
**Proposed Textual Changes to REB Operational Issues
in the *Tri-Council Policy Statement: Ethical Conduct for
Research Involving Humans (TCPS)***

Submitted by the

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A Working Committee of the
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TABLE OF CONTENTS

Introduction.....	1
ProGroup’s Textual Amendments to REB Operational Issues.....	1
B. Research Ethics Boards (REBs)	2
B1. Authority of the REB.....	2
B2. Membership of the REB.....	3
Article 1.3	3
Article 1.4	5
D2. Meetings and Attendance.....	6
Article 1.7	6
D3. Record Keeping	7
Article 1.8	7
D4. Decision Making	7
Article 1.9	7
D6. Appeals.....	8
Article 1.11	8

Introduction

Consistent with the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS), institutions are required to develop the necessary structure and procedures for the ethical review of research involving humans. This includes the establishment of efficient and effective ethics review processes with clear procedures regarding membership, operation of meetings, decision-making, and governance. Public consultations held in 2003 and 2004¹ identified several issues associated with Research Ethics Board (REB) operations as top community priorities for potential procedural and definitional changes to the TCPS.

Within its mandate as a working committee of the Interagency Advisory Panel on Research Ethics (PRE), the Sub-group on Procedural Issues for the TCPS (ProGroup)², recommends a number of textual changes to clarify issues, and address gaps and operational issues that warrant revision in light of the evolving needs of the TCPS user community. The document has been informed by ProGroup members' practical experience in the area, by the community's requests for interpretations and PRE's responses to those queries, as well as the Secretariat on Research Ethics' in-house research on the topics.

ProGroup submits the proposed textual changes to facilitate the appropriate revisions to several REB operational issues in the TCPS. The proposals are developed within current context recognizing the need to observe, acknowledge and respect the dynamic nature of research ethics review and the evolving needs in operationalizing the TCPS.

ProGroup's Textual Amendments to REB Operational Issues

The sequence and numbering system used in this document follow that in the current version of the TCPS. Text in *Italics* is proposed for addition, while text struck out is proposed for deletion.

¹ See ProGroup's identification and prioritization initiatives at <http://www.pre.ethics.gc.ca/english/workgroups/progroup.cfm>

² See more information on ProGroup at <http://www.pre.ethics.gc.ca/english/workgroups/progroup.cfm>

B. Research Ethics Boards (REBs)

B1. Authority of the REB

Article 1.2

The institution shall mandate its REB(s) to approve, reject, propose modifications to, or terminate any proposed or ongoing research involving humans that is conducted within, or by members of, the institution, using the considerations set forth in this Policy as the minimum standard. *The authority of the REB must be delegated through the institution's normal process of governance. In defining the REB's mandate and authority, the institution must make clear the jurisdiction of the REB and its relationship to other relevant bodies or authorities.*

Institutions must promote the significance of the work of the REB, and ensure that the contributions of the REB members and the REB Chair are valued and recognized. REBs should be responsible directly to the senior institutional administrator with responsibility for research involving humans for the institution (president, vice president, rector, Chief Executive Office (CEO), etc.), or a high level institutional committee responsible for such matters. This reporting structure should be specified in writing.

Institutions must ensure that REBs and their associated administration have sufficient and appropriate financial and administrative independence to fulfil their ~~primary~~ duties and to avoid possible conflict of interest. REBs and their associated administration should be distinct from research administration offices which directly approve and manage research grants and contracts.

Institutions must respect the authority delegated to the REB. The institution may not override negative REB decisions reached on grounds of ethics without undertaking a formal appeal process as set out below. Institutions may refuse to allow certain research within its jurisdiction, even though the REB has found it ethically acceptable.

Each institution is accountable for the research carried out within its own jurisdiction or under its auspices. *In cases where research could potentially involve review by more than one REB, an institution can authorize its REB(s) to accept the review decision 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 also ensure that REB members and the administrative personnel who support the REB are provided with regular training opportunities to ensure an understanding of their work and roles, and of the interpretation and application of the TCPS.

