish between research that poses minimal risk to research subjects and research that poses more than minimal risk.

The term "risk"—a frequently used concept in biomedical research—is less common in social sciences and humanities research, where "harm" is the more common term. To provide clarity and consistency of use, this paper recommends using the expanded term "risk of harm." That term is relevant to a wider range of research disciplines, research situations and research subjects.

However, the concept of "risk of harm" is value-laden and dependent on context. The value aspect of the concept is apparent when, with regard to "minimal risk," the question "'minimal' according to whom, or by what and whose standards" is asked. In that context, the TCPS offers guidance, in that its definition takes into account "those aspects of his or her everyday life that relate to the research" (Section 1, Part C.C1, paragraph 1). In the absence of this proviso, research with certain groups would be placed beyond the possibility of delegated review because the risk level either could not be assessed or because it would be considered above the minimal-risk threshold.

In assessing potential risk of harm to individuals, the ethics review process considers

- the probability of harm, and
- the magnitude of potential harm.

"Harm" can include the potential for

- physical injury,
- emotional or psychological harm,
- social harm (for example, stigmatization, insurability or employability),
- financial harm,

- intrusion on privacy,
- loss of trust, and
- negative impact of the research results.

On the surface, the meaning of “minimal risk of harm” is clear. The exposure of research subjects to a degree of harm roughly equivalent to what they might expect in the course of daily life or in the course of routine tests and examinations is described as “minimal risk.” The term “risk of harm” is used to mean some combination of degree of harm and probability of experiencing it. However, REBs and researchers seem to have difficulty agreeing on and applying this standard. One reason is that the formal definition is not explicit in several respects.

First, the attempt to define “risk of harm” combines the probability of harm and the magnitude of harm, and applies the word “minimal” to both. Second, it implies, that **by definition,** harms “ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests” 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.

An explanation of “risk of harm” 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 subjects might incur, the likelihood of subjects actually incurring harms, and the available methods of attenuating the harms all need to be considered. Research in certain disciplines, such as epidemiology, genetics or sociology, may present risks that go beyond the individual and may involve the interests of communities, societies or other groups.

The application of any definition of risk must also take into consideration the specifics of the institution whose REB conducts the ethics review process and the context of that institution. For example, it may be safer to conduct certain activities at one place rather than at another. Specifically, a project that is considered to pose “minimal risk” in one setting may be considered to pose a greater or unacceptable level of risk in another setting.

3.2 Considering Risk of Harms

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):

i) The magnitude or seriousness of the harm or detriment (risk of harm)
ii) The probability of occurrence of the harm
iii) The vulnerability of the research subjects

The proportionate approach to research ethics review is premised on the principle that the level of ethics review and the care in assessing the research should be in proportion to the risks of harm (in a very broad context) associated with the conduct of the research.

The assessment of risk of harm is one factor in a variety of determinations concerning research ethics, including these:

- The level at which the review should be conducted
- The requirements that will or should be imposed on the research with respect to:
    - risk minimization
    - peer review
    - consent (waiver)
    - ongoing review and monitoring
- The favorability of the ratio of benefit to harm ("Benefit" includes the perceived value of the research to the subject and also to the development of knowledge or benefit to society.)

The discussion to this point about risk of harm of research to research subjects rests on the assumption that the researcher always provides full information about the study and its known risks to the subjects so that they can make an informed decision about participation—that is, agree to bear the risks, if any, associated with participation in the study. In fact, this is the requirement under the TCPS unless the researcher has been granted an exemption by the REB in circumstances specified by the TCPS.

But what happens in cases in which the subject lacks full information about the study at the outset and thus may be unable to independently assess the level of risks of harm and the balance between them and to consider them in relation to the benefits of participation? In these cases, consent cannot be said to be fully informed.

Certain accepted research paradigms bring inherent limitations to prior full consent. 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. The researchers cannot possibly describe all aspects of the study to subjects at the outset as part of the informed consent process, because the researchers cannot be certain what is going to happen. The nature of this paradigm guarantees that consent at the onset of the research cannot be fully informed. However, it would be incumbent upon a researcher using this paradigm to present to the subject, in a timely manner, information that may affect the subject's decision.

In other cases, as in social psychology research, the practice of withholding full information about the study purpose at the outset is not uncommon. It is known as research involving deception or non-disclosure. This practice can make it difficult—or even impossible—for subjects to make a personal determination of risk of harm. 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-of-harm 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.

The assessment of risk of harm may be controversial with respect to any of these determinations. The assessment of risk of harm should go beyond those described in subsection 3.1 to include other considerations such as these:

- Complexity of the research
- Intrusiveness or invasiveness
- Accountability
- Integrity
- Conflict of interest
- Scientific rigour
- Recruitment
- Privacy and confidentiality
- Researcher experience and expertise
- REB and reviewer experience and expertise

- Sensitivity and nature of the research
- Involvement of special groups or communities

3.3 Considering Vulnerability

Another factor that must be considered is whether the potential research subject is "vulnerable." Part of this consideration should include the persistence of the state of vulnerability. However, an inherent weakness resides in the term "vulnerable person," given that it suggests that a person may be vulnerable or at risk simply because of membership in a group or class that has been previously designated as vulnerable—for example, children or prisoners. Membership in such a group is one factor that must be taken into account when assessing the vulnerability of an individual. In addition, other factors such as age or setting must be considered. Moreover, the presumption that vulnerability is a static state is incorrect: a person may be vulnerable in one circumstance, but not vulnerable in another. REBs and researchers must also avoid a paternalistic attitude when assessing the vulnerability of research subjects or groups.

