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**Ethics Review of Research in Multiple Settings and/or  
Involving Multiple REBs  
(Previously Multicentred Ethics Review)  
A Discussion Paper and Recommendations**

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ProGroup recognizes the valuable input and thoughtful contributions of the late Dr. Mike Enzle (a former ProGroup member) to this work.

*The content and views expressed in this document are those of members of this committee, and do not necessarily reflect those of the Interagency Advisory Panel or Secretariat on Research Ethics.*

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## Executive Summary

The need to clarify and develop a common understanding of what falls under a “Multicentred Ethics Review”, how to enable the existing traditional conventional Canadian model of ethics review by single Research Ethics Boards (REBs) of research requiring multiple REB involvement, and to further explore other alternatives for ethics review of multicentred research have been identified to require clarity and further development in the current *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS). To remedy this situation, ProGroup, a working committee of the Interagency Advisory Panel on Research Ethics (PRE), presents in this paper, discussions and proposals to better reflect the ethics review process of multicentred ethics review. The paper introduces the new concept of “research that may require multiple REB involvement” to replace the current “review of multicentred research” to better reflect the spectrum of REB involvement based on a proportionate approach to ethics review. The paper presents and makes textual recommendations to the TCPS on a description of what falls under research requiring multiple REB involvement. It introduces some alternative models of review that exist nationally and internationally to supplement the current model of ethics review by single REBs. These models or a mix of those are presented as options for flexibility in application for the range of disciplines covered by the TCPS. Their success is context driven and determined by several factors outlined in the paper.

The paper does not propose specific textual changes to the TCPS, but provides a list of some factors that potentially contribute to an effective ethics review process requiring multiple REB involvement. These include elements such as a decision-making framework for the selection of an appropriate multiple REB model, multiple REB communication and transparency, essential education in the ethics review of research requiring multiple REB involvement, securing adequate resources to support the ethics review process that involves multiple REBs, and addressing operational issues. In the paper, ProGroup identifies issues of liability and risk management that have emerged from ProGroup’s work. These issues are listed and proposed as a starting point for further development by experts in liability and risk management.

ProGroup anticipates that the community input on this paper will lead to refinements to the proposed textual recommendations of review of research requiring multiple REBs involvement for more clarity, detail and prominence in the TCPS.

# Ethics Review of Research in Multiple Settings and/or Involving Multiples REBs (Previously Multicentred Ethics Review)

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

### 1.1 Introduction and Background

Almost 20 years ago, in 1987, the ethics guidelines for research involving humans of the former Medical Research Council of Canada referred to multicentre trials<sup>1</sup>. When the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS)<sup>2</sup> was adopted a decade later, it also briefly addressed ethics review involving multicentred research, with intended application across the disciplines of Social Sciences and Humanities, Natural Sciences and Engineering and Health Sciences, the range of disciplines supported by the three Agencies<sup>3</sup>.

Subsequent developments have since confirmed challenges presented by the issue of the ethics review of research requiring multiple REB involvement (previously multicentred ethics review), particularly in the face of increasing collaborative research projects and networks involving researchers at more than one institution. Initiatives like the Tri-Agency Networks of Centres of Excellence<sup>4</sup>, and other Agency specific collaborative research initiatives and programs have synergized opportunities for collaboration to advance new research knowledge, but such collaboration has presented challenges. When a researcher, team or network proposes a project that requires conducting research involving humans at multiple institutions or sites across a provincial, national or international borders, for instance, the project encounters the prevailing model of ethics review in North America: prospective ethics review by interdisciplinary institutional research ethics boards (REBs) at the local level.

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<sup>1</sup> “Multicentre trials raise unique ethical and practical concerns. Pressures on an REB to comply with decisions taken in other centres cannot be accepted. Because parallel concerns may be raised in different institutions, it is important that REBs which are considering the participation of their institutions in a multicentre trial communicate with each other about the concerns raised in their discussions. If necessary, joint meetings of representatives of the different REBs should be convened...”. The Medical Research Council of Canada, *Guidelines on Research Involving Human Subjects*. Ottawa, 1987, page 18.

<sup>2</sup> Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), the Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*. 1998 (with 2000, 2002 and 2005 amendments) found at <http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm>

<sup>3</sup> The three Agencies refer to 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).

<sup>4</sup> The Networks of Centres of Excellence is supported and overseen by the three federal granting Agencies: CIHR, NSERC and SSHRC as well as Industry Canada. It provides funding for research and training within Canadian institutions, and fosters partnerships between university, government and industry. More information can be found at <http://www.nce.gc.ca/>

Local ethics review of the research project at every institution injects assembled expertise, analysis, and values into the project<sup>5</sup>. Multiple, independent reviews also risk yielding inconsistent ethics review processes, redundancy, and delays or inefficiency for time-sensitive research<sup>6,7,8</sup>. The costs of multiple reviews, some argue, are unlikely to confer added benefits<sup>9,10</sup>.

The dynamic has prompted questioning of the existing model, a search for alternatives, and further study and clarification in the TCPS of ethics review of multicentred or multisite<sup>11</sup> research.

## ***1.2 PRE's Project on Ethics Review of TCPS Multicentred Research***

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 in the TCPS, PRE created the Sub-group on Procedural Issues for the TCPS (ProGroup)<sup>12</sup>. 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.

Consistent with PRE's basic processes and principles, ProGroup's work is based on transparency, community engagement and consultations. Based on public consultations and feedback from the research ethics community in 2003 to identify<sup>13</sup> and prioritize<sup>14</sup> procedural and related definitional issues in the TCPS, ProGroup has identified a need to study several issues related to the TCPS. One of these includes clarifying and further developing Multi-centred Ethics Review in the TCPS. Discussions and consultations revealed the need to:

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<sup>5</sup> M.E. Enzle & R. Schmaltz, Ethics Review of Multi-Centre Clinical Trials in Canada. 2005. Vol. 13, No. 2 and 3, *Health Law Review*, pp. 51-57.

<sup>6</sup> M. H. Fitzgerald and P.A. Phillips. "Centralized and Non Centralized Ethics Review: A Five Nation Study," *Accountability in Research*. 2006. 13: 47-74.

