
**Refinements to the Continuing Research Ethics Review
in the TCPS:
Discussion and Recommendations**

Submitted by the

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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 concept and goals of continuing ethics review (CER) as well as the roles and responsibilities of those involved in applying the CER in research involving humans have been identified as being unclear 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), publicly consulted in Fall 2007 on an earlier version of this paper (see Appendix 1 for feedback regarding recent consultation). Based on the public input and commentary, the current paper includes revisions reflecting suggestions and other issues raised on the concept, goals and minimum scope of CER, as well as operational issues and roles and responsibilities of those involved in applying the CER process. Additionally in this paper, ProGroup makes general proposals and specific recommendations of textual amendments to the TCPS.

1.0 Identifying a Need for Procedural and Definitional Change in the TCPS¹

1.1 Background

In 1998, the [*Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans \(TCPS\)*](#)² was released. This document governs the ethical conduct of research involving humans within institutions and by researchers receiving funds from the three Canadian federal granting agencies: the Canadian Institutes of Health Research (CIHR), the Social Sciences and Humanities Research Council of Canada (SSHRC), and the Natural Sciences and Engineering Research Council of Canada (NSERC). To deliver on their commitment to keeping the TCPS a living or evolving document, in 2001 the Agencies created the Interagency Advisory Panel on Research Ethics (PRE). The mandate of PRE is to steward the evolution of the TCPS, especially with respect to new research developments and identified gaps in the original policy statement.

In March 2003, PRE created the subgroup on procedural issues for the TCPS ([*ProGroup*](#)), and mandated it to provide advice on priorities, methods and mechanisms for identifying gaps and procedural and definitional issues within the TCPS, and to coordinate a response to those issues. ProGroup's approach to its work is based on PRE's first principles, which include transparency, community engagement and consultation.

Public consultations in 2003 identified the clarification of Continuing Ethics Review (CER) processes as one of the top seven community priorities for potential procedural and definitional amendments in the TCPS. Consistent with the consultations, PRE issued a public call in 2004–05 for commissioned research to review national and international academic and policy literature on CER. Following on this commissioned research, ProGroup determined that the concept and goals of CER, as well as the roles and responsibilities of those involved in applying CER process, require further clarification. This discussion paper presents the identified issues. It also seeks the community's input on sharing good practices for CER that would reflect the various disciplinary needs and methodologies, and range in size of institutions. With respect to CER, ProGroup's goal is to evolve the TCPS while accommodating the need for consistency with other policies and guidelines, and ensuring flexibility in their application.

¹ ProGroup recognizes the work of the Virtual Scholars, Marie Hirtle (Institut de Recherches Cliniques de Montréal) and Karen Weisbaum (Queen's Univ.), conducted in support of ProGroup's work in the area of continuing ethics review in the TCPS. ProGroup also recognizes the valuable input of sounding board members: Adela Reid (Concordia Univ), Dean Sharpe (Univ. of Toronto), Patricia Lindley (Dalhousie Univ.), Diann Nicholson (IWK Health Centre, Nova Scotia), Lisa Given (Univ. of Alberta), Sandy Auld (Univ. of Guelph), Mary Ann Laviolette (Ottawa Hospital), and Jody Berube (College of Physicians and Surgeons, Alberta).

² Also referred to as the Policy or Policy statement in this document

Purpose of this Discussion Paper

This is a revised version of the CER discussion paper released in Fall, 2007³. Changes in the document respond to issues raised in the public feedback (see Appendix 1 for feedback regarding recent consultation). This paper concludes with recommendations of textual changes to the TCPS, as well as other proposals concerning the process and application of CER.

When writing this document, ProGroup considered the great variety of institutions, research domains, and researchers to which it would apply. Therefore, where possible, ProGroup suggests a flexible application of the principles and procedures outlined. The paper is not intended to identify or resolve all outstanding issues related to CER.

ProGroup encourages comments and reactions to this report from research ethics administrators, research ethics board members, researchers, research subjects/subject groups, and other parties interested in this policy.