Consider the case of elderly people. To conclude that elderly people are intrinsically vulnerable is an underestimation of their abilities. Some elderly people may be vulnerable in some situations (those involving their health, for example), but not in others (those involving social interactions).

Another example is research involving minors. In certain types of health research, elevated risks may make children more vulnerable—for example, in research requiring repeated blood sampling. However, in situations in which children are involved in low-risk studies (such as assessment of reading and mathematics instruction strategies), their level of vulnerability and the attendant risks may be negligible or low.

This paper recommends replacing "vulnerable person" by "vulnerability of the person or research subject." Vulnerability reflects reality. It exists along a continuum and is influenced by many factors including (but not limited to)

- Subject capacity (mental, emotional)
- Age
- Wellness or health status
- Institutionalization

- Power relationships
- Gender and gender identity
- Setting and recruitment
- Dependency.

Use of the term “vulnerability” also allows for a more enhanced understanding of risks of harm to research subjects.

4.0 Proportionate Approach to Research Ethics Assessment

TCPS Article 1.6 recommends the adoption of a proportionate approach to research ethics review. This recommendation implies varying levels of REB review for projects with various risk levels.

The options for the research ethics review process described within the TCPS are typical of those found in most regulations, policies or guidance notes:

- Full REB review (default)
- Expedited REB review
- Departmental review (undergraduate projects within formal course requirements)

The term ‘expedited’ review has proven to be quite controversial in the research ethics community and has given rise to numerous debates and to confusion. From the perspective of the researcher, the term creates an expectation - rightly or wrongly - that expedited review will mean a ’speedy’ review with less administrative burden. In some cases, an expedited review process may be viewed as a mechanism simply to reduce REB members’ workload. In fact, the mechanism was created to provide a level of flexibility in the research ethics review process to accommodate review of proposals presenting minimal risk of harm to subjects. Moreover, it allows researchers in certain disciplines to respond to sudden research opportunities that have become available where data collection must begin before the next REB meeting.

Other critical gaps not dealt with explicitly by the discussion of expedited review in the TCPS include but are not limited to:

- Who should conduct expedited review e.g. an individual or a group? And who makes the decision at each institution about the expedited review process?
- What minimum educational background, training, or experience do the reviewers require?
- From where does the person or persons delegated with the responsibility for expedited review draw his/her authority?
- What accountability structure is in place for the person(s) with this responsibility?
- What process efficiencies are implied?

These issues need to be addressed and expanded upon in the TCPS. To avoid confusion with old processes and terminology, this paper introduces a **Delegated Authority Framewor**k and a **Delegated Review Process** (Figure 1). The Delegated Authority Framework describes the relationship that must exist between the REB and those people authorized to conduct ethics reviews on behalf of the REB. The Delegated Review Process describes the act of delegating the review through a process other than that conducted by the full REB.

Figure 1

TERM	**EXPLANATION**
Principle: Proportionate Approach	**TCPS 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.* Proportionate review implies different levels of REB review for different research proposals.
Framework: Delegated Authority	The organizational structure, policies and procedures that determine the delegated review process at a particular institution. • Delegation of authority of REB • Credentials of delegated reviewers • Process of reporting to REB • Eligibility for delegated review
Process: Delegated Review	The act of undertaking a review by a process other than that conducted by the full REB.

4.1 The Framework: Delegated Authority

"Delegated authority" is not a new concept. This framework has evolved and been used effectively by REBs in many Canadian institutions as they apply the principle of proportionate review. Rather than deal with the three potentially disparate review processes currently specified in the TCPS, many institutions have found that formalization of a tiered ethics review structure has enhanced the review process by working towards a consistent application of the TCPS.

When considering expedited review as currently described in the TCPS, it is not clear

- under whose authority the person(s) conducting expedited review should operate
- who has ultimate authority to determine policy
- how the REB formally passes to or confers on an individual or group the authority to act on behalf of the REB.

The authorization of departmental review solely for the purpose of reviewing undergraduate course research is short-sighted and inefficient. Departmental committees can often provide valuable discipline-specific expertise beyond that needed for the review of student research. Utilizing this expertise within a Delegated Authority Framework for review of research proposals that pose minimal or even no harm to non-vulnerable subjects can help heavily burdened REBs.

As proposed, the Delegated Authority Framework would bring all expedited and departmental review processes under the authority of an REB. It should be noted that, to ensure adequate ethics review of research in different disciplines, it may be appropriate to create more than one REB at an institution.

Delegated Authority allows an REB to ensure that all research under its jurisdiction is assessed according to a consistent standard. It also provides the authority for the REB to intervene should the delegated review process need adjustment. The REB maintains high-level (not project-by-project) oversight, but it is ultimately responsible for ensuring that decisions made by delegated review adequately protect the research subjects and reflect the standards of the presiding REB.

