

1	2	(3)	4	5	(6)	(7)
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RN			ge	In general, this document provides detailed requirements but little ethical guidance. This is, we assume, consistent with its purpose and mandate. However, there is the danger that, like many Boards in the US, with the introduction of such detailed requirements, REB review may become concerned primarily with meeting these technical and detailed requirements, and concerned less with the conceptual ethical aspects of clinical trials.		
RN			ge	The title of the document is "Research ethics boards reviewing biomedical clinical trials" but in the body of the work, the only available definition is for 'clinical trials', not 'biomedical clinical trials'. This could lead to disagreement regarding which research would be covered by these standards. Because the scope of the Standard applies only to clinical trials, no input from social-sciences humanities research stakeholders has been obtained.		
RN			ed/te	The terms 'application' and 'protocol' are used interchangeably which may lead to confusion, as are the terms 'organization' and	Provide consistent use of institution or organization; provide a definition of institution or organization.	

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				'institution'. In addition, apparently some are interpreting the Standard as not allowing for the use of independent ethics boards.		
RN			ge/te	This Standard is duplicative of the Tri-Council Policy Statement (TCPS). The statement that neither the Food and Drugs Act nor the TCPS provides detailed standards is incorrect. The TCPS provides standards, and particularly in the proposed draft second version, there is adequate detail. The publication of the standard means that REBs will have to meet two standards. Given that the TCPS draft has completed the public consultation period and revisions are being incorporated, it would be wise to wait until the final version of the TCPS is issued before finalizing the Standard. Every effort should be made to harmonize the Standard with the TCPS.	Strongly recommend that you do not proceed with this Standard until the TCPS second draft is finalized. Work cooperatively and concurrently with the Panel on Research Ethics concerning general standards that may be applied in all contexts.	
RN			te	Both the terms "subjects" and "participants" are used. The term research 'subjects' was abandoned in the draft 2nd Edition of the TCPS.	Consistently use the currently accepted language "research participant".	

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RN	0	4 th para, bullet 6	te	One stated intended purpose of the Standard is to “reduce divergences in interpretation of regulations and guidelines”. This is not met by the Standard. It is in fact, adding one more interpretation document that must be adhered to in addition to the TCPS, the ICH-CGPs and the US Federal regulations. Publication of this Standard without attempting to harmonize it with existing regulations, guidelines and standards simply adds to this “complex patchwork” of regulations and guidelines.	Ensure that there is NO divergence between the Standard, the Health Canada regulations, the TCPS, the US regulations and established Good Clinical Practices. These standards should be consistent with the TCPS, ICH-GCP, NHP Regulations, Division 5, and all Canadian privacy legislation. In addition, a comparison of the US research ethics regulations should be undertaken with a view to obtaining the status of ‘equivalence’ with US policy.	
RN	1.1.		te	The scope should be restricted to Research Ethics Boards (REBs) that review, approve and provide continuing oversight of clinical trials that are performed under the <i>Food and Drugs Act and Regulations</i> when they are reviewing such clinical trials not when they are reviewing other kinds of studies.	Add a qualifier to restrict the scope as recommended.	
RN	2.1.1 & bibliography		te	It would be helpful if website URLs could be provided for reference sources found on the Internet.	Add reference URLs whenever available.	
RN	4.0.3	1 st sentence	te	The lead-in might be made more concrete.	Rather than “...recognizing the need for confidentiality...” perhaps it should say something like “Consistent with legal and	

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					ethical standards of confidentiality...`	
RN	4.0.3	1 st paragraph	ed	Improve readability	Consider splitting into two sentences	
RN	4.0.3	1 st paragraph	te	Suggest changes re the word “crucial” to improve clarity.	“crucial” in the send line should be expanded to either 1) define what information is considered “crucial” or 2) omit the word altogether.	
RN	4.0.3	1 st paragraph	te	Suggest re-wording to improve clarity	Suggest the paragraph be reformatted to increase clarity around the salient points that with appropriate provisions for the protection of confidentiality mechanisms be put in place to facilitate the exchange of information between REB’s as they relate to clinical trials and between REB’s and regulators as they relate to clinical trials.	
RN	4.1.2.1		te	“enter into an agreement” is inappropriate language given that it implies entering into a written or verbal contract when the reality is that researchers are governed by policies that require that they adhere to them.	Remove “enter into an agreement”	
RN	4.1.2.2	Bulleted list	te	Add additional sentence for clarification	Suggest that below line “j” the following sentence be added. “suitable rationale will be provided for any negative decisions”	
RN	4.1.2.2	(b)	te		the REB should have the authority to <i>require</i> ,	