B2. Membership of the REB

Article 1.3

The REB shall consist of at least five members, including both men and women, of whom:

- (a) At least two members have broad expertise in the *relevant research disciplines and methodologies* ~~methods or in the areas of research that are covered by the REB;~~**
- (b) At least one member is knowledgeable in ethics;**
- (c) For biomedical research, at least one member is knowledgeable in the relevant law; this is advisable but not mandatory for other areas of research; and**
- (d) At least one member has no affiliation with the institution, but is recruited from the community served by the institution.**

These basic membership requirements are designed to ensure the expertise, multidisciplinary and independence essential to competent research ethics review by REBs. The concept of independence implies that members of the REB under Article 1.3(a-c) should contain a majority of those whose main responsibilities are in research or teaching. The institution may need to exceed these minimum requirements in order to ensure an adequate and thorough review. The Agencies consider it essential that effective community representation be maintained. Thus, as the size of an REB increases beyond the minimum of five members, the number of community representatives should also increase. *Membership may need to be augmented to respond to other local, provincial requirements or legislations.*

~~The majority of members of an~~ REB *members* should have both the training and the expertise to make sound judgments on the ethics of research proposals involving human subjects. *Institutions should dedicate appropriate resources for education and training of REB members.* The terms of REB appointments should be arranged to balance the need to maintain continuity with the need to ensure diversity of opinion and the opportunity to spread knowledge and experience gained from REB membership throughout the institution and community.

Because the REB should reflect the ethical values of this Policy in the context of the society within which it operates, its membership should be broad enough to reflect that society. The members of the REB therefore play different but complementary roles. Article 1.3(a) indicates that general expertise in the relevant research disciplines and methodologies is essential. Article 1.3(b) requires a member knowledgeable in ethics, so as to alert the REB to potential ethics issues and options.

Knowledge of ethics of research involving humans is key within the REB membership as a whole. Under the TCPS, REBs and institutions share important responsibilities for ensuring relevant and effective knowledge in ethics for the research ethics review process. Article 1.3

(b) indicates that REB membership should include at least one member “knowledgeable in ethics”. This member needs to have sufficient knowledge to guide an REB in identifying and addressing ethics issues. A balance of ethics theory, practice and experience offers the most effective path to knowledge in ethics for REB membership. The kind and level of knowledge or expertise essential to a particular REB should be proportionate to the kind and complexity of ethics issues it deals with. For example, a member knowledgeable in ethics serving on a social sciences and humanities REB may have different contextual and disciplinary knowledge in ethics than has a member of a biomedical REB.

The role of the member knowledgeable in the applicable law is to alert REBs to legal issues and their implications, not to provide formal legal opinions or to serve as legal counsel for the REB. ~~An understanding of relevant legal issues and contexts is advisable for all REBs, although for non-biomedical research such insights may be sought from someone who sits on the REB only for specific research projects.~~ The institution’s legal counsel *and/or risk manager* should not be a member of the REB. *In house legal counsel might be seen to identify too closely with the institutions’ financial interest in having research go forward or, conversely, may be unduly concerned with protecting the institution from potential liability. This presents a potential source of conflict of interest that may undermine the independence and credibility of the REB in assuming its role. Any external legal counsel hired on a case-by-case basis by the institution should not sit as a member of that institution’s REBs while working for the institution.*

The community member requirement of Article 1.3(d) is essential to help broaden the perspective and value base of the REB beyond the institution, and thus advances dialogue with, and accountability to, local communities.

Community members play an important role on REBs by contributing a perspective during the research ethics process that is both unique and at arm’s length from the institution. Community members’ primary role on the REB is to reflect the perspective of the research participant. This is particularly important when research participants are vulnerable and/or risks to research participants are high.