An individual or group with delegated authority to act in this regard must have sufficient knowledge of research ethics and be sufficiently experienced with the conduct of the research ethics review process to ensure that research subjects are well protected, that consistent standards are applied, and that all aspects of the ethics review process are addressed. An understanding of, and proven experience in, research ethics review and the methodologies under consideration should be requirements for reviewers working

in a Delegated Authority Framework. These may be provided through formal training or membership on the REB, or both. The responsibility must be formally conveyed by the institution—for example, through the REB terms of reference or some other mechanism.

4.2 The Process: Delegated Review

This discussion paper proposes that the Delegated Review Process is an appropriate replacement for separate departmental and expedited review processes.

An application can be submitted for delegated review when the proposed research meets pre-specified eligibility criteria for this type and method of ethics review. Delegated review would therefore not add additional layers of review, because the entire REB does not have to do a preliminary screening of all protocols. For REBs with a centralized administrative process, people with specialized training would likely do an initial triage to confirm the project's eligibility for delegated review before forwarding the documents to the delegated reviewer or reviewers. Other REBs could have a different process. For example, the researcher could submit the project directly to a delegated reviewer, who would confirm the appropriateness of delegated review before initiating the ethics review process. The delegated reviewer or reviewers will always have the option to seek additional input from other reviewers or to refer a protocol to the full REB if, in the delegated reviewer's judgment, the level of risk of harm associated with the project or the vulnerability of the subjects, or both, exceeds the reviewer's mandate or if additional expertise is required.

Delegated review does not imply a lesser level of care or rigor in the review process than that of a full REB review, as may be implied by the current TCPS term "expedited review."

It is imperative that delegated reviewers be accountable to the primary REB; therefore, delegated review does not compromise institutional accountability. The delegated reviewers must maintain an ongoing and strong link to their REB by regular reporting about their activities and decisions. REBs retain the authority to accept the report as presented or to request a more rigorous review process. Institutions may develop their own mechanisms under which this reporting process will occur.

Delegated review does not imply or create for researchers an expectation of an accelerated timeline for the ethics review process in the way that the term "expedited review" may. Thus, the common REB–investigator conflicts engendered when researchers expect immediate turnaround of their applications are avoided.

4.3 Determining Eligibility for Delegated Review

Whether the option for delegated review is available for a given research project depends on a number of considerations:

- Does the research proposal meet the established pre-determined criteria?
- Does the research proposal pose risks of harm that are at or below a pre-determined threshold?
- Is the research proposal of a type that is specifically referenced in policy guidelines or regulatory documents as not requiring full REB review?
- What is the vulnerability of the research subjects?

Variations in describing minimal risk (whether as a matter of definition or of specified criteria) and the type of research that is eligible for delegated review places many institutions into conflict over how best to proceed. The concept of "minimal risk" is often so vague that, even within a single jurisdiction, significant variation may exist.

This discussion paper advocates a more nuanced approach to proportionate review. Such an approach would provide additional opportunities to assess risk of harm and would include an assessment of the vulnerability of the research subjects.

The interaction of vulnerability and risk of harm will determine the level of ethics review to be applied. The approach is reflected in the chart Concept of Proportionate Review for Research Requiring Research Ethics Board Review (Appendix 2).

An examination of the chart reveals that both risk of harm and vulnerability are concepts that can increase or decrease along a continuum of intensity. The level of the review should be commensurate with the level of risk of harm. Whether the research poses negligible, low or minimal risk of harm to research subjects, ethics review could be conducted through the delegated review process. In research in which risk of harm and vulnerability of subjects are both considered to be negligible, low or minimal, the primary ethical concerns are protection of privacy, confidentiality of each person's data, and free and fully informed consent of the subjects. Delegated review could include (for example):

- research with existing data or secondary use of data.
- research with no direct interaction with subjects (such as observational recording).
- questionnaire studies or interviews with adults on non-sensitive topics.
- questionnaire studies or interviews with children or adolescents on non-sensitive topics[*].
- research with adults, adolescents or children (or a combination) in which the procedures pose negligible, low or minimal risk of harm and those same procedures have previously received REB approval[*].
- research that involves physical manipulation, collection of biologic samples or non-invasive physiologic measurements when these activities pose little or no risk of harm to the subjects.

Conversely, delegated review would not normally be appropriate when:

- the research involves people or groups whose vulnerability could increase their risk by participating in the project. Possibilities include accident victims, people in highly stressful or dangerous situations, children, people who are not legally competent to consent, mentally incompetent people, prisoners, legal wards or therapeutically dependent people. However, an individual should not automatically be considered vulnerable simply because of membership in a group. For example, in the case of children, the REB may agree that some research is acceptable for delegated review if the research carries absolutely no risk of harm[*].
- the research uses highly personal, sensitive or incriminating topics or questions that could cause the subjects physical, social, financial or psychological harms.
- the research manipulates the behaviour of subjects beyond the subjects' range of normal activity or daily life.
- the research uses a level of deception that, had a subject known about it in advance, he or she likely would not have agreed to participate.
- the research withholds *key* information that could influence a subject's decision to participate in the research.

