

Research Ethics Board Qualification Manual

Version 3: September 22, 2014



Making Ontario a preferred location for global clinical trials, while maintaining the highest ethical standards

Acknowledgements

Clinical Trials Ontario (CTO) acknowledges the Toronto Academic Health Sciences Network (TAHSN) Qualification Manual as the source document for the CTO Qualification Manual. CTO is greatly indebted to TAHSN and to Ms. Anita Sengar and Mr. Nicholas Stavrinou, the original authors of the Manual. We are also grateful to the University Health Network as the home institution of Ms. Sengar who has provided leadership and expertise in the development of this Manual.

CTO also acknowledges the members of the CTO Research Ethics Review Advisory Group* who provided valuable advice in the development of the CTO REB Qualification process. We especially acknowledge the following members who participated on a sub-committee of the group and provided advice on the development of this Manual: Keitha McMurray, Albert Clark and Sharon Freitag. Finally, thank you to Ms. Marianne Vanderwel, Ms. Velma Marzinotto, Mr. Andrew Milroy, and the members of the NCIC CTG Office of Compliance and Oversight, all of whom contributed significantly to the development of the CTO REB Qualification Checklist and Manual.

Finally, CTO acknowledges the Government of Ontario for its support in advancing clinical research in Ontario.

*CTO Research Ethics Review Advisory Group Members:

Nancy Camack, Director, Clinical and Translational Research Administration, Ottawa Hospital Research Institute (OHRI)

Albert Clark, Chair, Health Sciences and Affiliated Hospitals Research Ethics Board, Queen's University

Michael D. Coughlin, Chair, Tri-Hospital Research Ethics Board (THREB): Associate Professor, Department of Psychiatry and Behavioural Neurosciences, McMaster University

Sharon Freitag, Director, Research Ethics Office, St. Michael's Hospital

Dianne Godkin, Senior Ethicist, Trillium Health Partners

Dario Kuzmanović, Research Ethics Analyst, University of Toronto

C. David Mazer, Chair, Research Ethics Board, St. Michael's Hospital; Vice-chair, Research, Department of Anesthesia, University of Toronto

Keitha McMurray, Director, Human Research Protections Program, Sunnybrook Health Sciences Centre

Kelly Morris, Manager, Research Services/Research Ethics, St. Joseph's Care Group / Thunder Bay Regional Health Sciences Centre

Anita Sengar, REB Operations Manager, University Health Network

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Introduction

Clinical Trials Ontario (CTO) is an independent not-for profit organization supported by the Government of Ontario to provide a streamlined approach to conducting multi-centre clinical trials in Ontario while ensuring the highest ethical standards for patient safety.

A strategic focus for CTO is to develop and support a streamlined research ethics review system in Ontario. Components of this Streamlined Research Ethics Review System include a Qualification Program to assess and qualify participating Research Ethics Boards (REB), a web-based Research Ethics Board Review system (eREB), and policies, procedures, tools and education to support a province-wide delegated board of record review model.

The delegated board of record model supports any single *CTO Qualified REB* in providing ethical review and continual oversight for a research study with multiple research sites across the province.

A Working Group on REB Streamlining was convened by CTO in September 2012 with members from the clinical trials and research ethics community in Ontario to begin discussions on the implementation of the delegated board of record model. The Working Group recommended that in order to establish trust and transparency across institutions and REBs, a process be developed to review and assess the quality of REBs and their compliance with applicable regulations, policies and standards. Members of the Working Group reviewed several models for assessing the quality of REBs and recommended that the Toronto Academic Health Sciences Network (TAHSN) REB Qualification Manual be used as a starting point for the CTO Qualification Program.

Further development of the CTO Qualification Program was undertaken by CTO with expert advice from REB Chairs and REB Administrators in Ontario through the Research Ethics Review Advisory Group. A pilot of the Qualification process was conducted in late 2013 and the CTO Manual was revised based on advice from the pilot and external expert reviews of the Manual.

This CTO REB Qualification Manual is intended as a guide for the review and Qualification of REBs. The requirements for Qualification reflected in the Manual have been informed by numerous sources including the Canadian General Standards Board: Research Ethics Oversight of Biomedical Clinical Trials (CGSB), Tri-Council Policy Statement 2 (TCPS2), the International Conference on Harmonization Good Clinical Practice guide (ICH GCP) and applicable US regulations (for a full list please see Section 1).

An REB that is Qualified by CTO will be compliant with the CTO REB Qualification Checklist. The CTO Qualification process is meant to provide assurances that REBs meet a minimum standard for REB governance, membership, operations and procedures as detailed in the CTO REB Qualification Checklist. Opportunities for supporting the continued advancement of quality in research ethics review in Ontario will be sought through the development of a 'community of practice' amongst REBs and REB Offices participating in the CTO system. CTO will encourage and support the development of policies, procedures, tools and education to enhance REB review and operational efficiencies.