REBs should husband their resources and expertise prudently. For example, in the event that the REB is reviewing a project that requires particular community or research subject representation, or a project that requires specific expertise not available from its regular members, the REB Chair should nominate appropriate *ad hoc* members for the duration of the review. Should this occur regularly, the membership of the REB should be modified.

Institutions should consider the nomination of substitute REB members and an alternate Chair so that Boards are not paralyzed by illness or other unforeseen eventualities. The use of substitute members should not, however, alter the membership structure as outlined in Article 1.3.

Article 1.4

- (a) **REBs shall be established by the highest levels of the institution, and cover as broad a range of research as is consistent with manageable workloads. Departmental REBs normally are not acceptable (except as discussed below for review of undergraduate research within course requirements). A multiplicity of REBs with small workloads within the same institution should be avoided.**
- (b) ~~Large Institutions may decide to create more than one REB, depending on their size and the nature and scope of human research conducted under their jurisdiction, usually to cover different areas of research. The jurisdiction of Each REB's operation should be clearly defined by normal process of governance within the institution formal Terms of Reference, and a mechanism should be established to coordinate the practices of all REBs within the institution.~~
- (c) ~~Small Institutions may wish to explore regional cooperation or alliances, including the sharing of REBs. For small institutions, this may also include the sharing of REBs and resources.~~

When an institution has more than one *REB* or *accepts the status of an external REB*, it should define their jurisdictions. Researchers ~~should~~ *must* apply for ethics review to the designated REB *only* and *must* not seek review by another REB *in lieu of the designated REB*, whether inside or outside the institution. REBs within an institution should have the authority to transfer research proposals among themselves *or to an external REB* to ensure review by an REB with the appropriate expertise. *Exchanges with external REBs must have appropriate agreements in place.* Furthermore, when more than one REB is established by an institution, lines of communication should be open between the REBs in order to keep each aware of the *other's activities related to research under review* and of the decisions made.

~~As a special exception to Article 1.4(a), an institution may decide that ethics review of research that is carried out by undergraduate students as part of their course work may be delegated to a departmental level process that complies with this Policy Statement. The institution should set out criteria for determining which categories of research proposal are suitable for consideration through this means, and establish procedures, such as who is responsible for implementing and overseeing the approval mechanisms. As with other levels of review, proper accountability demands appropriate record keeping. Departmental level review should not be used for research in which an undergraduate student is carrying out research that is part of a faculty member's own research program. Such research should be reviewed by the regular institutional REB procedures.~~

D2. Meetings and Attendance

Article 1.7

REBs shall meet regularly to discharge their responsibilities.

Face-to-face meetings are essential for adequate discussion of research proposals and for the collective education of the REB. *This procedural standard is intended to foster effective REB decision-making. The face-to-face medium provides interactive dynamics of immediate audio, visual and physical (non-verbal) exchanges that tend to heighten the quality and effectiveness of communications and decisions. Such a medium helps to foster collaborations that are essential for adequate discussion of research proposals and for the collective education of the REB. The TCPS standard of regular face-to-face meetings is thus intended to provide richer interaction and to produce, over time, high-quality thinking and decisions.*

Videoconferencing may occasionally be regarded as necessary for meetings when REB members are geographically dispersed and there is no other way of holding an effective REB meeting, when resource constraints prevent all meetings from being conducted face-to-face, or when exceptional or exigent circumstances significantly disrupt or limit the feasibility of face-to-face REB meetings, such as during a public health emergency. Appropriate measures to respect the privacy and confidentiality of information under review and the REB discussion may be best guaranteed in video communication through a secure transmission. Institutions need to develop written procedures for the occasional use of videoconference in the conduct of REB meetings.

A schedule of when the REB will sit to review research proposals should be communicated to researchers so that the research can be planned in an orderly way. *At a minimum, this would be 3 times per year.*

REBs should also hold general meetings, retreats and educational workshops in which members can (1) take advantage of educational opportunities that may benefit the overall operation of the REB, (2) discuss any general issues arising out of the REB's activities or (3) revise policies.