<sup>7</sup> A.G. Hunter "Is multicenter collaborative research in clinical genetics dead and, if so, what killed it?" 2005 *Am Med Genet A*. 134: 237-239.

<sup>8</sup> L.A. Green, J.C. Lowery, C.P. Kowalski, L. Wyszewianski. "Impact of institutional review board practice variation on observational health services research?" *Health Serv. Res.* 2006. Feb;41(1): 214-30

<sup>9</sup> G. Koski, J. Aungst, J. Kupersmith, K. Getz, & D. Rimoin. "Cooperative Research Ethics Review Boards: A Win-Win Solution?" *IRB: Ethics & Human Research*. May-June 2005. 27(3): 1-7.

<sup>10</sup> D.M. Dunn, A. Arscott & R.D. Mann. "Costs of seeking ethics approval before and after the introduction of multicentre research ethics committees." *Journal of the Royal Society of Medicine*. 2000. 93: 511-512.

<sup>11</sup> Note that some may distinguish multicentred from multisite research, the latter being done at a single centre with research subjects at multiple sites. Local REBs may still be responsible for studies involving its employees, academics and other research subjects. Therefore, the same issues are likely to persist. In this document, reference is made to multicentre and multisite interchangeably to refer to the need for ethics review by multiple REBs.

<sup>12</sup> More information on ProGroup, its activities and developments can be found at: <http://www.pre.ethics.gc.ca/english/workgroups/progroup.cfm>

<sup>13</sup> See Public Call for Input on the Identification of Procedural and Definitional Issues in the TCPS found at <http://www.pre.ethics.gc.ca/english/publicparticipation/callforcomments/revisingtcps.cfm>

<sup>14</sup> See On-line consultation for prioritizing procedural and related definitional issues in the TCPS found at <http://www.pre.ethics.gc.ca/english/publicparticipation/callforcomments/consultationprioritization.cfm>

- clarify and develop a common understanding of what falls under a “Multicentred Ethics Review”.
- be inclusive of all disciplines covered by the TCPS. “Multicentred” has given a connotation of a biomedical approach commonly used in clinical trials.
- give more prominence and detail to the topic in the TCPS, and refer to the range of REB involvement in the ethics review process.
- address operational issues (including but not restricted to legal and risk management issues).
- raise awareness within the community of the TCPS update of May 2000 Section 1, B.1, Authority of the REB, Article 1.2. (Page 1.3) that indicates that “Each institution is accountable for the research carried out in its own jurisdiction or under its auspices. **An institution can authorize its REB(s) to accept the review of other REBs constituted under the Tri-Council Policy Statement if it so wishes. This might involve specific agreements between institutions for sharing the work.**” (bolded text is added)
- clarify the roles and responsibilities of all involved in the ethics review of human research requiring multiple REB involvement.

The Interagency Advisory Panel on Research Ethics’ “Response to the Draft Report of the Experts Committee for Human Research Participant Protection in Canada” (22 November, 2007) also identified multicentred ethics review as a critical area in need of attention in the TCPS. ProGroup refers readers to this document<sup>15</sup> for further deliberation within the Canadian context.

### *1.2.1 The Purpose of this Discussion Paper*

This paper focuses on proposals and makes recommendations that address multicentred ethics review issues not yet considered in the TCPS, but identified as matters of concern during the consultations. It does not purport to identify or resolve all outstanding issues related to multiple REB involvement/multicentred research. While ProGroup recognizes the need to address issues and controversies in the ethics review of research at multinational and global levels, at this stage, the committee is only addressing the conduct of research requiring multiple REB involvement at the national level. Addressing it at the national level first will ultimately set the base for others, as they might be considered at a second stage. The paper is developed within current context recognizing the need to observe, acknowledge and respect the dynamic nature of research ethics review in this area.

ProGroup encourages comments and reactions to this report from research ethics administrators, research ethics board members, researchers, research subjects<sup>16</sup>, policy makers, and interested parties. Such input will help inform the drafting of textual recommendations related to the multicentred ethics review in the TCPS for consideration by PRE.

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<sup>15</sup> Document available on PRE’s website at <http://www.pre.ethics.gc.ca/english/policyinitiatives/governance.cfm>

<sup>16</sup> For the purpose of this document, the authors have opted to use the term “subject” rather than “participant,” to be consistent with its current use in the TCPS.

### *1.2.2 ProGroup's Methodology*

This discussion paper represents ProGroup's work on the area of the ethics review that requires multiple REB involvement including multicentred research in the TCPS. It was produced, in part, with the assistance of Virtual Scholars (VS)<sup>17</sup> who conducted research and study in the area of procedures for multi-centre human research ethics review in support of ProGroup's work on this area in October, 2005. It was supplemented by an additional literature review by the Secretariat on Research Ethics reflecting the most recent developments and contribution to the area. It was further complemented by the practical experience and expertise of ProGroup members as well as members of the sounding board dedicated to this area. Sounding board members<sup>18</sup> provided input on the authors' initial thinking on the area, as well as through feedback on drafts electronically and in face-to-face workshops held in May, 2007 and February, 2008.

## **2. Ethics Review of Multicentred Research**

### ***2.1 Review of Multicentred Research in the TCPS***

The existing TCPS offers some, but limited, guidance on the topic of multicentred ethics review, and has, therefore, been identified in public consultations to require clarification and potential revision. At least three provisions of the TCPS address ethics review of multicentred research. Together, they

- (i) stress the authority of each institutional REB for local review of research conducted under its jurisdiction or auspices as outlined in TCPS Article 1.2:

The institution in which research involving human subjects is carried out shall mandate the REB to approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human subjects that is conducted within, or by members of, the institution, using the considerations set forth in this Policy as the minimum standard.

- (ii) stress the institutional accountability, and enable institutions to accept the ethics review of research done by other duly constituted REBs – e.g., via intra-institutional agreements on common review process for multicentred research, as outlined through a TCPS May 2000 amendment in commentary to Article 1.2, section 1.B.1 (page 1.3)

Each institution is accountable for the research carried out in its own jurisdiction or under its auspices. An institution can authorize its REB(s) to

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<sup>17</sup> ProGroup recognizes the work of the Virtual Scholars, Ms. Karen Weisbaum of Queen's University and Ms. Marie Hirtle of Institut de Recherches Cliniques de Montréal (IRCM).