The Qualification review process as described in the Manual is intended to be transparent and educational for both the REB and the CTO Qualification Team. The CTO Qualification Team will generally consist of an Auditor with specific training in reviewing REBs, a CTO Program Coordinator, and two

experienced members from the research ethics community (e.g., REB Chair/Vice-Chair, REB Director/Manager/Coordinator).

An REB must have written REB Standard Operating Procedures in place prior to the initiation of the Qualification process. The primary components of the review process are:

- A Preliminary Questionnaire completed by the REB. The Preliminary Questionnaire assists both the REB and the CTO Qualification Team in preparing for the review.

- A two-day on-site Qualification visit which includes:
 - An Entrance Meeting on Day 1 between the designated REB Operations team members and the CTO Qualification Team.
 - A review of the systems, policies, procedures, documentation and facilities of the REB against the CTO REB Qualification Checklist found in Section 4 of this Manual.
 - Interviews with the Chair(s)/Vice Chair(s) of the REB, typically on Day 2.
 - An Exit Meeting during which the preliminary findings are summarized and discussed.

Following the on-site review, the REB is provided with a Qualification Report. REBs with Minor or Major findings will be provided with the opportunity to submit a Corrective Action Plan (CAP). The CTO Qualification Team will review the CAP and, upon acceptance of the plan, the REB will be designated as a *CTO Qualified REB*.

The CTO Qualification will remain in effect for three years from the date of issuance, with annual reporting to document changes in REB membership or other substantive changes (e.g., procedures, oversight responsibilities).

The CTO REB Qualification process and Manual are expected to evolve as the process is implemented across the province. To request a Qualification review or to submit comments on the Manual or the Qualification process please send an email to qualification@ctontario.ca.

We welcome your feedback.

Section 1: Overview of the CTO Qualification Review Process

OBJECTIVES

The CTO Qualification review process involves a review of systems, documentation, personnel, and facilities in order to assess the operations of the REB against applicable regulations, policies, and standards as reflected in the CTO REB Qualification Checklist.

SCOPE

The CTO REB Qualification process will include a review of documents, a facility tour, and interviews with the REB Chair(s) and Vice-Chair(s) and personnel that support REB operations. The review will include, but may not be limited to:

- REB Standard Operating Procedures
- REB files including meeting agenda and minutes, documentation received and correspondence issued
- REB Operations Personnel Qualifications
- REB Member Qualifications/Expertise
- Privacy and Confidentiality measures
- Record Storage
- Research Records

STANDARDS

The following policies, regulations, and standards have informed the development of the CTO Qualification Checklist and process:

- Canadian General Standards Board: Research ethics oversight of biomedical clinical trials (CGSB), with the exception of the Quality Management Section
- Canadian Food and Drug Regulations (FDR)
- Canadian Natural Health Products Regulations (NHPR)
- Canadian Medical Devices Regulations (MDR)
- US Code of Federal Regulations: 21 Part 50, 56, 312, 812 and 45 Part 46
- ICH Good Clinical Practice (ICH GCP)
- Tri Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2)
- Personal Health Information Protection Act, 2004 Chapter 3 Schedule A (PHIPA), and Ontario Regulation 329/04 Section 15 and 16 (O.Reg. 329/04)
- Provincial professional practice standards

PROCESS

Preparation for Qualification

1. To undergo a Qualification review, the REB must have Standard Operating Procedures (SOPs). CTO recommends that the REB SOPs and operations be reviewed against the **CTO REB Qualification Checklist (Section 4)** prior to requesting a Qualification review.

Please also note:

- a. The **Quality Management (Section 5)** component is optional. If the REB would like to have this included in the review, please let CTO know in advance of the visit.
 - b. An abbreviated Qualification review process will be used for REBs that have previously undergone the Toronto Academic Health Sciences Network (TAHSN) REB Qualification process. For further information, please contact CTO.
 - c. The right hand columns of the REB Qualification Checklist reference the original source(s) for the review criteria. This can also be used to identify conditions in which the criteria are applicable to your REB (e.g., studies under Health Canada or FDA oversight).
2. A two-day Qualification visit will be arranged by CTO with the REB contact person. Interviews with the REB Chair(s) and/or Vice-Chair(s), facility tour, and entrance and exit meetings will be scheduled. In addition, the REB contact person is asked to arrange a meeting room with internet access for the CTO Qualification Team for the duration of the visit.
 3. The REB Office will be asked to complete the **Preliminary Questionnaire (Section 2)** and provide the following materials (or links if the materials are publically accessible) for review at least two weeks prior to the Qualification visit:
 - a. REB Standard Operating Procedures
 - b. Current REB membership list
 - c. Organizational chart(s) depicting the reporting relationships of the REB and the REB office (if available)
 - d. Annual Report (if available)