REBs should also be aware that risks of harm may extend beyond the individual subjects alone. For example, communities or groups from which research subjects are recruited may be vulnerable depending on the research questions and the subsequent findings. These possibilities should be considered in the process of deciding the level of review. In certain exceptional cases, where risks of

[*] Subject to presiding legislation

harm or vulnerability of subjects (or both) are significantly high, the REB may decide to involve external experts or consultants in the ethics review process.

5.0 Next Steps

5.1 Continuing the Search for a Definition of Human Research

The intent of this discussion paper was to review and refine the process of proportionate review. The initial steps in the process involved determining what the definition of research with humans should be, and, from that, the requirement for ethics review of research involving humans. The definition of research involving humans in the TCPS is regarded as flexible by some and ambiguous by others. That definition has therefore been identified as a source of tension between REBs and researchers.

Section 2 of the paper reviewed a number of existing and representative definitions from the social sciences and humanities disciplines and the biomedical and health disciplines. The strengths and weakness of those definitions were considered in order to discover features that would be important in a new definition that might be more useful and acceptable to the range of research disciplines involved in research with humans. The definition of research with humans offered by the TCPS served as the framework for this consideration.

This paper recommends no longer relying solely on commonly used definitional terms, including "accepted scientific methods" and "generalizable." Instead, it advocates for an expansion to the use of terms that are thought to be more inclusive of the range of disciplines and their accepted techniques:

- traditional or emergent methodologies and techniques that are accepted as characteristic of the specific discipline, and

- contribution or addition to a body of knowledge, or obtaining or confirming knowledge, which includes the expectation that the knowledge will be disseminated.

Although this paper suggests an expanded definition of research involving humans, it also recognizes that the new definition may not be sufficient to provide the level of assistance REBs and researchers are seeking. In addition to the basic definition, discipline-specific guidance (in the form of interpretive comments) was thought to be critical to helping differentiate the nature of research in various disciplines.

The discussion paper notes that considerable ambiguity exists in applying requirements for ethics review. It also notes that distinguishing between research that requires REB review and research that does not is increasingly difficult because both types of research employ or include similar tools, methods and data collection practices; are funded by agencies that traditionally fund research; are undertaken by people or organizations primarily concerned with research; are of interest to the broader community; and are published in journals or presented at conferences.

As a result, this paper does not offer definitive criteria for identifying which activities involving humans may require research ethics review. However, it does advocate that a distinction should be made between the intended **purpose** of the activity and the **methods** employed (for example, interviews or surveys). The **purpose** should be used to assist REBs in defining the types of activities that will require research ethics review. Section 2 of this paper also emphasizes that REBs and researchers should work together to develop and publish *a priori* guidelines that will assist in differentiating between activities that require REB review and those that do not.

5.2 Moving to the Use of More Meaningful Terms: Risk of Harm and Vulnerability

The term "risk" may not be a term commonly used by researchers in all research disciplines. For clarity and consistency in the TCPS, this discussion paper recommends moving to the term "risk of harm," because that term may be more relevant to, and more easily understood by, a wider range of research disciplines, research situations and research subjects.

This paper recommends against sole reliance on the term "minimal risk," because risk is not a single point, but rather a fluid concept that occurs along a continuum. Further, a review of the literature fails to reveal a universally agreed-upon definition for "minimal risk." This failure may signal a concept that is value-laden and dependent on context. Moreover, an explanation of "risk of harm" must take into account the distinction between risk as a probability of harm and risk as a magnitude of harm. Thus, a project that is considered to pose "minimal risk" in one setting may be considered to pose a greater or an unacceptable level of risk in another setting.

This paper also recommends that an assessment of risk of harm should include other considerations, such as the complexity of the research; intrusiveness and invasiveness; accountability; integrity; conflict of interest; scientific rigour; recruitment; privacy and confidentiality; researcher experience and

expertise; REB and reviewer experience and expertise; sensitivity and nature of the research; and the involvement of special groups and communities.

This paper recommends against use of the term “vulnerable person,” because that term implies vulnerability or risk simply because of membership in a group or class previously designated as vulnerable. Membership is only one factor that must be taken into account when assessing the vulnerability of an individual. Like risk, vulnerability should not be considered to be a static state. An individual may be vulnerable in one circumstance, but not vulnerable in another. This paper emphasizes that REBs and researchers must avoid a paternalistic approach to the assessment of the vulnerability of research subjects or groups. It recommends that researchers and REBs work together to consider other factors contributing to vulnerability.

5.3 Towards a More Streamlined Ethics Review Process: Delegated Authority for Proportionate Review

This paper advocates for a more formalized and consistent approach to proportionate review than that currently described in the TCPS as “expedited review” or “departmental review.” To better meet the needs of REBs and researchers, this paper recommends the use of a Delegated Review Framework and within the framework, a Delegated Review Process.

The paper advocates for a proportionate review process that is flexible and responsive to sudden research opportunities.