<sup>18</sup> ProGroup recognizes the valuable input of sounding board members who participated at May, 2007 and/or February, 2008 meetings: Sandy Auld (Univ. of Guelph), Marie Josée Bernardi (CHUM, QC), Susan Blum (Univ. of Saskatchewan), Nathalie Desrosiers (MSSS, QC), Linda Dupont (UQO), Claudine Fecteau (MSSS, QC), Carol Gentile (Children's Hospital of Eastern Ontario), Janice Green (Athabasca Univ.), Ron Heslegrave (UHN, ON), Souad H'Mida (UMoncton), Patricia Lindley (Dalhousie Univ.), Ilde Lepore (McGill Univ.), Joseph Lévy (UQAM), Katia Maliantovitch (U. Montréal), Janet Manzo (OICR, ON), William Marr (Wilfrid Laurier Univ), Kelly Morris (Lakehead Univ), Richard Neuman (Memorial Univ), Diann Nicholson (IWK Health Centre, Nova Scotia), A. Nolet (SSS, QC), Sylvie Normandeau (U. Montreal), Lynn Penrod (Univ. of Alberta), Adela Reid (Concordia Univ), Suzette Salama (McMaster Univ.), Ray Saginur (Ottawa Hospital), Rodney Schmaltz (Grant MacEwan College), Rachel Zand (Univ. of Toronto).

accept the review of other REBs constituted under the Tri-Council Policy Statement if it so wishes. This might involve specific agreements between institutions for sharing the work.

- (iii) realize the need to have a process in place to review multicentred research, and to deal with the possibility of arriving at different conclusions on one or more aspects of the same research project. For that, the TCPS encourages both researchers and REBs to play a role in coordinating the review of multicentred research as outlined in TCPS Section 1.G. (Review of Multicentred Research).

Principles of institutional accountability require each local REB to be responsible for the ethical acceptability of research undertaken within its institution. However, in multicentred research, when several REBs consider the same proposal from the perspectives of their respective institutions, they may reach different conclusions on one or more aspects of the proposed research. To facilitate coordination of ethics review, when submitting a proposal for multicentred research, the researcher may wish to distinguish between core elements of the research—which cannot be altered without invalidating the pooling of data from the participating institutions—and those elements that can be altered to comply with local requirements without invalidating the research project. REBs may also wish to coordinate their review of multicentred projects, and to communicate any concerns that they may have with other REBs reviewing the same project. The needed communication would be facilitated if the researcher provides information on the institutional REBs that will consider the project.

## ***2.2 Multicentred Ethics Review in Other National and International and Global Research***

Similar to the TCPS, the Good Clinical Practice<sup>19</sup> (GCP) to which Canadian institutions adhere for the conduct of clinical trials provides some guidance for the review of multicentre trials under a coordinated effort<sup>20</sup>. The GCP defines a multicentre trial as “A clinical trial conducted according to a single protocol but at more than one site, and therefore, carried out by more than one investigator.”

Issues with the ethics review of multicentred research, the variation of requirements, and lack of uniformity amongst local REBs is not confined to the TCPS, or limited to the Canadian context. Such issues have arisen at the provincial level within Canada. For example, in 2007, the Quebec Ministry of Health and Social Services has developed a mechanism<sup>21</sup> for the ethical review and monitoring of multicentred research. Other

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<sup>19</sup> International Conference on Harmonization, *Guidance E6: Good Clinical Practice - Consolidated Guideline* (of ICH Technical Requirements for the Registration of Pharmaceuticals for Human Use) 1996, adopted by Health Canada in 1997: [http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6_e.html)

<sup>20</sup> The Good Clinical Practice (see above in footnote 5) refers to a “Coordinating Committee” and “Coordinating Investigator” as a committee and person one who have the coordination responsibility amongst different centres participating in a multicentre trial. In 5.23, it provides a list of elements that a multicentre trial sponsor should ensure to have in place.

<sup>21</sup> « Mécanisme encadrant l'examen éthique et le suivi continu des projets multicentriques », Québec, Ministère de la Santé et des Services sociaux, Direction générale adjointe de l'évaluation, de la recherche et des affaires extérieures, Unité de l'éthique, novembre 2007, 32p.

examples of initiatives in development include Alberta and Newfoundland, and the Canadian General Standards Board on behalf of Health Canada. Some have conducted evaluations to explore the challenges of obtaining research ethics board approval of multisite studies<sup>22</sup>. Others have suggested steps to be taken to improve inter-institutional coordination and cooperation in ethics review and other aspects of human subject protection, and provide an overview of some existing models in Canada, the UK and the US.<sup>23</sup>

Internationally, other countries<sup>24</sup>, such as the US<sup>25</sup>, and the UK<sup>26</sup> face similar challenges in the review of multicentred research and their success has varied and developed with experience. While similar concerns seem to transcend from medical to health to social sciences and humanities and to natural sciences and engineering research conducted in multisites or multicentres, the issues seem to have received more attention in the clinical research contexts as evidenced by the available literature in the area. What has been helpful in shedding some light on the applicability of such issues to other disciplines and the potential unique challenges posed to research in other disciplines are the results of the interviews conducted by the Virtual Scholars in 2005. Close to 20 experts representing a variety of disciplines and roles in research and ethics review were interviewed. While the results are based on a limited number of interviews, they bring value considering the lack of literature and policy in these areas. They also confirm the clear need for further direction and further policy development taking the spectrum of research and research disciplines into account. Feedback from interviews within this limited pool of respondents revealed that researchers and institutions are challenged in practice with coordination efforts of ethics review of multicentre studies in the area of social sciences and humanities.