On-site Review

1. The REB contact person should be available to assist the CTO Qualification Team as needed during the Qualification Review period.
2. The CTO Qualification Team will hold an **entrance meeting** with the REB Operations Personnel. During this meeting the CTO Qualification Team will provide an overview of the CTO REB Qualification process and answer any questions. The REB Operations Personnel will be asked to provide the CTO Qualification Team with an overview of the operations and structure of the REB and the REB Office and access to the requested documents.
3. The CTO Qualification Team will **review** the requested documents during the on-site visit and follow-up with the REB Operations Personnel as necessary for clarification. The following documents should be available (if not previously provided) for review by the CTO Qualification Team.
 - a. REB application forms

- b. Templates such as an informed consent template/checklist, REB member appointment letter(s) and confidentiality agreement/conflict of interest disclosure
- c. REB Operations Personnel records including job descriptions, CVs, orientation and training records, and conflict of interest/confidentiality agreements
- d. Examples of REB member appointment letters
- e. REB member records including evidence of qualifications (e.g., CVs, certifications), orientation and training records, and conflict of interest/confidentiality agreements
- f. REB meeting agenda and minutes
- g. REB study files (paper and/or electronic), including materials received, review documentation, and letters issued
- h. REB meeting agenda and minutes
- i. Additional documents as requested by the Qualification Team.

This material may be provided in paper format or electronically. If electronic, it must be accessible by the CTO Qualification Team during the on-site review period.

- 4. The REB Operations Personnel will lead a brief facility tour, showing the Qualification Team where and how paper records are stored (if applicable), outlining record security measures, and giving an overview of the office space.
- 5. The CTO Qualification Team will interview(s) the Chair(s) and/or Vice-Chair(s) at the arranged time.
- 6. An **exit meeting** will be held with the REB Operations Personnel at the end of the visit. During this meeting, the Qualification Team will discuss the preliminary comments and provide the REB Operations Personnel with an opportunity to clarify any findings (as applicable).

Qualification Report and REB Qualification

- 1. Following the Qualification visit, CTO will provide the REB with a Qualification Report.
- 2. If the Qualification Report does not contain any findings, the REB will be designated as a *CTO Qualified REB*.
- 3. If findings are identified, the REB will have the opportunity to submit a Corrective Action Plan (CAP). The CAP must be submitted to CTO within 3 months of the Qualification Report. Once the CAP has been reviewed by CTO and all findings have been resolved, the REB will be designated as a *CTO Qualified REB*.
- 4. *CTO Qualified REBs* will be provided with the CTO Qualification Seal and guidance on the Seal's use. The Seal signifies that the REB has achieved CTO Qualification status following a CTO Qualification review.
- 5. A list of *CTO Qualified REBs* will be posted publically on the CTO website.

Section 2: Preliminary Questionnaire

The purpose of the Preliminary Questionnaire is to assist the REB and the CTO Qualification Team in preparing for the on-site review process. Please complete and sign the Preliminary Questionnaire and email it to CTO at qualification@ctontario.ca along with the documents requested.

Please complete form by either checking the appropriate box and/or providing responses as applicable. Attach additional sheets as necessary.	
SECTION 1 - General Information	
a) Name of Institution	(b) Name of Research Ethics Board (REB) A separate questionnaire should be completed for each REB
c) Does the REB have any subcommittees or panels? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, please provide the purpose and focus of review for each subcommittee or panel:	
c) Please describe any affiliated institutions or external sites for which the REB is a Board of Record:	
d) Are there formal agreements covering the Board of Record arrangements with each of the affiliated institutions or external sites? Yes <input type="checkbox"/> No <input type="checkbox"/>	
e) Is there an Annual Report available either electronically or in hard copy? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, please provide a hard copy or the link to an online version:	
SECTION 2 - REB Standard Operating Procedures	
a) Please select one of the following options to submit your REB Standard Operating Procedures (SOPs) to CTO: <input type="checkbox"/> Option 1: Copy of REB SOPs enclosed <input type="checkbox"/> Option 2: REB SOPs are publicly available. Please provide website link:	

Preliminary Questionnaire

b) Are any SOPs under revision or currently being developed and have not been submitted?

Yes No

If yes, please list the titles of these SOPs and the expected completion date:

SECTION 3 - REB Governance

a) Please describe the formal reporting relationship of the REB to the home institution:

b) Please describe the formal reporting relationship of the REB Office, and personnel within the office, to the REB/institution:

c) If available, please provide an organizational chart(s) depicting the reporting relationships of the REB and the REB office.

Enclosed Not Available

SECTION 4 - REB Membership

a) Please select one of the following options to submit your REB membership list (including name, qualifications, gender, citizenship and areas of expertise and role(s) each member serves on the REB) to CTO. If the REB has subcommittees or panels please provide the membership for these as well.

Option 1: Copy of REB membership enclosed

Option 2: REB membership is publicly available. Please provide website link:

b) Are any changes expected to the REB membership in the near future?