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					not just <i>request</i> , modifications to a trial before ethics approval is granted	
RN	4.1.3		te	The requirement that the organization provide resources for education and training should be spelled out specifically in this section.	Add "educational funding"	
RN	4.2.1.		ge/te	The definition of REB membership does NOT mesh with the US regulatory requirements or with the TCPS, or even with the Canadian <i>Food and Drugs Act and Regulations</i> .	Ensure that REB membership requirements in the Standard match the requirements of the Canadian regulations (Health Canada, privacy), the TCPS, US federal regulations and ICH GCP.	
RN	4.2.1.1		te	The review of natural products requires a REB member with experience in this area.	REBs reviewing clinical trials of natural products must have a REB member experienced with natural products.	
RN	4.2.1.1.		te	Given the definitions of "community person" and "layperson" in the Standard, the REB could be composed entirely of practicing scientists with one formerly practicing scientist/clinician. There should be at least one "non-scientist" and preferably two on the REB. Community members also have a role to play in promoting public accountability and promoting also the interests of the broader community, not just to "represent" participants. Moreover, all members have a	There should be one non-scientist, period. The definition of the community person should include "their role should reflect the perspective of the participant."	

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				mandate to advocate for the participant An effort should be made to be consistent with TCPS guidelines and US regulations on REB membership.		
RN	4.2.1.1	e & f		Clarify “knowledgeable in law relevant to clinical trials” and “knowledgeable in ethics relevant to clinical trials”. It would be difficult to meet this requirement.	Make less restrictive. Delete “relevant to clinical trials.” “one member who is knowledgeable in law “one member who is knowledgeable in ethics	
RN	4.2.1.1	g	te	The qualifiers on the Aboriginal member should be removed allowing that person to fill any one of the 5 positions on the REB. An Aboriginal member should be considered when applicable to the population or research reviewed by the REB.	“at least one member, if available and if appropriate to the research reviewed by the REB) who is from local, rural or urban Aboriginal communities (First Nations, Inuit and Métis), and who is not affiliated with the sponsor.” Delete “or research facilities where clinical trials are conducted”	
RN	4.2.1.1.		te	In light of the often complex scientific, clinical, legal and ethical issues raised in clinical trials, and given the number of overlapping responsibilities, 5 members is too		

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				few for a REB reviewing clinical trials.		
RN	4.2.1.1.		te	If there are only 5 members and one member can have more than 1 role, finding alternate members with the same qualifications as the member they replace would be difficult.		
RN	4.2.1.4		ed/te		"The REB shall strive for a membership that reflects the ethnic, cultural, socio-demographic diversity of the community in which it operates."	
RN	4.2.1.10		ed	This requirement should be made subject to 4.0.3. the need to exchange information, particularly between REBs	Change wording	
RN	4.2.2.1		te	This requirement is not realistic, nor is it necessary. REBs can benefit from having "fresh" eyes (i.e. inexperience) and also fresh "energy" coming onto a Board without the requirement of being a member for two years...plus it is often extremely difficult or impossible to get current members to agree to be REB Chairs. In whose opinion is their knowledge broad and deep?	Change wording / recommendation Remove the requirements to be an "experienced and respected REB member and with at least two years experience". Remove "a broad and deep knowledge of ethical literature and debates" and inserting something such as "current knowledge of national (and if applicable, international) guidelines..."	
RN	4.2.2.3		te	Is this a reasonable expectation for a chair? The list of duties would be daunting to most	Change wording to reflect the administrative staff e.g. "with the support of the	

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				that would consider taking on the position and does not reflect reality in many if not most REBs. The more common arrangement is that of a shared responsibility between the REB Chair and the REB senior administrator, e.g., the REB Manager. For example the REB Manager or other REB administrator interacts with the P.I.s and research coordinators, not the REB Chair. The Standard should reflect the requirement for professional REB administrators.	administrative staff'	
RN	4.2.2.3.1.	a)	te	What is a review of the "highest quality"...?	Change wording or define specifically e.g. "in accordance with this Standard and the requirements of all applicable regulations, guidelines...etc. etc.	
RN	4.2.2.3.1	b)	te	What are the "elements of an ethics review"? If these are set out later in the Standard, the section should be referenced here.	Include reference to 4.3.2.1	
RN	4.2.2.4		te	This is repetitive with 4.2.2.2 ("overall leadership..."). Would it make more sense to include (b) – (d) with 4.2.2.2?	Move to 4.2.2.2	
RN	4.2.2.5	a)	ge/te	Although the Chair is ultimately responsible for ensuring that training occurs, how this gets assessed and done will be handled in policies	Change 4.2.2.5 to "The REB Chair is responsible to ensure that REB members, administrators and staff are trained."	