### ***2.3 A Closer Look at Multicentred Ethics Review Issues***

In looking closely at issues of multicentred ethics review, there is a variety of points of view. On one hand, and as outlined by some in the literature<sup>27</sup>, some value the benefits of ethics reviews done at multiple sites. The number of REB members who participate in the review process and the diversity and variability of their experience and expertise bring a higher level of assurance in the ethics review process; such that the dissenting opinion of one of many REBs reviewing the same research may serve to identify an omission relevant to human subject protections that other reviewing REBs may not have seen e.g. risk of harm dependent on particular characteristics of local populations. Furthermore, REBs apply other local, provincial and territorial policies and guidelines that may bring new requirements or elements for consideration, and thus may contribute to a

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<sup>22</sup> Carolyn S. Dewa, Jennifer Gold. "Planning for Multi-site Ethics Review". *Canadian Journal of Program Evaluation*. Special issue 2004. 19(3).

<sup>23</sup> M.E. Enzle, R. Schmaltz . "Ethics review of multi-centre clinical trials in Canada". *Health Law Review*. 2005; 13 (2-3):51-7.

<sup>24</sup> M. H. Fitzgerald, P.A. Phillips. "Centralized and Non Centralized Ethics Review: A Five Nation Study," *Accountability in Research*. 2006. 13: 47-74.

<sup>25</sup> See <http://www.hhs.gov/ohrp/> National Conference on Alternative IRB Models. November, 2006

<sup>26</sup> See <http://www.nres.npsa.nhs.uk/> for the National Research Ethics Service

<sup>27</sup> M.E. Enzle, R. Schmaltz "Ethics review of multi-centre clinical trials in Canada". *Health Law Review*. 2005; 13 (2-3): 51-7.

strengthened ethics review of research. Above all, multiple reviews are likely to promote and increase trust in the ethics review process and human research protection in general.

On the other hand, several concerns have been raised by the current system of multicentred ethics review process, most of which center on inefficiency and inconsistency as reported by the Virtual Scholars as well as in the literature<sup>28,29</sup>. Multiple reviews of the same study may result in the following:

- From a researcher's perspective:
  - Waste of time and resources spent on document preparation for ethics review especially with inconsistent feedback and associated requirements for revised materials from various sites.
  - Delays in the commencement of research activities.
  - Potential impact on integrity of research methodology, and the validity of data resulting from substantially modifying studies as required at local level as a recommendation of the REB. While this concern may occur for research requiring a single review, it is likely to multiply for research requiring multiple REB reviews.
  - Potential for inconsistent REB decisions at various centres.
- From an REB perspective:
  - Required time and lack of efficiency of REBs.
  - Duplication of research ethics reviews by local REBs.
  - Constraining of one REB's ability to take action or make its own decision by another REB's decision.
  - Distributed and confused responsibility for the ongoing review process, appeals, adverse event reporting and response.
- From the perspective of Research Subjects and the Public:
  - Potential implication of delays on timing of research findings that would benefit research subjects and the public in general.
  - Redundancy of reviews creates unnecessary waste of public funds on human resources, wasted material resources, and wasted time.
  - Potential impact on trust in the integrity of the ethics approval process in general.

There seems to be several possible reasons for the variability in ethics review process, decision making and the outcomes of reviews as outlined by some<sup>30</sup>, and confirmed by the Virtual Scholars' interviews:

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<sup>28</sup> *Ibid*

<sup>29</sup> J.L. Gold , C.S. Dewa. "Institutional review boards and multisite studies in health services research: is there a better way?". *Health Services Research*. 2005 Feb; 40(1): 291-307.

<sup>30</sup> J.L. Gold , C.S. Dewa . "Institutional review boards and multisite studies in health services research: is there a better way?" *Health Services Research*. 2005 Feb; 40(1): 291-307.

- Absence of standardized research ethics review process and procedures despite the application of a common set of ethical principles of the TCPS.
- Variability of expertise, background and experience of REB members
- Influence of local institutional or professional culture and thinking
- Influence of other regional, provincial, and territorial requirements, policies and guidelines in considering multicentre studies that cross provincial boundaries. For example, REBs and researchers need to follow relevant health information privacy legislation in their province when conducting or reviewing research involving the collection of personal health information.

### **3. ProGroup’s Working Recommendations**

#### ***3.1 What Falls Under a “Multicentred Ethics Review”/ Research that May Require Multiple REB involvement in the TCPS?***

ProGroup recognizes the need to develop a common understanding within the research ethics community of what constitutes multicentred ethics review. In order to facilitate such a development, ProGroup makes the following proposals based on an analysis of the current situation, and building on the input of experts of the sounding board at face-to-face meetings:

1. Given that multiple scenarios could fall under multicentred ethics review, ProGroup opted to propose a description that is intended to be inclusive of such possibilities.
2. Given the goals of the TCPS stating that “*This Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS) describes standards and procedures for governing research involving human subjects,” (TCPS page. i.2), ProGroup opted to focus the policy on those standards and procedures for the ethics review of multicentred research.
3. Giving consideration to practice and to the proportionate approach to research ethics review, ProGroup opted also to include in its proposal the spectrum of involvement of the REB that may range from conducting full ethics review, to simply noting that a review has been conducted at another institution. Because the term “multicentred ethics review” does not adequately reflect the spectrum of REB involvement, of research and of research disciplines, ProGroup proposes the new term of “multiple REB involvement”<sup>31</sup> to facilitate this understanding.

These proposals are to be complemented by strengthening the “proportionate approach” to ethics assessment for research requiring multiple REB involvement. Using the new terminology will also allow for a shift from the current “multicentred” that has been perceived to give a biomedical connotation. Also, the following proposes making necessary references to other relevant procedures in the TCPS such as the Continuing ethics review that should be agreed to at the outset following TCPS Article 1.13.

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<sup>31</sup> From this point forward in this document, reference will be made to research requiring multiple REB involvement rather than the current term in the TCPS of ethics review of multicentred research.

Proposed text for the TCPS:

### **Research that May Require Multiple REBs Involvement:**

Research involving humans that may require the involvement of multiple REBs includes, but is not limited to, the following:

- a. A research project conducted by a team of researchers affiliated with different institutions/organizations.
- b. Several research projects autonomously conducted by researchers affiliated with different institutions, with data combined together at some point to form one overall research project.
- c. A research project conducted by a researcher affiliated with one institution/organization, but collecting data or involving research participants/subjects at one or more other different institutions.
- d. A research project conducted by a researcher with multiple institutional affiliations (e.g. two universities, a university and a college, or a university and a hospital).
- e. A research project conducted by a researcher at one institution/organization that requires the limited involvement of other collaborators/co-investigators<sup>32</sup> affiliated with different institutions/organizations e.g. statisticians, lab or X-ray technicians, social workers, and school teachers.