Yes No

If yes, please describe:

SECTION 5 - REB Office/Administrative Support

a) Please provide a list of individuals working with the REB (e.g., REB Operations Personnel), their roles and responsibilities:

Preliminary Questionnaire

SECTION 6 - Research Reviewed by the REB	
a) Please estimate how many reviews the REB conducts annually in each of the categories:	
_____ Initial Reviews	_____ Continuing Reviews / Renewals
_____ Amendments	_____ Reportable Events (unanticipated problems, deviations, etc.)
b) How many studies (total) are currently approved and require ongoing review by the REB?	_____
(i) How many of these are clinical trials?	_____
(ii) How many of these are multi-centre clinical trials?	_____
c) Please provide a brief description of the types of studies reviewed by the REB (e.g. clinical trials, epidemiologic studies, etc.):	
d) Please indicate how often your REB meets:	
e) Are the meeting dates and deadline dates for REB submissions publically posted?	
Yes <input type="checkbox"/> No <input type="checkbox"/>	
If yes, please provide website link:	
f) Please provide a brief description of any metrics collected by the REB (e.g., time from meeting to letter issuance, etc.):	
SECTION 7 - REB Records	
a) Are REB records (minutes, correspondence, etc.) available for inspection?	
Yes <input type="checkbox"/> No <input type="checkbox"/>	
b) Please indicate where and how REB records are stored. If records are stored electronically, please provide website link:	
c) Please describe measures to protect the privacy and confidentiality of the records:	

Preliminary Questionnaire

SECTION 8 - REB Compliance Inspections

a) Has the REB been inspected by a regulatory agency such as the Food and Drug Administration or Health Canada within the last 5 years?

Yes No

If Yes:

	When was the inspection? (YYYY/MM/DD)	Type of inspection		Is the report available for review?	
		Routine	For Cause		
1		<input type="checkbox"/>	<input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
2		<input type="checkbox"/>	<input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
3		<input type="checkbox"/>	<input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
4		<input type="checkbox"/>	<input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
5		<input type="checkbox"/>	<input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>

b) Does the REB hold an accreditation?

Yes No

If Yes:

- (i) Name of the accreditation:
- (ii) Accreditation Expiration Date: _____ / ____ / ____
(YYYY / MM / DD)

SECTION 9 - Regulatory Compliance

a) Please indicate what regulations, policies, etc. your REB is either required to comply with or complies with on a voluntary basis.

Compliance?

Canadian General Standards Board	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Canadian Medical Device Regulations	Yes <input type="checkbox"/>	No <input type="checkbox"/>
US Code of Federal Regulations	Yes <input type="checkbox"/>	No <input type="checkbox"/>
ICH GCP	Yes <input type="checkbox"/>	No <input type="checkbox"/>
PHIPA and Ontario Regulation 329/04	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Other (Please specify):	Yes <input type="checkbox"/>	No <input type="checkbox"/>

SECTION 10 - Review Focus

a) If you have any areas of compliance you would like the reviewers to pay particular attention to, please describe:

This form has been completed by:

Print Name:	Signature:
Title:	Date: (YYYY/ MM/ DD)

Section 3: Classification of Review Findings

PURPOSE

The purpose of this guidance is to ensure consistency of classification among reviews.

DEFINITIONS

The requirements for Qualification are reflected in the elements listed in the CTO REB Qualification Checklist.

Review findings are classified Minor and Major. Definitions are provided here:

<i>Minor:</i>	Modifications are required to demonstrate compliance with one or more Qualification requirements; however, the process as-is does not pose a significant risk to REB operations or to the ethical oversight of the research.
<i>Major</i>	There is evidence of systemic non-compliance with one or more of the Qualification requirements.

The classification of a finding may be upgraded from Minor to Major depending on the frequency of the finding. For example, if a small number of isolated process deviations are found, and determined to have minimal impact, then these would likely be classified as Minor. However, a large number of deviations within a specific process, or deviations that pose a risk to participant rights or safety, would likely be upgraded to a classification of Major.

Section 4: CTO REB Qualification Checklist

- **CGSB:** Canadian General Standards Board: Research ethics oversight of biomedical clinical trials
- **TCPS2:** Tri Council Policy Statement: Ethical Conduct for Research Involving Humans
- **HC:** Canadian Food and Drug Regulations (FDR) and, Natural Health Products Regulations (NHPR) and, Medical Devices Regulations (MDR)
- **GCP:** ICH Good Clinical Practice
- **FDA:** Food and Drug Administration US Code of Federal Regulations: 21 Part 50, 56, 312, 812
- **DHHS:** US Code of Federal Regulations: 45 Part 46
- **PHIPA:** Personal Health Information Protection Act, 2004 Chapter 3 Schedule A, and Ontario Regulation 329/04 Section 15 and 16