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				and procedures and will often be delegated to administrative professionals.	Delete the remainder.	
RN	4.2.3		te	Given the important role of administrative staff in meeting the operational requirements of the REB this section is given rather short shrift.	4.2.3.3 As appropriate, duties and responsibilities of the REB Chair for REB operations may be shared with or delegated to senior administrative staff.	
RN	4.3.0	After 2 nd sentence	te	Standard Operating Policies and procedures provide the framework for the ethical and scientifically sound conduct of human research.	<u>Add</u> – Written Standard Operating Policies and procedures (SOPs) promote quality and uniformity in ethics review and oversight processes; facilitate compliance with applicable ethical, regulatory and institutional requirements; and provide the framework for ensuring the protection of the rights, safety and well-being of research participants.	
RN	4.3.1.	g)	te	Do not make this (or any of the others “mandatory”), make them permissive. In this instance, the indication would only be a rough estimate and could be completely wrong. It should not be mandatory.	Suggest changing the word “publicize” to “publish”, and insert “and make available to applicants”.	

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RN	4.3.1.3	Sentence 1	te	This addition provides more background information.	<u>Add</u> : REB members often can only rely on the documentation submitted by investigators, or other parties for initial and continuing review. Therefore the submitted materials must provide the REB with enough information about a study to assess whether it adequately meets the criteria for REB approval.	
RN	4.3.1.3			the documents required should include also the identity of the trial sponsor and a summary of the funding arrangements for the study, including the study budget.		
RN	4.3.1.3	e)	te	Some institutions/REBs have other mechanisms (e.g., Department Head sign off/attestation) to assess or attest to the PI's ability to perform research at the institution.	Add: "and/or other relevant information to satisfy itself that the PI has the qualifications, experience, expertise, and resources to conduct research at the institution."	
RN	4.3.1.3	n)	te	The REB would consider the insurance and indemnity language in the consent form; however, contract review and negotiation is the responsibility of the institution through its contract/legal office. There should be communication between the two to ensure that the language in the contract appropriately reflects what is in the consent form.		
RN	4.3.1.3	(n)	te		The information should also include a	

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Date : 2009-Sep-03 Comments from the Canadian Association of Research Ethics Boards (CAREB)	Document: C**/CGSB-191.1-2009 CD-01 Research Ethics Boards Reviewing Biomedical Clinical Trials / Comités d'éthique de la recherche examinant les demandes d'essais cliniques biomédicaux
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					statement that there is no insurance coverage maintained, if that is the case.	
RN	4.3.1.3	r)	te	Regular trial monitoring should be separate and in addition to any use of a DSMB/DSMC.	Modify: "a description of whom (e.g., sponsor, CRO) will monitor the conduct of the study on an ongoing basis, as well as a description of a data and safety monitoring committee/board (who, how often, relationship to sponsor), or the justification for not using a DSMC/DSMB."	
RN	4.3.1.3	(r)	te		Information should include a statement that there will be no DSMC/DSMB, if that is the case	
RN	4.3.1.3	s)	te	It can be difficult to obtain information on decisions made by other REBs. The REB has to rely on the investigator and/or sponsor for this information and often cannot enforce its submission, at least not in a timely fashion.	Delete or modify to reflect reality.	
RN	4.3.1.3	(t)	te		This agreement should also require the investigator to abide by REB decisions (see 4.1.2.1).	
RN	4.3.1.3	u)	te	Depending on the level of risk, the REB may request scientific information such as a peer review be done as a condition of approval.	Add: u) scientific evaluations, if any, that accompany the protocol.	
RN	4.3.1.3	v)	te	Current best practice requires that clinical	Add: v) Evidence of clinical trial registration	