2.0 Continuing Ethics Review (CER) as it is Today

2.1 CER in the TCPS

Canadian institutions that are bound by the three agencies' Memorandum of Understanding on the Roles and Responsibilities in the Management of Federal Grants and Awards (MOU)⁴ are required to follow the TCPS in the conduct of research involving humans. This includes the creation of a continuing ethics review procedure (detailed in TCPS Article 1.13), as described below.

F. Review Procedures for Ongoing Research

[Article 1.13](#)

- (a) Ongoing research shall be subject to continuing ethics review. The rigour of the review should be in accordance with a proportionate approach to ethics assessment.**
- (b) As part of each research proposal submitted for REB [Research Ethics Board] review, the researcher shall propose to the REB the continuing review process deemed appropriate for that project.**
- (c) Normally, continuing review should consist of at least the submission of a succinct annual status report to the REB. The REB shall be promptly notified when the project concludes.**

³ An Open Invitation For Comments on a Discussion Paper: Refinements to the Continuing Research Ethics Review in the TCPS. Call for Comments: Open from 19 September to 19 November, 2007
<http://www.pre.ethics.gc.ca/english/workgroups/progroup/CER07ConsultInstr.cfm>

⁴ http://www.nserc.gc.ca/institution/mou_e.htm

Beyond scrutinizing reports, the REB itself should not normally carry out the continuing ethics review, except in specific cases where the REB believes that it is best suited to intervene. For research posing significant risks, the REB should receive reports on the progress of the research project at intervals to be predetermined. These reports should include an assessment of how closely the researcher and the research team have complied with the ethical safeguards initially proposed.

In accordance with the principle of proportionate review, research that exposes subjects to minimal risk or less requires only a minimal review process. The continuing review of research exceeding the threshold of minimal risk that is referred to in Article 1.13(b), in addition to annual review (Article 1.13[c]) might include:

- Establishment of a safety monitoring committee;
- Periodic review by a third party of the documents generated by the study;
- Review of reports of adverse events;
- Review of patients' charts; or
- A random audit of the process of free and informed consent.

Other models of a continuing ethics review may be designed by researchers and REBs to fit particular circumstances.

The process of a continuing ethics review should be understood as a collective responsibility, to be carried out with a common interest in maintaining the highest ethical and scientific standards. Research institutions should strive to educate researchers on the process of a continuing ethics review through workshops, seminars and other educational opportunities.

Unfortunately, many elements of CER are left unclear in this statement. ProGroup therefore examined CER as it is currently conducted, and attempted to document many of the issues involved in creating a practical and effective CER process.

2.2 Overview of Other Agencies' CER Requirements

In addition to the TCPS, institutions and researchers may be subject to other legislation and policies, including applicable provincial laws. Additionally, Health Canada adopted the *International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use Guidance E6: Good Clinical Practice: Consolidated Guideline (ICH-GCP-E6)*⁵, in which article 3.1.4 states, "The IRB/IEC should conduct continuing review of each ongoing trial at intervals appropriate to the degree of risk to human subjects, but at least once per year."

In the United States, the Department of Health and Human Services' Office for Human Research Protections (OHRP) has developed detailed guidance on continuing review⁶ as a regulatory

⁵ http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6_e.html

⁶ <http://www.hhs.gov/ohrp/humansubjects/guidance/contrev0107.htm>

requirement. Additionally, the Federal (Common Rule) Policy for the Protection of Human Subjects states, “An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.”⁷

3.0 Overview of CER

3.1. Context for this Discussion Paper

Throughout this document, the term “Research Ethics Board (REB) review” refers to review undertaken by the full REB, or delegated to an individual or a subcommittee of an REB. Similarly, the term “REB” may not mean the entire committee, but rather the chair or delegate. In this way, ProGroup fully supports a proportionate approach to the continuing ethics review process, in line with that taken for the initial review.

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

In this discussion paper, ProGroup does not address various jurisdictional issues. Specific jurisdictions may require that CER follow a specific process or collect particular information. Researchers and REB administrators will need to be familiar with the various laws, rules and regulations that apply to research in their jurisdiction or subject area.