Multiple REB involvement can range from conducting multiple reviews of the same project or of its elements, to accepting the review of other REBs constituted under the TCPS (as per Article 1.2). The decision on the level of ethics review of research that may require multiple REB involvement should be proportionate to the risk involved in the research. Continuing ethics review for such research should follow the same process developed for the initial review provided the risks have not changed, and following Article 1.13 of the TCPS<sup>33</sup>.

### **3.2 Consideration of Models of Review for Research Requiring Multiple REBs Involvement**

Some models exist both nationally and internationally, with variability in their success in addressing multcentred issues. ProGroup identified the following models to complement the Canadian conventional ethics review by institutional REBs. These models provide options and flexibility in their application for the range of disciplines covered by the TCPS. However, the intent of this document is not to prescribe a specific model for certain types of disciplines. Several factors need to be considered in making a decision on

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<sup>32</sup> CIHR, NSERC and SSHRC have their own set of definitions of a collaborator versus co-applicant or co-investigator found at <http://www.cihr-irsc.gc.ca/e/22630.html#1-B1> for CIHR, SSHRC's website at [http://www.sshrc.ca/web/apply/background/definitions\\_e.asp#11](http://www.sshrc.ca/web/apply/background/definitions_e.asp#11), and NSERC's website at [http://www.nserc.gc.ca/professors\\_e.asp?nav=profnav&lbi=11a1](http://www.nserc.gc.ca/professors_e.asp?nav=profnav&lbi=11a1)

<sup>33</sup> Please note ProGroup's recent report on "Refinements to the Continuing Research Ethics Review in the TCPS: Discussion and Recommendations." In the report, ProGroup discusses and proposes textual recommendations for the concept, goals of continuing ethics review (CER), as well as the roles and responsibilities of those involved in applying the CER to research involving humans.

the selection of an appropriate multiple REB model as will be stated in section 4 of this document.

1. *Ethics Review by Single REBs*: Currently the most frequently followed process in Canada whereby each institutional REB undertakes ethics review of the research proposed within the auspices of the institution or by its members. The traditional conventional Canadian multiple REB model is to seek research ethics review and approval from local REBs concurrently or sequentially.
2. *Central REB model*: Central REBs tend to address either particular kinds of research (e.g. oncology) or methods for a designated region. Examples include the Ontario Cancer Research Ethics Board<sup>34</sup> and the US National Cancer Institute<sup>35</sup> for clinical trials involving cancer research, while in the UK, a system of regional REBs carry out multicentre reviews for health research.<sup>36</sup> It may be useful to note that the success of these models may be partially due not only to being the biomedical REB model but also disease site specific in the US and Ontario. While in the UK, the central REB funding model is provided by the National Health Service under the auspices of the National Patient Safety Agency. Central REBs may act as the REB responsible for the proposed research (please refer to the websites cited for details on central REB process). Central review may or may not be preceded or followed by local full or delegated REB review.
3. *Reciprocal REB model*: Multiple institutions create agreements under which they will accept, with some form of local oversight, the review results of each other's REBs (e.g. the Alberta Province-wide reciprocal approval initiative). Principal researcher is acting as lead: each of X number of REBs accepts ethics review of REBs with which they have reciprocity.
4. *Shared REB model*: Multiple institutions create a single REB for researchers under their jurisdiction. The University of Alberta and the Capital Health Region and the Caritas Group of hospitals have created a joint Health REB, as has the McGill University Faculty of Medicine for itself and some of its affiliated hospitals/Health Centres.
5. *Delegation or Agency model*: An institution forms an affiliation agreement or contract with another in which one of the institution's REB acts as the REB for the other.
6. *Ad Hoc Review*: Reciprocity agreements to be established on a case-by-case basis of need for single reviews.

Proposed text for the TCPS:

**Models for the Ethics Review of Research that May Require Multiple REB Involvement:**

The success of ethics review models involves consideration to context. The context is to be determined by the discipline being reviewed, relationships between REBs, and between their institutions, the availability of appropriate experience and expertise within

<sup>34</sup> <http://www.ocrn.on.ca/OCREB/about.htm> accessed 09-Jan-08

<sup>35</sup> <http://www.ncicirb.org/> accessed 09-Jan-08

<sup>36</sup> <http://www.nres.npsa.nhs.uk/aboutus/managing-nres/> accessed 09-Jan-08

or available to the reviewing REB, the scope of the project under review and the study population, the potential for conflict of interest and undue influence, and the level of risk associated with the research under review. Federal, provincial and territorial policies and legislations, and institutional requirements also need to be taken into consideration. The use of one or a mix of the following models should be informed by the basic requirement of the TCPS as per Article 1.2 of the TCPS that research ethics remains the responsibility of the institution.

The following models<sup>37</sup> are intended to provide options and flexibility in their application for the range of disciplines covered by the TCPS. At the onset, roles and responsibilities of all involved in the process need to be clarified and agreed to. Whichever model is adopted, it needs to follow the guiding ethical principles of the TCPS (page i.5) with the underlying goal of research participant/subject respect, protection and safety.

1. **Ethics Review by Single REBs:** The traditional conventional Canadian multiple REB model that seeks research ethics review and approval from each local REB concurrently or sequentially.
2. **Central REB Model:** central REBs tend to address either particular kinds of research (e.g. oncology) or methods for a designated region, and may act as the REB responsible for the proposed research. Central review may or may not be preceded or followed by local full or delegated REB review.
3. **Reciprocal REB Model:** Multiple institutions create agreements under which they will accept, with some form of oversight, the ethics review results of each other's REBs. Each of the REBs accepts ethics reviews of others with or without following this by a delegated review.
4. **Shared REB Model:** Multiple institutions create a single REB for researchers under their respective jurisdictions.
5. **Delegation or Agency Model:** An institution forms an affiliation agreement or contract with another in which one of the institution's REB acts as the REB for the other.
6. **Ad hoc Review Model:** Reciprocity agreements to be established for research projects on a case-by-case basis.