#	Criteria	CGSB	TCPS2	HC	GCP	FDA	DHHS	PHIPA	Comments
SECTION A - Governance, mandate, authority, and resources									
Governance and mandate of the REB									
1	The highest body within an organization shall: a) Establish or appoint REB(s) to review the ethical acceptability of all research involving humans conducted within their jurisdiction or under their auspices, that is, by their faculty, staff or students, regardless of where the research is conducted, in accordance with this Policy; b) Define an appropriate reporting relationship with the REB(s); c) Ensure the REB(s) are provided with necessary and sufficient ongoing financial and administrative resources to fulfill their duties.	4.2.1.1, 4.2.4.1, 4.2.2.1, 4.2.2.2	6.1, 6.2, 6.3				45 CFR 46.103(b)(1)		
2	REB(s) are independent in their decision making and are accountable to the highest body that established them for the process of research ethics review. REBs shall function impartially, provide a fair hearing to the researchers involved, and provide reasoned and appropriately documented opinions and decisions.	4.2.2.2	6.2, 6.4, 6.13						
3	Research that has been approved by an REB may be subject to further appropriate review and approval or disapproval by officials of the organization. However, those officials may not approve the research if it has not been approved by an REB.	4.2.2.5				21 CFR 56.112, 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.112		
4	An REB should have policies and procedures to manage conflicts of interest that may affect the operations of the REB. When clearly in a conflict of interest, the REB member shall be excluded when the REB discusses its decision, reaches a consensus or votes on the application. When in any doubt as to whether a conflict of interest exists, the REB member shall disclose the situation to the REB Chair and abide by the REB's decision regarding any actions required to mitigate his or her real or perceived conflict of interest.	4.2.2.6, 4.3.2.8, 4.4.4.4.9	7.1, 7.2, 7.3	FDR C.05.010, NHPR part 4, s.74	3.2.1	21 CFR 56.107(e), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.107(e)	O.Reg.32 9/04 s.15.(2)	

CTO REB Qualification Checklist

#	Criteria	CGSB	TCPS2	HC	GCP	FDA	DHHS	PHIPA	Comments
5	The highest body of an organization involved in multi-institutional studies may use joint review, reliance upon the review of another qualified REB, or similar arrangements aimed at avoidance of duplication of effort.	4.2.2.3, 4.2.3.3, 4.2.3.4	8.1			21 CFR 56.114, 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.114		
6	The REB Chair and administrators should assess the educational and training needs of REB members and address any knowledge gaps.	4.2.4.2 (a-c)	6.7						
REB authority									
7	The organization shall grant the REB the mandate to review the ethical acceptability of research on behalf of the organization, including approving, rejecting, proposing modifications to, or terminating any proposed or ongoing research involving humans. This mandate shall apply to research conducted under the auspices or within the jurisdiction of the organization, using the considerations set forth in applicable regulations.	4.2.3.2	6.3	FDR C.05.001, NHRP part 4, s.74	3.1.2	21 CFR 56.109(a), 21 CFR 56.113, 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.109(a), 45 CFR 46.113		
8	When an application is submitted, the REB requires the applicant to comply with all REB decisions with respect to the ethical conduct of the trial.	4.2.3.1							
9	An REB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the REB's requirements or that has been associated with unexpected serious harm to participants. Any suspension or termination of approval shall include a statement of the reasons for the REB's action and shall be reported promptly to the researcher, appropriate institutional officials, and the relevant regulatory authorities.	4.2.3.2(d)	6.3		3.1.2	21 CFR 56.113, 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.113		
SECTION B - REB Composition, appointment, and administrative support									
General									
1	The REB should establish, document in writing, and follow its procedures when determining its composition (names and qualifications of the members) and the authority under which it is established. In appointing REB members, organizations shall establish their terms to allow for continuity of the research ethics review process.	4.2.2.4	6.6		3.3.1				
2	The REB should consist of a reasonable number of members, who collectively have the qualifications and experience to review and evaluate the science, medical aspects, and ethics of the proposed research.	4.3.1.1	6.7	FDR C.05.001, NHRP part 4, s.74	3.2.1	21 CFR 56.107(a), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.107(a)		
3	The REB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human participants.	4.3.1.1	6.4		3.2.1	21 CFR 56.107(a), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.107(a)		
REB members									
	See Table 1 for REB Membership requirements								
4	A member of the REB may not fulfil more than two representative capacities and disciplines. (For research subject to TCPS2, Article 6.4 states that only one capacity may be filled).	4.3.2.2	6.4						
5	An REB may appoint alternate members with qualifications comparable to the primary member for whom they serve as an alternate.	4.3.2.4	6.4						