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				trials be registered in a public registry.	in an easily-accessible public registry.	
RN	4.3.2.1.1	b), c)	te	The documentation is listed in 4.3.1.3	Revise to: "In reviewing the submitted materials (see 4.3.1.3) the REB shall provide a thorough ethical review of the proposed research including:..."	
RN	4.3.2.1.1	a)	te	For added clarity.	Change to "a) the feasibility, suitability and appropriateness of the trial; (see 4.3.2.1.3 and 4.3.2.1.4)"	
RN	4.3.2.1.2	End of line	ed	There are 11, not 14 subsections	Change 4.3.2.1.14 to 4.3.2.1.11	
RN	4.3.2.1.5	(b)	te	The review of safety of the intervention should include, if appropriate, relevant background safety information derived from earlier human, animal and in vitro studies		
RN	4.3.2.1.5	e)	te	The REB would consider the insurance and indemnity language in the consent form; however, contract review and negotiation is the responsibility of the institution through its contract/legal office. There should be communication between the two to ensure that the language in the contract appropriately reflects what is in the consent form.		
RN	4.3.2.1.8		te		This list should include the identity of the sponsor	
RN	4.3.2.1.8	(f)	te		We assume that the reference here is to "...	

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					available <i>alternative</i> procedures..."	
RN	4.3.2.1.8	(k)	te		add the words "or that no such compensation is planned."	
RN	4.3.2.1.8	(l)	te		add the words "or that no such treatment is planned."	
RN	4.3.2.1.8	(r)	te	It is not clear why disclosure of payments is limited to those that are prorated. Why not disclose all payments, even one-time payments?		
RN	4.3.2.1.11	d)	te	In the era of genomics, it is questionable if information can be truly anonymised.	Change "anonymised" to "de-identified"	
RN	4.3.2.2.1			Is it the organization's responsibility to authorize someone to identify categories of trials that can be reviewed by a delegated review process? I would think this is under the authority of the REB.		
RN	4.3.2.2.3		ed	This sub-point is out of sequence.	Change to 4.3.2.2.2	
RN	4.3.2.2.3. - really 4.3.2.2.2	c)	te	The language should be consistent (annual report versus periodic reports or continuing review). No change to the clinical trial protocol by itself may not be sufficient to qualify it for delegated review. However, there are other conditions that would qualify for delegated review.	Change to: c) continuing reviews of previously-approved research that is greater than minimal risk where: • (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-	

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					related interventions; and (iii) the research remains active only for long-term follow-up of subjects; OR	
					<ul style="list-style-type: none"> • Where no subjects have been enrolled and no additional risks have been identified; OR • Where the remaining research activities are limited to data analysis. 	
RN	4.3.2.3.4		ed	The phrase, "... shall include including both..." in the second to last line may be strictly grammatical, but is confusing		
RN	4.3.2.3.4		te	<p>Ignores the quorum requirements of the TCPS and U.S. regulations, i.e., 50% plus one.</p> <p>Canada should be able to come up with its own rules around quorum provided they are reasonable and defensible. A reasonable alternative to the standard Roberts Rules of Order adopted by the USA should be justified in the Standard or elsewhere. The draft Ed 2 of the TCPS is less clear on the quorum requirements.</p>	<p>Include the rationale for adopting a definition of quorum that is not compliant with Roberts Rules of Order that has been adopted by the USA DHHS.</p> <p>Perhaps it would be best to wait for the final version of the TCPS and harmonize the definition of quorum with that in the TCPS.</p>	
RN	4.3.2.3.7		te	Applicants and investigators should also not be present when the Board votes on the	Change to: "Applicants and investigators shall not be present when the Board discusses	

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				application	its decision or votes on the research.”	
RN	4.3.2.4.1		ge/te	Delegated review can be conducted by individual members of the REB, or by a subcommittee of REB members. Delegated review by trained REB administrative staff should also be acceptable.		
RN	4.3.2.4.2	c)	te	If the delegated reviewers are not authorized to reject research, this should be explicitly stated.	Add: “The decision to reject the research must be made by the full REB.”	
RN	4.3.4.2			It would be helpful to have more guidance to REBs about the content of annual reports. For example, it is helpful for the REB to know the initially expected enrollment, the number of participants enrolled during the current reporting period, the number of participants enrolled in all, and the expected completion date. There may be other information that ought to be required as well		
RN	4.3.4.2.2		te	Except for individual local SAE reports, which do have value for the REB of record, there is little evidence that the stream of external (non-local) SAE reports received by each REB of record in multi-centre clinical trials contributes to participant safety. REBs do not have access to the data required for	For participant safety and identification of risks, the REB shall require prompt and timely submission of adverse event reports and/or periodic summary reports, provided by the trial sponsor, that provide interpretation of the SAE reports. Summary reports should include a proposed course of action should	