Furthermore, CER for multicentred research, and appeal processes for CER are detailed in complementary documents currently being developed by ProGroup.

3.2 Why is CER Needed?

The primary goal of CER is to ensure that all stages of a research project are conducted in accordance with the guiding principles outlined in the TCPS. CER ensures the continued ethical acceptability of research, thereby ensuring the safety and protection of all research subjects for the duration of the project. CER is a collective responsibility shared among researchers, REBs and institutions. ProGroup further recognizes that subjects or subject groups have an important role in the CER process, but believes that they hold no specific responsibility for ensuring the continuing ethical acceptability of research.

CER processes provide those involved in the research process (e.g. researchers, REBs, subjects or subject groups) with multiple opportunities to reflect on the ethical issues surrounding the research. This reflection can show whether the stated risks, or other unknown risks, were incurred and how they affected the safety and well being of subjects or subject groups. This reflective practice enables both researchers and REBs to be more effective in protecting research subjects in current and future research. This practice is especially important in new and emerging

⁷ Article §46.109e of the United States Department of Health and Human Services Code of Federal Regulations PART 46, PROTECTION OF HUMAN SUBJECTS (Revised June 23, 2005) (adopted by more than 15 US federal departments, including health, education, defense, veteran affairs and justice)
<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.109>

fields, where the ethical implications are not yet well understood. Here, reflection can be characterized as a continuing dialogue between the subjects or subject groups, REBs and researchers to evolve the principles and practices surrounding research ethics – which can feed back to REBs, researchers, funding agencies, regulatory bodies, and institutions.

CER also serves an administrative function by allowing institutions (including REB administrative offices) to track which research is ongoing and which has been completed.

Another type of continuing review is quality assurance (QA) or monitoring of ongoing research. This extends beyond the functions and mandate of the REB. Although there is currently no clear distinction in the research community between the two processes, ProGroup is cognizant of the need for both CER and QA to be complementary rather than independent. In this discussion paper, ProGroup does not address this need, nor the jurisdictional and definitional issues surrounding QA and monitoring.

3.3 What is the Minimum Scope of CER?

All research that has been approved by an REB is also subject to CER during the period the research is active (e.g., the REB file is still open). Typically, CER is accomplished by a report from the researchers to the REB. Minimally, this is stated in the TCPS as a “succinct annual status report to the REB.”⁸ REBs have the authority to determine a more frequent reporting schedule, normally at the time of first review. However, if the need arises; e.g., if the risk level of the research increases because of the discovery of new knowledge or addition of new procedures, the reporting schedule may be adjusted. Furthermore, REBs may require a more detailed level of reporting. The REB should take its decision as to the frequency and level of reporting using a proportionate approach to research ethics review.

Certain classes of events must be reported to the REB. These include changes/revisions to research (Section 3.4.7), unexpected and unanticipated events (Section 3.4.8), and deviations and violations to an approved project (Section 3.4.9). Furthermore, new situations may arise in the future that would also require reporting to the REB.

3.4 Operational Issues of CER

3.4.1 Proportionate Review

Just as the initial review of a research proposal should be proportionate to the risk involved in the research, so should the CER of the same research proposal. Research that involves minimal or no risk to the research subject should be held to the minimum standard of CER: e.g., a short annual report. Research that poses greater than minimal risk may require a more extensive CER. This could include more frequent reporting to the REB, review of the consent process, review of subject records, etc.

The level at which CER occurs (e.g., frequency of reports, required details in reports) should be determined at the time of initial review of the research by the REB or an authorized delegate of the REB, but the level may change throughout the life of the project.

⁸ TCPS Article 1.13c at <http://www.pre.ethics.gc.ca/english/policystatement/section1.cfm#1F>

3.4.2 When Does CER Start and End?

Research is subject to CER from the date of initial REB approval until completion of the study. The effective approval and study completion date may vary from institution to institution. Researchers have pointed out that for some types of research (e.g., qualitative research or longitudinal research), there may be some difficulty in establishing start or end dates. For these cases, the REB should work with researchers to determine a reasonable timeline for CER.