CTO REB Qualification Checklist

#	Criteria	CGSB	TCPS2	HC	GCP	FDA	DHHS	PHIPA	Comments
6	In appointing alternate, additional REB members, organizations should consider the qualifications and expertise their REBs require.	4.3.2.4, 4.3.2.5	6.5			21 CFR 56.107(f), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.107(f)		
7	When the REB lacks the experience or expertise to conduct competent ethics review of a particular biomedical clinical trial, the REB shall seek the assistance of one or more ad hoc advisors. Ad hoc advisors shall not be voting members or participate in the decisions of the REB. An REB which regularly seeks recourse to ad hoc advisors in the same or similar disciplines should re-examine its composition.	4.3.2.6							
8	Organizations should provide REB members with necessary training opportunities to effectively review the ethical issues raised by research proposals that fall within the mandate of their REB.	4.3.2.7	6.7						
9	REB members and ad hoc advisors shall maintain the confidentiality of the documents submitted for ethics review and of the REB discussions.	4.3.2.9							
REB Chair and Vice-Chair or equivalent									
10	The REB Chair is responsible for ensuring that the REB review process conforms to all applicable regulatory requirements. The Chair should have at least two years of experience on an REB and knowledge of international and national regulations along with local policies.	4.3.3.1	6.6, 6.8		3.3, 3.3.1	21 CFR 56.108(a) and 108(b), 21 CFR 312.66, 21 CFR 812.60			
11	The REB Chair, in collaboration with administrative staff, as appropriate, shall advise the organization on policies and procedures related to the ethical conduct of research involving human subjects. The Chair shall advise the organization on the evaluation of performance of REB members and administrative staff.	4.3.3.2							
12	The REB Vice-Chair or equivalent shall: a) discharge the responsibilities of the Chair when the Chair is unable to do so; b) discharge the responsibilities assigned by the Chair; and c) assist in the overall operation of the REB, as requested.	4.3.3.4							
REB administrative staff									
13	The organization with an REB should have established policies and procedures that define administrative staff roles and responsibilities, and the appointment of administrative staff as REB members.	4.3.4.1, 4.3.4.2	6.2						
14	REB administrative staff responsibilities may include a) pre-review of submissions and requests to the REB; b) quality management activities (see Quality Management Checklist, if applicable); c) management of administrative issues involving REB research ethics oversight; d) implementation of REB directives; and e) provision of advice and information to the REB.	4.3.4.3	6.2						
15	When administrative staff serve as REB members, it should be ensured that they: a) have the necessary expertise and experience; b) can fulfill their responsibilities independently; c) are not counted towards quorum and do not vote; d) perform delegated reviews according to requirements for normal REB members as indicated in Sec. D of this checklist.	4.3.4.4, 4.3.4.5, 4.3.4.6	6.4, 6.2						
16	REB administrative staff shall be subject to privacy and confidentiality policies of the organization and the REB.	4.3.4.7							

CTO REB Qualification Checklist

#	Criteria	CGSB	TCPS2	HC	GCP	FDA	DHHS	PHIPA	Comments
SECTION C - REB operating procedures									
REB standard operating procedures									
1	The REB should perform its functions according to written operating procedures, maintain written records of its activities and minutes of its meetings, and comply with applicable regulatory requirement(s).	4.4.1.1, 4.5.2.1			3.2.2, 3.3	21 CFR 56.108(a) and 108(b), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.103(b)(4) and 103(b)(5)		
2	When there are discrepancies among regulations, the REB/organization shall establish procedures to document the rationale for its decisions that attempts to strike a balance between the compliance with applicable regulatory and ethical requirements.	4.4.1.2							
3	The REB should establish a procedure which specifies that no participant should be admitted to a study before the REB issues its written approval/favourable opinion of the research.				3.3.6				
Standard operating procedures for REB operations during publicly declared emergencies									
4	In collaboration with their researchers, organizations and their REBs should develop preparedness plans for emergency research ethics review. Research ethics review during publicly declared emergencies may follow modified procedures and practices.	4.4.2.2, 4.4.2.3, 4.4.2.4, 4.5.2.1(p)	6.21						
5	REBs should give special care to requests for exceptions during publicly declared emergencies.	4.4.2.1	6.23						
6	Research ethics policies and procedures for emergencies take effect once an emergency has been publicly declared. They should cease to apply as soon as is feasible after the end of the publicly declared emergency.	4.4.2.3	6.22						
Application procedures									
	See Table 3 for Submission requirements								
7	Clear written requirements for submission of an application are required. These requirements shall include, but are not limited to: a) the name and address of the REB office where application materials are to be submitted; b) the format for submission, including provisions for electronic submission (if any); c) deadlines for submission in relation to review dates; and d) the means by which an application will be acknowledged, including notification when the application is incomplete.	4.4.3.1							
8	The REB may request more information than is outlined in Table 2 and Table 3 be given to participants when, in the judgment of the REB, the additional information would add meaningfully to the protection of the rights, safety and/or well-being of the participants.	4.4.3.4		FDR C.05.010(d), NHPR Part 4, s.74(d)	3.1.2, 3.1.5	21 CFR 56.109(b), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.109(b)		
SECTION D - Ethics review processes									
Requirements and criteria for ethics review									
	See Table 2 for Informed Consent Elements								
1	A signed and dated copy of informed consent should be given to participants.	4.4.4.2.10	3.12	FDR C.05.010 (h), NHPR part 4, s.74	4.8.11	21 CFR 50.27(a), 21 CFR 56.109(c), 21 CFR 312.66, 21 CFR 812.6	45 CFR 46.117(a)		