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				such an assessment and most REBs do not have the resources, either the financial or the required range of human expertise, to conduct such an analysis. It is thus incumbent on the trial sponsor to provide REBs with a periodic discussion of the SAEs reported and assessment of the risk/benefit ratio of the trial. Along with this discussion should be proposed changes to the protocol or consent forms to address any concerns arising from the SAE reports	changes in study risks warrant. The REB shall conduct reviews of the reports promptly and take appropriate steps to ensure that the clinical trial does not expose participants to any potential increase in risk beyond that known and disclosed at the participant's enrolment in the clinical trial.	
RN	4.3.4.2.2		te	Move the provision for receipt of protocol violations from 4.3.4.2.2 as these are strictly local reports	The REB shall require prompt and timely submission of protocol violation reports. Protocol violations shall be required by the REB where in the opinion of the investigator or sponsor they increase the possible risk to the subject or compromise the scientific integrity of the study	
RN	4.3.4.3		te	Add reference to criteria used to determine if the trial qualifies for delegated review.	Add: "(see 4.3.2.2.2)	
RN	4.3.4.5		te	It may be helpful for this article to provide more guidance to REBs with respect to the reporting of proposed amendments than is found in the second sentence. For example, reportable amendments may include any		

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				amendments to the protocol that affect participants' safety or that might reasonably be expected to alter any participants' willingness to participate, or to continue to participate, in the study. In addition, certainly any change of principal investigator, or local site investigator ought to be promptly reported. There may be other types of amendments that require reporting as well		
RN	4.3.4.7		te	The REB should also have the authority to review any study documentation for compliance with trial procedures, REB requirements, and ethical standards.		
RN	4.4	Preamble	te		Add: The REB should prepare and maintain adequate documentation of its activities.	
RN	4.4.1		te		Change 4.4.1.1 to: The REB shall document its policies and standard operating procedures. These policies and procedures shall include, but not be limited to the following: a) Managing conflicts of interest for REB members, and REB office personnel; b) Composition of the REB; c) Selection, appointment terms, duties and performance evaluations of REB	

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					members including the Chair & Vice Chair; d) training and education of REB members and REB office personnel; e) Delegation of signing authority; f) uses and disclosure of personal health information; g) REB application/submission procedures; h) REB meeting administration; i) Procedures for initial and continuing reviews and criteria for REB approval, including full Board versus delegated reviews; j) Appeal of a REB decision; k) communication with investigators and investigator staff, with research participants and with other entities; l) informed consent processes; m) Managing PI non-compliance; n) Document management and retention.	
RN	4.4.2.2		te	The REB should only be required to retain documents that are not already archived at the investigator site and/or with the sponsor.	Delete and replace with: At a minimum, the REB shall maintain a record of the following documents: a) current and archived membership lists,	

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					b) REB meetings minutes, d) current and archived SOPs	
RN	4.4.3	NEW	te	Although the retention period may vary across applicable regulations and may change, the Standard should make reference to a retention period.	Add: 4.4.3 Document retention 4.4.3.1 The REB records required by this Standard shall be retained for the greatest length of time stipulated in any applicable regulations from the time the study is closed at centres of the REB oversight.	
RN	4.5		ge	With respect to section 4.5 as a whole, we believe that some confusion emerges from the failure to adequately distinguish between: A. The Quality Management System (QMS) policies and procedures, which we assume are the responsibility of the organization and targeted at the quality and effectiveness of the REB's operations, policies, procedures and administration, and B. The REB's operations, policies, procedures and administration themselves, which we assume are the subject of QMS oversight		
RN	4.5		ge/te	It is difficult to see how such a system could be put in place at an institution which undertakes only a few clinical trials per year.		
RN	4.5		te	It is not always clear whether references to	Broadly, we recommend that s. 4.5 be re-	