In order to plan and build the appropriate model of ethics review of research involving multiple REBs, ethics needs to be an integral part of the research, and not an afterthought. The development of a model is a collective/collaborative responsibility that involves the institution, researchers, and REBs. It ought to be informed by the subject-centered focus of the ethics review process, and basic requirement of the TCPS that research ethics remains the responsibility of the institution as per Article 1.2 of the TCPS. Special attention needs to be given to the particular characteristics of local populations. Therefore, a pure Central REB model does not respect the principles of the TCPS. Only a hybrid central model taking into consideration the needs of local populations would respect the subject-centered focus of the TCPS, and the responsibility of the local institution. Such a hybrid central REB model would inform and facilitate the decision-making process for the local institutional REB which should not abdicate its roles and

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<sup>37</sup> The list does not suggest an order of priority.

responsibilities. In general, the above should be taken within the evolutionary nature of the TCPS that will require further reflection and deliberation with time.

Sensitivity to context is a key issue in the process of ethics review. There is a need for flexibility and empowerment for REBs to respond to different situations based on context, for example, local, provincial, and national requirements. A balanced perspective suggests that a unified response by all involved REBs is not expected, but a consistent framework of ethics review ought to be applied with clear roles and responsibilities, and with a framework for decision-making processes.

**From this point on in this document, the objective is to provide some background material that informed and guided ProGroup's presentation and recommendations for the proposed revisions to the TCPS (Section 3 of this document). The following sections will hopefully provide explanations and suggestions for further development in this area.**

#### **4. Factors Contributing to an Effective Process of Review of Research Requiring Multiple REBs Involvement**

##### ***4.1 Decision-making Framework for the Selection of an Appropriate Multiple REB Model(s)***

As already stated, the success of the ethics review model (that may be one or a mix of the above models) selected involves consideration to context. The context may be determined by, but is not limited to:

- discipline and field of research being reviewed
- scope of the project under review and the study population
- relationships between REBs to be involved in the ethics review
- relationships between REBs and their institutions
- relationships between investigators and REBs
- appropriate experience and expertise within, or available to, the reviewing REB
- potential for conflict of interest (perceived or real) and undue influence. This could exist at the REB, institutional, investigator, sponsor, and-or participant levels
- federal, provincial, territorial; national, international and global policies; legislations and institutional requirements also need to be taken into consideration, and
- level of risk associated with the research under review.

##### ***4.1.1 Discipline and Field of Research Being Reviewed***

Defining and understanding the discipline and field of research will facilitate identifying the appropriate REBs and the appropriate model to review the proposed research. Such an understanding of the discipline and field of research should be first informed by input from the researcher. Normally, the researcher would propose a model, and the REB would consider the proposed model and subsequently make the decision on the selection.

For matching the disciplines, fields of research with the appropriate REBs, specialized research ethics boards such as pediatric, social sciences, biomedical, population health, education ...etc. need to be recognized and understood by all involved in the research and research ethics process. For example, some REBs are specialized in areas such as oncology, population health, social sciences and education, amongst others, and these would be logical choices of REBs to select in addressing those disciplines or fields of research.

#### *4.1.2 Relationships between REBs to be Involved in the Ethics Review*

There are a variety of formal and informal REB Chair, members, and administrative relationships already established in Canada. These established links may be useful in facilitating and informing the selection of a model by REBs.

#### *4.1.3 Relationships between REBs and their Institutions*

As stated in the commentary to Article 1.2 of the TCPS: “Each institution is accountable for the research carried out in its own jurisdiction or under its auspices.” Institutions delegate the authority to the REB through their normal process of governance. Delegation of authority takes various forms and involves a variety of relationships within institutions. The nature and dynamic of these relationships between REBs and their institutions is likely to influence the adoption of the models selected by the REBs.

It is worthwhile noting that this is a key issue in this discussion paper – what is the role and authority of the REB – the paper alludes to the fact that the REB has the power to accept alternate modalities, when, in fact the institutional legal liability, and risk assessors will more likely make the determination.

REBs may not always have the expertise or experience to adequately assess the acceptability of other REBs or inter-institutional agreements. These decisions are not lightly made, and can take considerable time to implement depending upon the policies at each institution. In some cases, it may just be easier and faster to do the multiple reviews than to orchestrate multi-institutional agreements and arrangements especially if the project meets the institution’s guidelines for delegated review.

#### *4.1.4 Relationships between Investigators and REBs*

The relationship between an investigator and his/her REB is essential in informing the selection of the appropriate model, and serves as a two-way education process. Therefore, early communication is necessary between investigators and REBs about proposed research and the scope of the project(s) that will require multiple REB involvement. For example, as a practical application, it may be helpful to suggest a mutually agreed upon multiple REB review process-map that a primary investigator/lead researcher and home institution could then follow and update as necessary. This does not only inform the models to be selected, but may also guide the selection of the number and nature of REBs to be involved in addition to the local REB, potential institutional or REB constraints, and the development of links with other institutional REBs and researchers. The final decision regarding the appropriate model to be implemented is the responsibility of the principal REB.

#### *4.1.5 Appropriate Experience and Expertise Within, or Available to, the Reviewing REB*

To enable and empower REBs to take advantage of relationships such as reciprocal REB arrangements, identification of education, skills and experience available within a particular REB will be necessary for the selection of the model. Sharing of information such as terms of reference and documentation is essential to facilitate such arrangements. REBs may request the input of external expertise not available from its regular members. Should this occur regularly, the membership of the REB should be modified to add this expertise in accordance to commentary to Article 1.3 of the TCPS.

#### *4.1.6 Potential for Conflict of Interest (Perceived or Real) and Undue Influence. This Could Exist at the REB, Institutional, Investigator, Sponsor, and/or Participant Levels*

In selecting the appropriate model for ethics review, the REB should pay particular attention to the possible conflict of interest e.g. the interrelations between researchers that may influence the protection of subjects. Some of the models might help in reducing perceived, potential, or real situations of conflict of interest or undue influence, and some may increase it.