CTO REB Qualification Checklist

#	Criteria	CGSB	TCPS2	HC	GCP	FDA	DHHS	PHIPA	Comments
2	Where the protocol indicates that prior consent of the research participant or the participant's appropriate representative is not possible, the REB should determine that the proposed protocol and/or other document(s) adequately addresses relevant ethical concerns and meets applicable regulatory requirements for such research (e.g., in emergency situations).	4.4.4.2.13 4.4.4.2.15	3.2, 3.7, 3.8 (a-f), 3.9 (a,b, e), 3.10, 10.3,	FDR C.05.010, NHRP part 4, s.74	2.9, 3.1.6, 3.1.7, 4.8.12, 4.8.13, 4.8.14(e), 4.8.15	21 CFR 50.20, 21 CFR 50.23, 21 CFR 50.24, 21 CFR 50.27, 21 CFR 56.109(b) and 109(c), 21 CFR 56.111(a)(4), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.101(i), 45 CFR 46.109(b) and 109(c), 45 CFR 46.111(a)(4), 45 CFR 46.116(c)(1) and 116(c) (2); 116(d)(1-4)	2004, c. 3, Sched. A s.18(1)(a), 2004, c. 3, Sched. A, s.44 (3) (d)	
3	Waivers, deferred or verbal consent, and use of substitute decision makers or translation, can only be approved by the REB.	4.4.4.2.12 4.4.4.2.13 4.4.4.2.15	3.7			21 CFR 56.109(c), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.109(c)		
4	The REB may, for some or all participants, waive the requirement that the participant, or the participant's appropriate representative, sign a written consent form if it finds that the research presents no more than minimal risk of harm to participant and involves no procedures for which written consent is normally required outside the research context; or in cases where the documentation requirement is waived, the REB may require the researcher to provide participants with a written statement regarding the study.	4.4.4.2.12 4.4.4.2.13 4.4.4.2.15				21 CFR 56.109(c) and 109(d), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.116(c) and 116(d)		
5	The REB may approve research without requiring that the researcher obtain the participant's consent where the REB is satisfied, and documents, that all of the following apply: a) the research involves no more than minimal risk to the participants; b) the lack of the participant's consent is unlikely to adversely affect the welfare of the participant; c) it is impossible or impracticable to carry out the research and to answer the research question properly, given the research design, if the prior consent of the participant is required; d) whenever possible and appropriate, after participation, or at a later time during the study, participants will be debriefed and provided with additional pertinent information, at which point they will have the opportunity to refuse consent; and e) the research does not involve a therapeutic intervention, or other clinical or diagnostic interventions.	4.4.4.2.12 4.4.4.2.13 4.4.4.2.15	3.7, 3.9, 5.5, 12.3			21 CFR 56.109(c) and 109(d), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.116(c) and 116(d)		
6	The REB may find that for some or all participants, an exception from informed consent for emergency research is met. Subject to all applicable legal and regulatory requirements, research involving medical emergencies shall be conducted only if it addresses the emergency needs of the individuals involved, and then only in accordance with criteria established in advance of such research by the REB. The REB may allow research that involves medical emergencies to be carried out without the consent of participants, or of their authorized third party, if all of the requirements apply.	4.4.4.2.6, 4.4.4.2.7	3.8		2.2	21 CFR 56.109(c) and 109(d); 21 CFR 50.24, 21 CFR 312.66, 21 CFR 812.60			
7	There should be written REB procedures to evaluate applications for ethics review and determining whether research or changes to the research shall be reviewed at a convened meeting or by delegated review, based on applicable regulations.	4.4.4.1.1, 4.4.6.4, 4.4.7.4, 4.4.7.5	6.12	FDR C.05.010 (c), NHRP part 4, s.74	3.2.2, 3.3.3, 3.3.5	21 CFR 56.108(a) and 108(b), 21 CFR 56.110(a) and 110(b)(1) and 110(b)(2), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.103(b)(4) and 103(b)(5), 45 CFR 46.110(a) and (b)(1) and 110(b)(2)		