The paper provides a detailed description for ethics review that centres on delegated authority. Within the Delegated Review Framework, the REB officially delegates ethics reviews of pre-specified types of research involving humans to an individual or individuals with adequate training and experience to do this work on its behalf. Notably, delegated review does not add additional layers of review because preliminary screening of all protocols is done by an individual or individuals and not by the entire REB. However, the REB retains ultimate responsibility for ensuring that decisions made through the Delegated Review Process adequately protect the research subjects and reflect its standards.

To ensure that the process is fairly and consistently applied, institutions must work with their research communities to identify and communicate to researchers the pre-specified types of research involving humans that can undergo ethics review through a Delegated Review Process. This paper makes recommendations for putting the principle of proportionate review into operation.

Appendix 1: Sentinel Resources and a Representative Sample of Definitions of Research

1.1 Alberta Research Ethics Community Consensus Initiative (ARECCI), 2004 May 10. *Draft Recommendations for Ethics Screening and Review of Research, Program Evaluation, and Quality Assurance or Quality Improvement*.

> For purposes of ethics review, Research, PE, and QA/QA regarding human health and the provision of health services should be distinguished by the original **primary purpose** of the investigation. If the purposes is: A) To contribute to the growing body of knowledge regarding health that is generally accessible through standard search procedures, then the investigation is research; B) To justify the introduction, continuation, elimination, or significant modification of a health program in the Province, a health region, or a service delivery or related organization, then the investigation is Program Evaluation; C) To improve or assess service delivery within the Province, a health region, a service delivery or related organization, or an individual practice, then the investigation is Quality Assurance/Quality Improvement.

1.2 Centre for Research in Art and Design, United Kingdom

The widely accepted definition of research as disciplined inquiry applies equally to research in art and design. The generic characteristics of this kind of inquiry – that research should be accessible, transparent and transferable – are useful criteria for shaping and evaluating research:

- **accessible** – a public activity, open to scrutiny by peers
- **transparent** – clear in its structure, process and outcomes
- **transferable** – useful beyond the specific research project, applicable in principles (if not specifics) to other researchers and research contexts.

1.3 Council for International Organizations of Medical Sciences (CIOMS), 2002, revised. *International Ethical Guidelines for Biomedical Research Involving Human Subjects.* Geneva. http://www.cioms.ch/frame_guidelines_nov_2002.htm

> The term “research” refers to a class of activity designed to develop or contribute to generalizable knowledge. Generalizable knowledge consists of theories, principles or relationships, or the accumulation of information on which they are based, that can be corroborated by accepted scientific methods of observation and inference. In the present context “research” includes both medical and behavioural studies pertaining to human health. Usually “research” is modified by the adjective “biomedical” to indicate its relation to health. . . .

1.4 Department of Health and Human Services (DHHS), National Institutes of Health (NIH). Common Rule, United States, 2001 November 13, revised. *Code of Federal Regulations*. *Title 45, Part 46, Protection of Human Subjects, 5 U.S.C. 301; Sec. 474(a); Stat. 352 (42 U.S.C. 2891-3a).* http://ohsr.od.nih.gov/guidelines/45cfr46.html

> Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. — Subsection A, 46.102(d).

1.5 Health Canada (HC), (Undated). *Research Ethics Board Policies and Procedures: Ethical Review of Research Involving Humans*. http://www.hc-sc.gc.ca/sr-sr/alt_formats/ocs-besc/pdf/procedures.pdf

> Research is an activity designed to test an hypothesis, permit conclusions to be drawn and thereby to develop or contribute to generalizable knowledge. Generalizable knowledge consists of theories, principles or relationships, or the accumulation of information on which they are based, that can be corroborated by accepted scientific methods of observation and inference.

1.6 National Bioethics Advisory Commission (NBAC), United States, 2001. *Ethical and Policy Issues in Research Involving Human Participants, Volume I*. Bethesda, MD.

Federal policy should cover research involving human participants that entails systematic collection or analysis of data with the intent to generate new knowledge.
— p.40

1.7 National Committee for Research Ethics in the Social Sciences and the Humanities (NESH), Norway, 2001. *Guidelines for Research Ethics in the Social Sciences, Law and the Humanities*. http://www.etikkom.no/Engelsk/Publications/NESHguide.

Research is first and foremost a socially organized and systematic search for the most comprehensive knowledge possible. On the one hand, the primary obligation of research is to meet the demand for truth and the internal scholarly standards developed within the research community. On the other hand, research is distinguished by its unique and institutionally guaranteed freedom to seek and to impart new knowledge. Its methodological requirements help to set it apart from *journalism*, while its essential freedom distinguishes it from *consultancy*.
— Introduction

Research seeks new and better insight. Knowledge is an end in itself. It may also be useful in many connections, and contribute to richer lives for many people. But in the long run, research can only be useful if it also seeks knowledge for its own sake.

This demand that knowledge and insight be sought for their own sake points to the most important obligation of research: to seek the truth.
— Section 1

1.8 National Health and Medical Research Council (NHMRC), Australia, 1999. *National Statement on Ethical Conduct in Research Involving Humans.* http://www7.health.gov.au/nhmrc/publications/humans/preamble.htm

There are many definitions of research. These include systematic investigation to establish facts, principles or knowledge and a study of some matter with the objective of obtaining or confirming knowledge. A defining feature of research is the validity of its results. The

knowledge that is generated by research is valid in the sense that what is discovered about the particular facts investigated can be justifiably claimed to be true for all like facts.