3.4.3 Term of Approval

At the time of first review, the REB should determine the term of approval. Although the default length of time for approval is normally one year, the length of time for approval could be much shorter or longer. For instance, some institutions approve research projects for the length of the project, with a requirement to provide an annual report on the progress of the research.

In general, regardless of the term of approval, projects will need to be re-reviewed or amended if the context surrounding the research project changes. Although the REB holds responsibility for reviewing projects in light of changes in context, the researcher has a responsibility to be familiar with the environment in which the research is being conducted and to notify the REB about changes that may affect the ethics of the research.

3.4.4 Minimum Reporting Interval

For research projects lasting longer than one year, the TCPS requires at minimum a succinct annual report. For research lasting less than one year, a succinct end-of-study report may suffice. End-of-study reports are particularly relevant for student research, where the student may no longer be reachable after the end of an academic term.

Following a proportionate approach (outlined in Article 1.6 of the TCPS), an REB has the option of requesting more frequent and substantive reports if necessary.

3.4.5 Scheduled Versus Ad Hoc Review

REBs may specify that the CER process be either scheduled or ad hoc for any research that they approve.

Scheduled CER is generally accomplished through submission of a brief report to the REB. The timing and content of the report is at the discretion of the REB and will vary depending on the institution, type of research, and level of risk involved in the research (see Section 3.4.9). Additionally, some research, such as that involving clinical trials, may be mandated by other governing bodies to provide certain types of information.

Ad hoc CER is generally triggered by the researcher and could include such things as review of proposed revisions to recruitment letters or informed consent documents, as submitted by the researcher(s) to the REB. It may also include review of the conduct of research, including the way consent is obtained or the data are stored. The REB may take an active role in the review activities or may use an external body such as a Quality Assurance/Monitoring Committee to undertake the review.

3.4.6 Record Keeping and Data Retention

REBs must maintain comprehensive files, including accurate minutes and attendance sheets of all meetings. With respect to CER, they should also maintain complete study files, including original application, documentation regarding changes (including approval or acceptance of such changes), as well as annual and end-of-study reports. For additional information on requirements regarding record-keeping and data retention, please refer to the PRE interpretations on the topic^{9, 10}.

3.4.7 Revisions to Research Project

Any revision(s) to an approved proposal should be submitted to the REB for review. In some cases, the chair or delegate of the REB can note the change and inform the researcher that the change has been accepted, and the research can continue as before. In other cases, the chair or delegate of the REB may determine that the revisions to the original proposal require ethics review and no new subjects may be enrolled until approval is granted.

The nature of changes to a research project can occur along a continuum from administrative to procedural issues. Examples of changes that may require a more extensive review include a change in study procedures or change in information given to the subjects in the informed consent documentation. Examples of changes that may be dealt with by acceptance of the REB chair or delegate, with little or no subsequent review, include change of researcher contact information or revision of analysis procedures. REBs should follow a proportionate approach in determining the type of review necessary.

No changes to a research project, no matter how small, should be implemented until accepted or approved by an REB unless immediate implementation is necessary for research subject safety. . It is not the size of the change that dictates the review process, but rather the ethical implications and risk associated with the proposed change.

3.4.8 Unexpected and Unanticipated Events

Reporting of harmful events protects the research subjects by ensuring that their safety is continually monitored and that changes are made to the research as necessary.

In the case of clinical trials, unexpected or unanticipated events and reporting requirements are defined in ICH/GCP. An REB may stipulate a timeframe for the reporting of such events. In some cases, such events may be identified by Data Safety Monitoring Boards (DSMB) or study sponsors. If the event has immediate implications for the safety and protection of research subjects, the REB may require that the research be halted until the matter can be addressed. An institution must provide written procedures for dealing with serious unexpected and unanticipated events.

For other kinds of research, institutions and REBs will need to decide which types of unexpected or unanticipated events should be reported to the REB, and should develop an appropriate standard operating procedure or process for dealing with them.