Unexpected circumstances such as emergencies may prevent individual member(s) from attending the REB meeting. In these exceptional cases, input from member(s) by other means would be acceptable. Regular attendance by REB members at meetings is important, and frequent unexplained absences should be construed as a notice of resignation.

Quorum should be established at fifty percent of appointed voting members plus one. Quorum must include the minimum expertise and number in TCPS Article 1.3. Institutions should also establish quorum rules for REBs. When there is less than full attendance, decisions requiring full review should be adopted only if the members

~~attending the meeting possess the range of background and expertise stipulated in Article 1.3.~~

REBs and researchers may request informal meetings with each other prior to the formal review process, in order to expedite and facilitate the review process. Such informal meetings cannot, however, substitute for the formal review process.

D3. Record Keeping

Article 1.8

Minutes of all REB meetings shall be prepared and maintained by the REB. The minutes shall clearly document the REB's *discussions*, decisions and any dissents, and the reasons for them. *Such records should be kept indefinitely.*

In addition, the REB shall maintain all documentation related to the study submitted to the REB for review throughout the life of the study.

In order to assist internal and external audits or research monitoring, and to facilitate reconsideration or appeals, the minutes *and other relevant documentation* must be accessible to authorized representatives of the institution, researchers and funding agencies.

Article 1.8 indicates the need for REBs to act, and be seen to be acting, fairly and reasonably. To ensure accurate and fair administration and integrity of the research process, the maintenance of satisfactory records and documentation is essential. Failure to do so may expose researchers and institutions to legal liability.

D4. Decision Making

Article 1.9

REBs shall meet face-to-face to review proposed research that is not ~~delegated to expedited~~ *assigned to delegated* review. REB review shall be based upon fully detailed research proposals or, where applicable, progress reports. The REB shall function impartially, provide a fair hearing to those involved and provide reasoned and appropriately documented opinions and decisions.

The REB shall accommodate reasonable requests from researchers to participate in discussions about their proposals, but those researchers *must* ~~may~~ not be present when the REB is making its decision. Decisions of REB's must be communicated in writing in a timely manner to the researcher. When an REB is considering a negative decision, it shall provide the researcher with all the reasons for doing so and give the researcher an opportunity to reply before making a final decision.

Especially in complex research proposals, the formal REB decision on whether to allow the

research will often be preceded by extensive discussion (1) of ethical concerns and (2) of possible means of improving such aspects as the research design or the information to be provided in the process of free and informed consent. Participation by the researcher in such discussions is often very helpful to both REBs and researchers. Such discussions may result in a deferral of the REB's decision until the researcher has considered the discussions and possibly modified the proposal. Such discussions are an essential part of the educational role of the REB.

The REB must reach a decision on whether to allow the proposed research. Article 1.9 outlines the duty of REBs to function impartially and to provide reasoned and well-documented decisions. In the event that a minority within the REB membership considers a research project unethical, even though it is acceptable to a majority of members, an effort should be made to reach consensus. Consultation with the researcher, external advice, and/or further reflection by the REB may be helpful. If disagreement persists, a decision should be made under the procedural rules mandated by the institution. In such instances, the position of those disagreeing may be communicated to the researcher. The Chair should monitor the REB's decisions for consistency, ensure that these decisions are recorded properly, and ensure that researchers are given *timely* written communication of the REB's decisions (with reasons for negative decisions) as soon as possible.

D6. Appeals

Article 1.11

- (a) **In cases when researchers and REBs cannot reach agreement through discussion and reconsideration, an institution should permit review of an REB decision by an *established* appeal board process provided that the board's membership and procedures meet the requirements of this Policy. ~~No ad hoc appeal boards are permitted.~~**
- (b) **Small institutions may wish to explore regional cooperation or alliances, including the sharing of appeal boards. If two institutions decide to use each other's REB as an appeal board, a formal letter of agreement is required.**
- (c) **The Agencies will not entertain any appeals of REB decisions.**

Proposal from ProGroup to PRE re. the above Article 1.11:

ProGroup views "Appeals of REB decisions" to be an important area that requires attention and clarification in the second edition of the TCPS. Given the need for further deliberation on this significant issue and the potential impact of its change, within the time limitations, ProGroup provides several recommendations reflecting its thinking on the topic based on the members' practical experience:

- Recommendation 1: Consider making a change to the requirement that a) institutions need to have a permanent appeal committee in place, and that b) such committees cannot be ad hoc committees.