1.9 National Health and Medical Research Council (NHMRC), Australia, 2004 December**.** *Review of the National Statement on Ethical Conduct in Research Involving Humans. First Consultation.*

Defining Research. It is difficult to provide a definition of research that will be universally accepted. What this Statement proposes is not a definition by which all must simply abide, but a very useful reference point for institutions in arriving at descriptions of what activities require review by HRECs. Research is original investigation undertaken in order to gain knowledge and understanding and make this widely available. It includes:

- work of direct relevance to the needs of commerce and industry, as well as to the public and voluntary sectors;
- scholarship;
- the invention and generation of new ideas, images, performances and artifacts including design, where these lead to new insights; and
- the use of existing knowledge in experimental development to produce new or substantially improved materials, devices, products, processes, including design and construction.

It excludes routine testing and analysis of materials, components and processes as distinct from the development of new analytical techniques. It also excludes the development of teaching materials that do not embody original research.

1.10 The Arts and Humanities Research Board, United Kingdom.

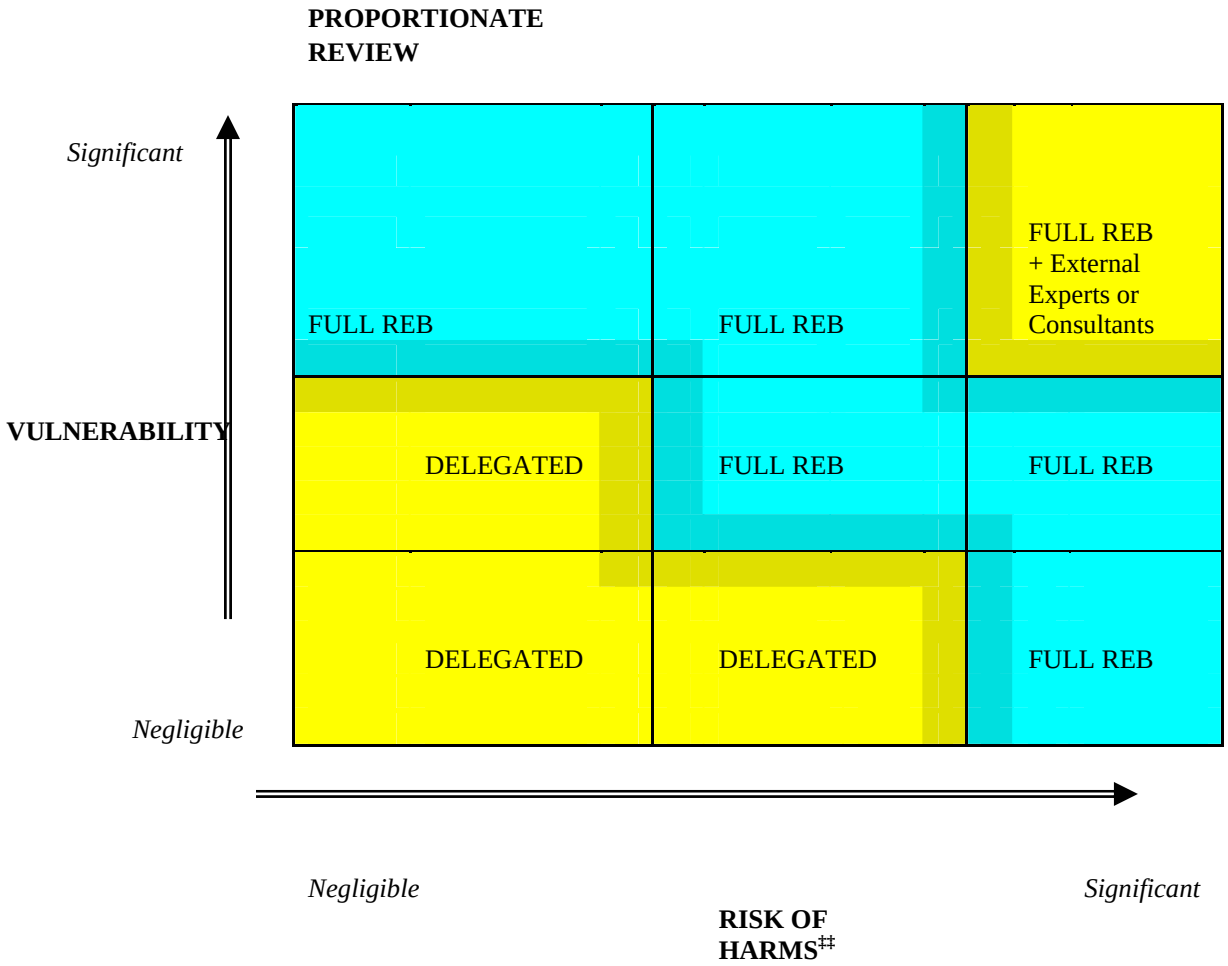
Research is described as a process built around three key features:

- clearly-articulated **research questions** to be addressed through the research, and a related series of objectives which will enable the questions to be explored and answered
- the specification of a **research context** for the questions, and a rationale for why it is important that these particular questions should be answered or explored; this description of context should make clear what other research is being or has been conducted in this area; and what particular contribution this particular project will

make to the advancement of creativity, insights, knowledge and understanding in this area.