⁹ <http://www.pre.ethics.gc.ca/english/policyinitiatives/interpretations/interpretation012.cfm>

¹⁰ <http://www.pre.ethics.gc.ca/english/policyinitiatives/interpretations/interpretation019.cfm>

In still other kinds of research (especially in the social sciences and humanities), it is not always clear before the research is undertaken what events may occur during the course of the research project. Here, researchers should report any event that occurred as a result of the research and that may affect the safety and well-being of the research subjects. In many cases, researchers will simply need to use their best judgment as to what should be reported to the REB. In other cases, the researchers and REBs may work together to develop a list of types of reportable events. The point in reporting would not be punitive, but simply informational and educational, so that the REB can better protect research subjects in future research projects. Depending on the nature of the unexpected event, REBs may require that researchers adjust their procedures to prevent such events from re-occurring during the research project.

3.4.9 Deviations and Violations to an Approved Project

Deviations and violations occur when unavoidable departures from the originally planned research procedure occur. This can happen for any number of reasons, e.g., a subject forgot to take a study medication, or a translator is unavailable.

The final decision as to which type of deviations and violations to report to the REB is up to the REB. Usually, these will include only deviations and violations that affect the safety and well-being of research subjects. The report to the REB should include a description of the incident, including details of how the researcher(s) dealt with the situation.

Note that here, ProGroup is talking about deviations to the **approved** study procedure. In many types of qualitative research, the study design evolves over time—hence changes to the study would have been accepted and expected. These types of evolutionary practices would not be considered deviations and violations.

3.4.10 Content of the Report

The TCPS provides some guidance on what should be covered in a report; namely, progress on the research implementation, and whether the research has deviated from the approved proposal and the ethical safeguards. To provide this information, a report may include details such as the following (in addition to a project title and/or a study identifier such as a reference number):

- date of last approval
- status of the study, which could include:
 - number of research subjects recruited to date
 - whether recruitment is open or closed
 - other relevant details
- changes related to funding (e.g., funding source)
- information regarding the current informed consent documentation, which could include:
 - date or version number
 - actual copy of letter
- number and type of unexpected or unanticipated events that have occurred, with confirmation that they have already been reported to the REB
- new information related to risk
- problems encountered during conduct of the research

- changes in study investigators.

Not all of the above items will be appropriate for all types of research. The REB will need to determine (possibly with the assistance of the researcher) which types of information are necessary for ethics or administrative purposes. Additionally, the REB may require additional information not listed here in order to adequately assess the research.

4.0 Roles and Responsibilities of Involved Parties

In addition to the collective responsibilities of all parties involved in research ethics review to ensure the safety and protection of research subjects, each party has particular obligations with respect to CER. These are detailed below. A notable absence from the list is non-academic partners and sponsors of the research. These are institution specific and vary depending on their role in research.

4.1 Researcher

Researchers must monitor their research/research program to ensure that the research is conducted in an ethical manner. Related to this point, researchers need to understand the basics of conducting ethical research. When researchers write their proposal, they need to state the research objective and method(s) utilized. Researchers must also share, with the relevant research community, information about unanticipated events with ethical consequences.

Additionally, the principal investigator (researcher) is obligated to advise the REB of any proposed revisions to the research program, and to obtain appropriate approval or acceptance before instituting the changes, even if it means suspending the research project until REB approval is received. The principal investigator (researcher) must also report to the REB all unanticipated or unexpected events and any deviations or violations that occur.

The principal investigator (researcher) must supervise all team members in the application of the research procedures, and ensure that they are versed in the conduct of ethical research.

Additionally, the principal investigator (researcher) needs to ensure that all data are stored in a secure and confidential manner. The researcher also needs to confirm that the subjects understand their role in the research project including reporting health changes or other concerns to the researcher or third party contact. Finally, the principal investigator (researcher) has a responsibility to inform the subjects of any pertinent changes in the research that could potentially affect them, and, if necessary, to ask the subjects to re-consent.