#### *4.1.7 Federal, Provincial and Territorial and National, International and Global Policies and Legislations, and Institutional Requirements Also Need to be Taken into Consideration*

#### *4.1.8 Level of Risk Associated with the Research under Review*

Generally, the level of risk associated with the ethics review of research in multiple settings and/or involving multiple REBs is no different from the level of risk of the same research if requiring a single REB review. However, in selecting the appropriate model and determining the level of involvement of REBs in the review process, it is essential that REBs take a proportionate approach. This would depend on the level of risk involved in the research. Special attention should be given to the study population and the level of involvement of members of their institution in the research. The level of involvement of an REB might range from conducting ethics review to noting that a review has taken place in another jurisdiction.

## **4.2 Multiple REB Communication and Transparency**

As previously outlined in the document, the TCPS, through the May 2000 amendment, states that “Each institution is accountable for the research carried out in its own jurisdiction or under its auspices. An institution can authorize its REB(s) to accept the review of other REBs constituted under the Tri-Council Policy Statement if it so wishes. This might involve specific agreements between institutions for sharing the work.” Institutions must respect the authority delegated to the REB. However, institutions may refuse the REB’s selection of certain models for research requiring multiple REB involvement, even though the REB has found it acceptable.

Factors contributing to an effective and successful process of ethics review of research involving multiple REBs may include, but are not limited to, trust between local committees; supportive policy environment through buy-in of participating institutions; and connection and ongoing communication between central and local REBs. Transparency would facilitate the ethics review process involving multiple REBs by allowing access to, and appropriately engaging the local context. To facilitate this

process, REBs may consider, and some already do, public sharing (e.g. by posting on the internet) of their institutional policies, procedures, and templates of consent documentation and application forms used to guide the operations of their REBs.

#### ***4.3 Essential Education in the Ethics Review of Research Involving Multiple REBs***

Appropriate education and comprehension of the ethical framework of the TCPS is at the heart of this process. It is essential to raise awareness of the viable models, available options as well as flexibility that exists to effectively operationalize multiple REB review in Canada. To do so, REBs may consider making public the REB models that they have adopted, and criteria for the applicability of the models to their research.

#### ***4.4 Securing Adequate Resources to Support the Ethics Review Process that Involves Multiple REBs***

The nature of the ethics review of research involving multiple REBs requires the dedication of time, effort and financial and human resources. The level of resources will depend on the selected ethics review model and whether these are ad-hoc or ongoing needs. The availability of resources will facilitate an effective conduct of REB review, will likely enable REBs and encourage them to be responsive, potentially yielding shorter times for completing the ethics review process. It is appropriate to operationalize the additional resource requirements for this type of ethics review. Options to secure such resources are proposed in section 6 of this document.

#### ***4.5 Appropriately Addressing Operational Issues***

The following REB operational issues deserve appropriate attention and consideration for the success of the ethics review of research requiring multiple REB involvement.

##### ***4.5.1. Development of Tools to Facilitate Submission and Review According to the Model Selected***

This may include the development of a basic set of requirements and documentation on which institutions can build, e.g. templates of information consent documentation, applications forms, research ethics review tools to encourage transparency, reproducibility, generalizability, and potentially contributing to consistency and harmonization of activities between REBs.

##### ***4.5.2 Timing of Completing the Ethics Review***

Institutions should enable their REBs to complete ethics reviews within shorter time frames. When selecting a model that have multiple REB reviews, the more REBs are involved, the more attention should be given to responding to the review results within limited timelines. In such case, serious consideration should be given to the proportionate approach to ethics review, to the timing of conducting parallel reviews, and to facilitating the process to integrate them.

##### ***4.5.3 Scholarly Review as Part of the Ethics Review***

As with the commentary to Article 1.5 in the TCPS; “REBs should normally avoid duplicating previous professional peer-review assessments unless there is a good and defined reason to do so.” This is particularly crucial in ethics review involving multiple REBs.

#### *4.5.4 Record Keeping*

It is essential to keep an official record of all necessary documentation related to the agreed upon multiple REB review process. Records may include minutes of REB meetings (as per Article 1.8 of the TCPS), pertinent agreements, or other documents on which an REB makes a decision. REBs may have different requirements for operational issues such as record keeping.

#### *4.5.5 Continuing Ethics Review Including Reporting of Amendments*

The continuing ethics review process and the process of reporting amendments and adverse events ought to be negotiated and agreed upon at the time of selecting the multiple REB review model. It may follow the same process as the initial review, but may include requests for additional information as required, especially if the risks of the research have changed.

#### *4.5.6 Reconsideration and Appeals*

As with the above, the process of reconsideration and appeals for the ethics review process that involves multiple REBs needs to be negotiated and agreed upon at the outset.

#### *4.5.7 Complaints*

There should be clarity and agreement on identifying a contact for research subjects in case of complaints about the research and how they would be resolved. It is also necessary that the contact keeps all involved REBs abreast of such complaints and how they have been addressed.

### **5. Liability and Risk Management**

This section is intended to provide some identified issues of liability and risk management that have emerged from ProGroup's work on the ethics review of research requiring multiple REB involvement. Time limitations have not allowed ProGroup to pursue this very important work. ProGroup supports the conduct of an appropriate consultative process to effectively discuss the issues of legal liability and risk management to inform the development of policy recommendations.