- the specification of appropriate **research methods** for addressing and answering the research questions, and a rationale for the use of particular methods.

Appendix 2:
Concept of Proportionate Review for Research Requiring Research Ethics Board Review



‡‡ Benefits harm ratio is an important consideration during ethics review. However, benefits do not usually factor into eligibility for delegated review.

On-line Form to Submit Comments on the Discussion Paper

"Refinements to the Proportionate Approach to Research Ethics Review in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS)"

Consultation Open: 22 December 2005 to 6 March 2006

Please use this form to submit your comments on the Discussion Paper entitled "Refinements to the Proportionate Approach to Research Ethics Review in the TCPS" to ProGroup, a working committee of the Interagency Advisory Panel on Research Ethics (PRE). The purpose of the on-line form is to manage and analyze comments from the research ethics community on the Discussion Paper. You will be presented with a number of specific questions followed by a question calling for more general comments. ProGroup strongly encourages you to provide responses to and comments on both types of questions, and to make these as specific as possible. Examples and evidence supporting any point(s) being made should be referenced and if possible, copies of supporting documents provided to the Secretariat on Research Ethics.

Your responses to the demographic section at the end of the form will shed light on the representation of the feedback received and the level of the outreach of this consultation. Your responses to this consultation will be used for the purpose of this consultation only and not for any other purpose. Any resulting reports will provide aggregate data only unless clearly requested by individuals or organizations to attribute their response(s). Should individual comments be included, they will be presented as anonymous quotations.

To send the form electronically, click on the "Submit Comments" button found at the bottom of this form. You may also print the form and send it by fax to (613) 996-7117 or by regular mail at 350 Albert Street Ottawa ON CANADA K1A 1H5. Regardless of the transmission method you choose, you will receive an acknowledgement of receipt of your submission.

Email:
Please provide your email address to receive an acknowledgement of receipt of your submission.

QUESTIONS

1. Toward an Understanding of Research Involving Humans

Currently, the TCPS (page 1.1) defines research as "a systematic investigation to establish facts, principles or generalizable knowledge". This Discussion Paper recommends an expansion to the definition of research, from sole reliance on "accepted scientific methods" and "generalizable" to more encompassing statements including:

1a. "Traditional or emergent methodologies and techniques that are accepted as characteristic of the specific discipline" and

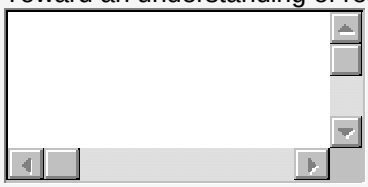
1b. "Contribution or addition to a body of knowledge or obtaining or confirming knowledge" which includes the expectation that this information will be disseminated.

Please choose one option:

I **agree** that **both** elements 1a. and 1b. should be addressed in the definition of research

- I **agree** that element **1a. only** should be addressed in the definition of research
- I **agree** that element **1b. only** should be addressed in the definition of research
- I **agree** that the current definition of research in the TCPS needs to be expanded but **not** with elements 1a. and/or 1b above.
- I **do not agree** that the current definition of research in the TCPS needs to be changed

Specific Comments on Question 1:
Toward an understanding of research involving humans



2. Proposed Approach to Supplement the Definition of Research in the TCPS

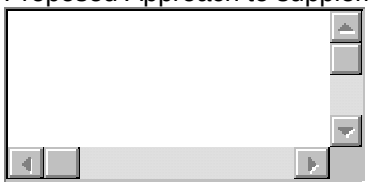
ProGroup suggests supplementing the definition of research by discipline-specific guidance in supporting commentary in the TCPS.

Based on your experience, is the suggestion of supplementing the definition of research an appropriate means to clarify the needs of TCPS users within disciplines of Health, Social Sciences and Humanities and Natural Sciences and Engineering?

Please choose one option:

- I agree with the use of supporting commentary to supplement the definition of research
- I do not agree with the use of supporting commentary to supplement the definition of research

Specific Comments on Question 2:
Proposed Approach to supplement the definition of research in the TCPS



3. Expanding the term "Risk" to "Risk of Harms":

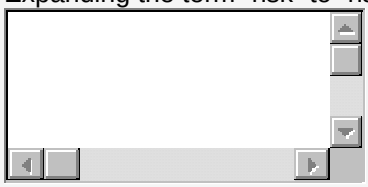
To provide clarity and consistency of use, the Discussion Paper proposes expanding the term "risk" to "risk of harms", a term with more relevance to a wider range of research disciplines, research situations and research subjects.

Based on your experience, do you agree with the proposed change?