4.2 Research Ethics Board

Like the researchers, the REB has an obligation to ensure that continuing research is conducted in an ethical manner. The REB must have clear policies and processes that researchers will use to report any changes to approved research. The REB must also have an established process to review and take appropriate action regarding proposed changes to the approved research, including reporting to senior administration and other administrative units where necessary and appropriate.

Related to this, the REB must also have a mechanism for responding to complaints by subjects and/or subject groups.

The REB must set its expectations for annual (or more frequent) reports on the status of any research project. It must also establish requirements for reporting of unexpected or unanticipated events and deviations and violations, and have written processes for dealing with such reports.

Additionally, the REB is obliged to provide feedback to researchers in a timely manner.

Finally, the REB has the responsibility to communicate its processes and procedures to everyone involved in the research process.

4.3 Institution

Institutions are ultimately responsible for ensuring that research conducted within their jurisdiction is ethically sound. To do so, institutions need to ensure that their REBs have the appropriate infrastructure, financial support and independence to carry out CER. The institution must ensure that guidelines for continuing review and procedures are in place for the REB to follow, and are communicated to appropriate bodies both inter- and intra-institutionally.

Institutions must also ensure that their REB members, administrators, researchers and research staff receive appropriate education and training related to the ethics of research involving humans.

Additionally, institutions need to have clear policies describing the mandate of the REB(s) and the extent of the REB's authority with regard to rescinding REB approval once a study is underway.

4.4 Research Subject

Research subjects have the right and responsibility to report or question any event that concerns them, to either the researchers or a third-party contact identified in the informed consent documents. Additionally, in biomedical intervention studies such as clinical trials, research subjects must report any changes in their health status to the researcher or the research staff.

4.5 Third-party Contact

Every informed consent document should contain contact information for a third party (e.g., the REB office or the patient ombudsman at a hospital) to whom the research subject can address concerns about the way a study is conducted or about their rights as a research subject. This third party is responsible for ensuring that the research subjects' questions are answered and concern(s) are dealt with in a timely manner. This may involve contacting the researcher and/or REB to report and resolve the issues. The third-party contact is responsible for reporting back to the subjects/subject groups in a timely fashion and ensuring that dialogue is maintained until the issue is resolved.

5.0 Resources

To institute a proper CER requires substantial resources. These resource requirements fall into the following areas:

- institutional support (e.g., appropriate mandates and authorities for the REB)
- personnel
- finances
- infrastructure/facilities
- communications
- education.

It is also important that written procedures for CER be created and communicated to all parties involved in research.

6.0 Recommendations and Proposals

ProGroup's identification of the need for clarity in the TCPS has been confirmed in community consultations.

In addition to the following proposed textual amendments to the TCPS, ProGroup has the following proposals to strengthen the concept of the CER in the Canadian context:

- Consider convening a workshop for developing a guidance document on CER and its best practices.
- Expand the TCPS on-line tutorial to include responsibilities related to CER.
- Develop an educational resource for REB administrators on how to implement effective CER processes.
- Stress the importance of adequate financial and human resources for implementation of an effective CER.
- Clearly define the necessary elements of the annual report – refer to section 3.4.10 of this document.

Proposed Textual Amendments to the TCPS:

ProGroup recommends that the current text of the TCPS 1.13 should be replaced by the text in the box below. This text reflects the following key elements of CER:

- a. Specifies the time frame for CER, strengthens the collective responsibility in CER.
- b. Gives sole responsibility to the REB to determine the appropriate CER process.
- c. Defines “the minimum” scope of CER, and gives the REB more latitude to require a more comprehensive CER.
- d. Reiterates the importance of proportionate approach in CER (originally in 1.13a).
- e. Documents the need to keep adequate records related to CER.

- f. Requires an end of study report to be submitted, including a proposed timeframe.
- g. Requires researchers to report any unanticipated or unexpected events and deviations, from the approved research. This is a key element currently lacking in the TCPS.
- h. Requires researchers to obtain acceptance or approval of changes before implementing them. This is another key element currently lacking in the TCPS.

It is also expected that the proposed text will be supplemented by elucidative commentary reflecting the content of this document.