#### **5.1 Context**

Issues of institutional accountability, insurance and liability have been one of the main reported challenges to the development of multicentred agreements and delegation of review to a central or shared REB models as reported by the Virtual Scholars. As presented in May 2007, at ProGroup's request and support, at the CAREB annual general meeting on the topic of institutional liability concerns, "Risk will always be present for Institutions engaged in research. The challenge is to find the right balance between acceptable risks and the benefits of the research." and we "must acknowledge that different Institutions operate in different environments and have different appetites for risk."<sup>38</sup>

As previously indicated in this document, one of the May 2000 updates to the TCPS, at the end of Section [1.B1](#) (page 1.3), extends the authority of an REB to accept the ethics

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<sup>38</sup> "Multi-Centred Ethics Review Institutional Liability Concerns" presented by David W. Head, Director, Enterprise Risk Management, Memorial University of Newfoundland – found at <http://www.careb-accr.ca/>

review of research done by other duly constituted REBs as per the TCPS guidelines. This might involve specific agreements between institutions for sharing the work. However, each institution remains accountable for the research carried out in its own jurisdiction or under its auspices. An interpretation by the Agencies of this amendment, and later confirmed by PRE in one of its interpretations<sup>39</sup>, outlined some of the basic requirements that may apply for this provision of sharing a review requiring multiple REB involvement amongst institutions:

- All institutions involved must adopt and adhere to the TCPS, and the cross-institutional agreement must be formalized and documented.
- The decision to allow an REB to recognize decisions made by another institution's REB must be made at the highest institutional level, by the body that originally defined the jurisdiction of the REB and its relationship to other relevant bodies or authorities (in accordance with TCPS article 1.2).
- Approvals based on cross-institutional agreements should be brought to the attention of the full REB, in the same way as are decisions that are reached by delegated review.
- The principle of accountability requires that, regardless of the review mechanism, the REB continues to be responsible for the ethics of all research involving human subjects that is carried out within its institution or under its auspices (in accordance with TCPS article 1.14).

## ***5.2 Examples of Elements to Include in Agreements***

The following are examples of basic elements that could be considered for inclusion in agreements. They are by no means proposed as fully representative.<sup>40</sup>

- *Roles and Responsibilities:* Clear division of roles and responsibilities within the primary institution and other external institutions. This should be applied to all parties involved including the roles and responsibilities of the REBs, administration, researchers and institutional counsels, and needs to be publicly available for transparency and increase of assurance in the process.
- *Warranties:* Parties may require warranties about each other's policies and procedures. How to achieve this –
- *Duties:* Duties of REBs in all institutions should be clarified
- *Insurance:* Each party should be adequately insured.
- *Indemnification:* varies according to organization.
- *Confidentiality provisions*
- *Payment terms* (if applicable)

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<sup>39</sup> PRE's interpretation entitled "Proposed Establishment of Extra-Jurisdictional REB Subcommittee" found at <http://www.pre.ethics.gc.ca/english/policyinitiatives/interpretations/interpretation018.cfm>

<sup>40</sup> Some of the proposed elements were included in a handout developed by Diane Elizabeth Lopez, Harvard University, and distributed at the *Alternative Models of IRB Review* conference in Washington, DC, November, 2006.

- *Termination provision*: including term of years, transition of review studies, obligations, records.

### **5.3 Suggested areas to be addressed concerning legal liability and risk management issues related to review of research requiring multiple REBs involvement in the TCPS**

ProGroup identified the following issues and concerns that may need to be addressed by experts in the field of legal liability and risk management regarding ethics review of research requiring multiple REB involvement.

- Provincial matters: Are liability issues within the same province different from those resulting from ethics review across provinces?
- Should agreements amongst institutions be limited to those eligible to receive agency funds i.e. those adhering to the policies of the three Agencies; what about if other entities/organizations are involved?
- Do the same liability issues apply to various ethics review models (hybrid-central model vs. ad-hoc, etc...)?
- What are other factors impacting on liability issues such as level of risk, nature of research, size of study, length of study...etc?
- What kind of information can be shared in an “administrative space” for REBs across institutions to facilitate the process and build trust in the process?
- Is the issue of liability a perception rather than reality? To what extent is there an increase in liability introduced by the ethics review of research requiring multiple REB involvement? Liability already exists within institutions. REBs doing well are likely to do well in any other model. Other sources of liability and risk exist such as occupational, health and financial, how much is the liability of ethics review of research requiring multiple REB involvement different?
- Define the liability; whose liability are we addressing? The REB review may be a secondary ground for liability and the cases are normally focused on the Principal Investigators/ and institutions that employ the researchers.
- Need to clearly define the relationship between insurance and liability.
- Need a clear line between risk management and liability issues. For example, the possible damage to the institution’s reputation seems to be within the responsibilities of accountability and risk management.
- What would constitute “due diligence” to address liability issues related to various models of the ethics review of research involving multiple REBs?
- What are the lessons learned regarding liability issues from experience of existing models (refer to section 2.2 of this document for examples)?
- What is a recommended approach to address liability issues and facilitate agreements? E.g. criteria to be developed, templates, a paper developed by a working committee of university counsels/legal advisors providing their views and advice on the issue?
- Is it an institutional agreement and/or an REB agreement?

## **6. Proposals**

Research involving humans that requires multiple REB involvement also requires buy-in, trust, and adequate resources for all those involved. It is, therefore, proposed that Tri-council policies and funding for research ethics in general, and more specifically for ethics review of multiple REB involvement, be developed in the following areas:

- Allowing for research ethics board submission and review expenses as eligible expenses in grant funding of research that require multiple REB involvement.
- Funding networking workshops to facilitate the implementation of research requiring multiple REB involvement.
- Funding to build-in evaluation tools and indicators to assess the utility and applicability of models requiring multiple REB involvement.
- Designing web-based flexible examples of REB pathways for implementing the various REB models to inform both REBs and researchers on the possible approaches for the ethics review of research requiring multiple REB involvement.
- Educating REB members and those concerned and involved in the process of the ethics review of research requiring multiple REB involvement.

## **7. Conclusion and Next Steps**

Variations in viewpoints persist in the ethics review of research requiring multiple REB involvement in the TCPS. Some individuals, including researchers, some REB members and administrators, believe in taking advantage of mechanisms that streamline REB review procedures and decrease redundancy, time and cost of reviewing the same application at multiple sites. Others have expressed concerns about the sharing or delegation of authority partly due to issues of liability and accountability, and partly due to the potential for diminishing the institutional ability to ensure the ethical acceptability of research conducted within its jurisdiction in accordance with its own standards. The latter may be partly attributed to the requirement in the TCPS of 1998 that each institution is fully responsible for research ethics review of research conducted under its auspices. In 2008, ProGroup respectfully submits this paper for deliberation and comments to facilitate appropriate revisions to the previous multicentred ethics review section of the TCPS.