Please choose one option:

- I agree with the proposed change from "risk" to "risk of harms".
- I do not agree with the proposed change from "risk" to "risk of harms"

Specific Comments on Question 3:
Expanding the term “risk” to “risk of harms”



4. Considering Risk of Harms

The Discussion Paper proposes that the assessment of risk/risk of harms should include other considerations such as the complexity of the research; intrusiveness/invasiveness; accountability; integrity; conflict of interest; scientific rigour; recruitment; privacy/confidentiality; researcher experience/expertise; REB and reviewer experience/expertise; sensitivity or nature of the research; and the involving elements of special groups/communities.

From your experience, do you agree with the additional considerations listed above in the assessment of risk/risk of harms?

Please choose one option:

- ○ I agree with the addition of the proposed considerations in the assessment of risk/risk of harms.
- ○ I agree with the addition of the proposed considerations in the assessment of risk/risk of harms described above but think that other elements should be considered.
- ○ I disagree with the assessment of risk/risk of harms described above.

Specific Comments on Question 4:
Considerations in the assessment of risk/risk of harms

5. Considering Vulnerability

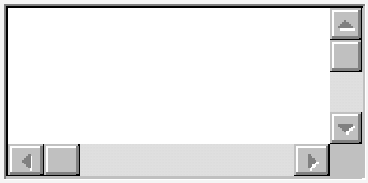
The Discussion Paper proposes replacing “vulnerable persons” by “vulnerability of persons or research subjects” to reflect the reality that vulnerability exists along a continuum, and to allow for a more enhanced understanding of risk/risk of harms to research subjects.

From your perspective, the change from “vulnerable” to “vulnerability of persons or research subjects” is:

Please choose one option:

- ○ Necessary
- ○ Unnecessary

Specific Comments on Question 5:
Replacing “vulnerable persons” by “vulnerability of persons or research subjects”



6. The Delegated Authority Framework and Review

The Discussion Paper proposes a delegated authority framework for the ethics and review process as an appropriate replacement for the current terminology and process of departmental and expedited review.

6a. The **term**: “delegated authority framework” should replace the terms "departmental" and "expedited" review.

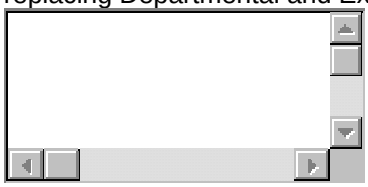
6b. The "delegated authority framework" review **process** should replace the current expedited and departmental review processes.

Please choose one option:

- ☐ I **agree** with both **6a. and 6b.**, i.e. the term and process of review should be replaced.
- ☐ I **agree** with **6a. only**, i.e. only the term of review should be replaced.
- ☐ I **agree** with **6b. only**, i.e. only the process of review should be replaced.
- ☐ I **agree** that the term and process of review should be replaced but **not** with elements **6a. and 6b.** above.
- ☐ I **do not agree** that current terminology and process of departmental and expedited review need to be changed.

Specific Comments on Question 6:

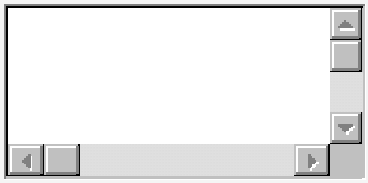
The concept (term and process) of Delegated Authority Framework for the Ethics Review Process replacing Departmental and Expedited Research Ethics Review



7. General Comments

In providing general comments, please also consider such elements as:

- The practicality and flexibility of the proposed refinements in its application within institutions, and to various disciplines: Health, Natural Sciences, Social Sciences, Engineering, and Humanities,
- Any potential gaps, missing elements or inconsistencies with other local, provincial, national or international models,
- Any unclear elements that require further elaboration,
- The potential for the proposed to balance enhanced research subjects protection with research facilitation, and
- The potential for the proposed to respond to the needs of Research Ethics Boards (REBs), researchers, research subjects, and institutions.



DEMOGRAPHICS

The following set of questions is designed to assist ProGroup in analyzing and determining the representation of the feedback received and the outreach of this consultation.

8. In which province or territory do you currently reside?

(Select one option from the list)

9. In your current work or studies, are you affiliated with any of the following?

*(Select **one** option that best describes your **primary affiliation**)*

- ☐ University
- ☐ College
- ☐ Hospital or Regional Health Authority
- ☐ Research Institute
- ☐ Private Industry
- ☐ Provincial Government
- ☐ Federal Government
- ☐ Non-governmental organization
- ☐ Others (please specify)

10. Which of the following best describes your experience with research involving humans?

*(Select **one option** that best describes your **main experience**)*

- ☐ I am (have been) a participant in research
- ☐ I am (was) a researcher
- ☐ I administer (have administered) research involving humans
- ☐ I am (was) involved with the administration of Research Ethics Boards
- ☐ I am (was) a member or chair of a Research Ethics Board
- ☐ I have no experience in research involving humans

11. In what discipline is your scope of experience in the ethical conduct of research involving humans

*(Check **all that apply**)*

- [ ] Behavioural Sciences
- [ ] Biomedical
- [ ] Engineering
- [ ] Health Sciences
- [ ] Humanities
- [ ] Natural Sciences
- [ ] Social Sciences
- [ ] Interdisciplinary
- [ ] Others (please specify)

Submit Comments

Thank you.
You will automatically receive a copy of your comments upon submission.