Based on experience, appeals of REB decisions very rarely occur within institutions. Having an ongoing appeal committee that does not meet unless an appeal occurs would be wasteful of resources, and would not provide sufficient expertise to assess the work. Further, by the nature of their role and frequency of meeting, appeal committees are typically de facto, ad hoc. Instead, ProGroup proposes a requirement that institutions must have an established mechanism and procedure in place (i.e. a published guideline) for entertaining appeals, but eliminate the need that this be a permanent appeals committee.

- Recommendation 2: Consider clarifying that the bases for appeals should be on procedural grounds only such that an appeal mechanism is not used to re-review the research and the REB decision, and potentially to render another opinion as to its ethical acceptability. Having an appeal board do another round of review undermines the work of the REB and of its independence. For this reason, the appeal committee's role should be focused on a determination of whether or not appropriate procedural guidelines were followed during the initial ethics review process.

From an institutional (and research participant) risk perspective, it would be very concerning and could be dangerous if an "appeal REB" approved research initially turned down by the regular REB. The regular REB would be more experienced in assessing the type of research under appeal, associated risks, and methodological issues unless there were significant irregularities in the process, membership and reconsideration process employed by the regular REB at the time it made its decision.

- Recommendation 3: Consider clarifying that if the appeal process addresses procedural issues only, a committee that mirrors the composition of an REB as described in Article 1.3 of the TCPS would not be required.

Based on the above recommendations, adherence to procedures does not require expertise on the appeal board to mirror that of an REB. It would require a person with good judgment, or a committee at a senior level within the institution, to assess any procedural errors that may have occurred based on clear guidelines. From a practical point of view, it is challenging enough to appoint REBs members with appropriate expertise and to conduct appropriate REB training sessions for the regular REBs (plus administration resources). To undertake this for a parallel appeal REBs that in many cases do virtually no work would be difficult to do and to justify.

Some have suggested that former REB members could populate an appeal REB or that another institutional REB could review the submission. These are not practical solutions. Research ethics is not static and requires that an REB and its members have current knowledge and expertise with accepted norms of the research under review. In addition, it has the potential to set up an adversarial system among REBs asked to

review and reassess the work of the other whether within the same institution or outside.

To further illustrate the issue, the following is an example of an institutional Terms of Reference of an Appeal Committee in place at a large research intensive university that addresses the above issues.

Principal Investigators have the right to request an appeal of an REB decision once the period of reconsideration has occurred and has been exhausted, and the REB has issued a final decision. The scope of any appeal will be limited to procedural and jurisdictional issues. That is, the Appeal Committee will determine whether the REB acted outside its mandate and/or committed a breach of the process for ethics review as set out in the most recent version of the institution's guidelines or policies and the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*.

The Appeal Committee has no jurisdiction to make a decision regarding the ethical acceptability of the research study involved in the process under appeal. It should be stressed that the appeals process is not a substitute for the REB and the researcher working closely together to ensure high quality research, nor is it a forum to merely seek a second opinion. It is expected that an appeal will be an exceptionally rare occurrence.

The Appeal Committee **shall**:

- 1) dismiss the Appeal;
- 2) declare the original REB decision void and direct the responsible REB to reconsider the application while ensuring the REB is compliant with all procedural and jurisdictional requirements; or,
- 3) in the case of protocols reviewed by delegated review, direct the investigator to submit the protocol, as a new submission, for review by the full REB.