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				<p>QMS and to “the system” are intended as references to A or B above. For example, s. 4.5.2.1 and 4.5.2.2 together appear to mandate periodic reviews, by the organization, of its QMS practices (A above). But if so, the provision seems merely to repeat the requirements of 4.5.1.2 and 4.5.1.3(b), which also mandate reviews of the QMS. Further, the principal elements of the 4.5.2.1 QMS review (found in 4.5.2.3) and the possible uses of such review (found in 4.5.2.4) make more sense in the context of a review of the REB operations themselves (B above). However, if the review described in s. 4.5.2 is really intended to target the REB’s operations (B above) then it seems repetitive of s. 4.5.3, which clearly seems to refer also to the REB operations themselves. It may be that the Standard seeks to draw a distinction between “review” and “monitoring” but if so, that distinction is not explained. And then further, the heading to s. 4.5.3 and 4.5.3.1 seem to refer to monitoring of the REB operations (B above). However, 4.5.3(a) and (b) then refer to improving the effectiveness of the QMS (A</p>	<p>considered in light of the potential for confusion raised by the distinction between A and B above, and the need for a clear explanation of the requirements relating to the assessment of these two levels of policies and practices. In addition, we also recommend that s. 4.5 be re-considered with a view to reducing repetition of substantive requirements. The Standard refers separately to obligations of review, monitoring, performance measurement, analysis and evaluation, and continual improvement. Where these obligations entail distinct types of activities, they should be explained and distinguished more carefully. It may be that QMS-related obligations can be more effectively described using fewer such categories</p>	

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				above) and of the “quality management system” (spelled out and not capitalized). Are these references intended to be to the same thing? If so, they should be referred to in the same way. If not, the difference should be clarified. Confusions of this kind reappear in s. 4.5.6 and 4.5.7 in similar ways.		
RN	4.5.0.2	b) and c)	te	It would be helpful for the Standard to offer more guidance as to what is meant by “suitability” and “effectiveness” of the REB activities.		
RN	4.5.0.2 and 4.5.2.1	c)	te	It would be helpful for the Standard to offer more guidance as to the length of the “planned intervals” referred to. While it is understandable that, due to organizational differences, the appropriate interval may vary at different institutions, some indication of a maximum acceptable interval, or a range of acceptable interval, would be helpful.		
RN	4.5.1.3		te	It would be helpful for the Standard to recognize that some of the functions of establishing, implementing, and evaluating the QMS may be delegated to another authority within the organization, with the higher authority still having ultimate		

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				responsibility.		
RN	4.5.2.3		te	We are supportive of the recognition that there is a need for performance metrics for the REB. It is hoped that the implementation for this Standard will address some of the challenges and solutions for establishing metrics.		
RN	4.5.3.2	b)	te	Unclear what the difference is between quality management system, and the Quality Management System in 4.5.3.2.a above. Section seems redundant with Continuous Improvement section.		
RN	4.5.3.2	c)	te	The obligation of the organization to “monitor the clinical trial,” if it is the sponsor, appears to be misplaced in this section on Monitoring of REB and REB administration, as is acknowledged in the parenthesized sentence. Perhaps this obligation can be placed elsewhere and further guidance offered as to the scope of required monitoring.		
RN	4.5.4	b)	te	refers to REB metrics. We are of the view that performance and other metrics are of central importance to any quality management oversight. It would be helpful then if the Standard could supply additional appropriate		

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				metrics or categories of metrics that may be applied to the work of REBs. In addition, it would be helpful to have some sense of the acceptable range of values to apply in the assessment of these metrics for a particular REB. Organizations should also be encouraged to document and measure other institutional processes that impact on REB metrics (for example, contract review metrics).		
RN	4.5.5			The use of the term “deviation” in this context may be confusing to those familiar with its common usage referring to an on-study deviation from a clinical trial protocol.		
RN	4.5.5.2	b) 2)	te	We assume that the clinical trial referred to in this passage is that which was affected by the deviation in question. If so, then this should be more clearly stated along with the possibility that more than one clinical trial may have been affected by a procedural deviation.		
RN	4.5.6.3	a)	te	It would be helpful to suggest the range of external persons or organizations that should be queried as to their satisfaction.		
RN	4.5.6.3	c)	te	The phrase “characteristics, and trends of		

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Date : 2009-Sep-03 Comments from the Canadian Association of Research Ethics Boards (CAREB)	Document: C**/CGSB-191.1-2009 CD-01 Research Ethics Boards Reviewing Biomedical Clinical Trials / Comités d'éthique de la recherche examinant les demandes d'essais cliniques biomédicaux
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				processes, procedures, and outcomes” is unclear and could be better explained.		
RN	4.5.7		te	It is recommended that the Organization also be identified as having a role in the Continual Improvement of the QMS.		
RN	4.5.7.2	b)	te	It is unclear to us what it would mean for a <i>potential</i> deviation to re-occur. It may also be that 4.5.7.1 and 4.5.7.2 can be merged to describe this set of requirements more simply and clearly		

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