F. Continuing Ethics Review

- a. Ongoing research shall be subject to continuing ethics review. The process of continuing ethics review is a collective responsibility shared by the institution, the REB and the researcher.
- b. The REB makes the final determination as to the nature and frequency of the continuing ethics review in accordance with a proportionate approach to ethics assessment.
- c. At minimum, continuing ethics review shall consist of an annual status report on the research, followed by an end-of-study report. For research of less than one year in duration, an end-of-study report may be sufficient. The end-of-study report shall be submitted to the REB no later than 3 months from the date of study closure.
- d. REBs need to document the continuing review of ongoing research to ensure accurate and adequate administration and integrity of the research process in accordance with its record keeping responsibilities (see Article 1.8).
- e. A researcher must report to the REB any unanticipated or unexpected events and deviations from the approved research.
- f. A researcher should not implement any changes to the research without documented approval or acceptance by the REB, except when necessary to eliminate an immediate hazard(s) to the research subjects. The level of REB review required to assess the changes shall follow a proportionate approach to ethics assessment. This may result in a change to the initial continuing ethics review process.

**Feedback to the Interagency Advisory Panel on Research Ethics (PRE) and the Research Ethics Community
Regarding**

**The Subgroup on Procedural Issues for the TCPS (ProGroup)'s
Recent Consultation on
Refinements to the Continuing Research Ethics Review in the TCPS**

January 2008

ProGroup's discussion paper "Refinements to the Continuing Research Ethics Review in the TCPS" was posted on the PRE web site for two months: 19 September to 19 November, 2007, and was disseminated widely for public consultation. The consultation yielded approximately 30 submissions from individual researchers, research ethics boards, research administrators, and other groups and associations with interest in the research ethics field. Comments received were from a broad regional representation, affiliation to various size institutions, and a wide spectrum of disciplinary affiliations reflecting their knowledge as well as their practical experience in the area of Continuing Ethics Review (CER) within the Canadian context. Comments were received through the built-in on-line consultation tool, and through direct correspondence to the Secretariat on Research Ethics.

Thanks to members of the community who took part in the consultation, ProGroup found the comments to be thoughtful, clear, and valuable in changing and making proposals/recommendations in the enclosed revised version of the document.

ProGroup undertook a detailed review of each comment. It found the comments to be generally in support of the CER process, and the proposed direction in the document. Suggestions and other constructive criticism revealed some areas in need of clarity, specificity, or further elaboration in the document. Where ProGroup felt it appropriate, these were addressed in the revised discussion paper. Other suggestions fell outside the scope of the paper. Some of these are outlined in the following:

- Relationship and process of communication between CER and Quality Assurance, Data Safety Monitoring Board, and Audit Committees. ProGroup had indicated in the consultation document that this is out of the scope of the paper, and is still of this view.
- Some comments expressed frustration and questioned the need for CER especially in the Social Sciences and Humanities. ProGroup felt that such comments expressed an implementation of the CER process at the institutional level that will likely benefit from the clarification and details that the current CER document offers.

- Some comments questioned the current practice in some institutions of approving a project for its duration rather than approval on annual basis. ProGroup felt this was an implementation issue. What was previously brought to ProGroup's attention is that institutions have different approaches in implementing the approval process. Some institutions approve projects on an annual basis, whereas others approve for the duration of the project conditional on the submission of the minimum of annual reports for review and confirmation of approval.
- Some raised the issue of jurisdictional anomalies. ProGroup views the TCPS as the minimum standard, and institutions need to abide by other provincial or other requirements where these apply.

One major theme that appeared in many of the comments is the availability of appropriate resources to support CER. ProGroup reflected this in the proposals in the enclosed document.

The enclosed revised version of the document is intended to reflect many of the practical applications of an effective CER process at institutions and to make other related proposals as a continuum to this current work. We additionally suggest potential wording changes to the TCPS to allow for greater clarification in the implementation of CER. With time and the emerging and evolving needs of the research ethics community in the application of the ethics review process, CER, as with other areas in the TCPS will require further reflection and development.

Respectfully submitted by

ProGroup.