CTO REB Qualification Checklist

#	Criteria	CGSB	TCPS2	HC	GCP	FDA	DHHS	PHIPA	Comments
8	The REB should consider the qualifications of the researcher for the proposed study, as documented by a current curriculum vitae and/or by any other relevant documentation the REB requests.	4.4.4.2.4 (c)			3.1.3				
9	In order to approve research covered by these regulations the REB shall determine that all of the requirements under criteria 10 through 21 (listed below) are satisfied.	4.4.4.2.2, 4.4.4.2.3,				21 CFR 56.111, 21 CFR 312.66, 21 CFR 812.60			
10	Risks to participants are minimized: a) by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk; and b) whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.	4.4.4.2.5, 4.4.4.2.6			2.2	21 CFR 56.111(a)(1), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.111(a)(1)		
11	Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may be expected to result. In evaluating risks and benefits, the REB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that participants would receive even if not participating in the research). The REB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibilities.	4.4.4.2.5, 4.4.4.2.6			2.2	21 CFR 56.111(a)(2), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.111(a)(2)		
12	Selection of participants is equitable. In making this assessment the REB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons.	4.4.4.2.14	4.1		3.1.1	21 CFR 56.111(a)(3), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.111(b)		
13	Informed consent will be sought from each prospective participant or the participant's appropriate representative, in accordance with applicable regulations.	4.4.4.2.8	3.2			21 CFR 56.111(a)(4), 50 Subpart B, 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.111(a)(4)		
14	Informed consent will be appropriately documented, in accordance with and to the extent required by applicable regulations.	4.4.4.2.12, 4.4.4.2.13, 4.4.4.2.15				21 CFR 56.111(a)(5), 21 CFR 50.27, 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.111(a)(5)		
15	The REB shall determine that the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.	4.4.6.8,	11.7			21 CFR 56.111(a)(6), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.111(a)(6)		
16	The REB shall determine that there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.	4.4.4.2.4 (f), 4.4.4.2.16	5.2, 5.3			21 CFR 56.111(a)(7), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.111(a)(7)		
17	When some or all of the participants, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons, are likely to be vulnerable to coercion or undue influence additional safeguards have been included in the study to protect the rights and welfare of these participants.	4.4.4.2.7, 4.4.4.2.14	4.6, 4.7		3.1.1	21 CFR 56.111(b)	45 CFR 46.111(b)		

CTO REB Qualification Checklist

#	Criteria	CGSB	TCPS2	HC	GCP	FDA	DHHS	PHIPA	Comments
18	For research involving individuals that lack the capacity to provide informed consent: a) the researcher demonstrates that the research is being carried out for the participant’s direct benefit, or for the benefit of other persons in the same category. If the research does not have the potential for direct benefit to the participant but only for the benefit of the other persons in the same category, the researcher shall demonstrate that the research will expose the participant to only a minimal risk and minimal burden, and demonstrate how the participant’s welfare will be protected throughout the participation in research; and b) when authorization for participation was granted by an authorized third party, and a participant acquires or regains capacity during the course of the research, the researcher shall promptly seek the participant’s consent as a condition of continuing participation.	4.4.4.2.7, 4.4.4.2.15	3.9, 4.6		3.1.1				
19	In order to approve research in which some or all of the participants are children, an REB must determine that all research is in compliance with applicable regulations.					21 CFR 50 Subpart D	45 CFR 46 Subpart D		
20	The REB should review the: a) Amount and method of payment to participants to assure that neither presents problems of coercion or undue influence; b) Payments to a participant should be prorated and not contingent on completion of the study; c) Information regarding payment to participants, including the methods, amounts, schedule of payment to research participants, is set forth in the written informed consent form and any other written information to be provided to participants; and d) The way payment will be prorated should be specified.	4.4.4.2.9 (u)			3.1.2, 3.1.8, 3.1.9				
21	The confidentiality of records that could identify participants should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).	4.4.4.2.16	5.5, 5.7		2.11, 4.8.10(o)	21 CFR 56.111(a)(7), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.111(a)(7)	2004, c. 3, Sched. A, s. 44 (3)	
Review at a convened meeting of the REB									
22	REB shall have a procedure for scheduling, notifying its members of, and conducting its meetings. REBs shall have regular meetings to discharge their responsibilities, and shall normally meet face to face to review proposed research that is not assigned to delegated review.	4.4.4.3.1, 4.4.4.4.2	6.10	FDR C.05.010(c), NHPR Part 4, s.74	3.3.2, 3.3.3, 3.3.5	21 CFR 56.108(c), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.108(b)		
23	REB shall have a process for proportionate approach to research ethics review. The selection of the level of REB review shall be determined by the level of foreseeable risks to participants: the lower the level of risk, the lower the level of scrutiny (delegated review); the higher the level of risk, the higher the level of scrutiny (full board review). The mechanism and procedures related to delegation of the conduct of the review should be made public.	4.4.4.3.2, 4.4.4.5.1, 4.4.4.5.2, 4.4.4.5.3	6.12	FDR C.05.010(c), NHPR Part 4, s.74	3.3.5	21 CFR 56.108(c), 21 CFR 56.110(a) and 110(b), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.108(b), 45 CFR 46.110(a) and 110(b)		

CTO REB Qualification Checklist

#	Criteria	CGSB	TCPS2	HC	GCP	FDA	DHHS	PHIPA	Comments
24	The REB should review a proposed study within a reasonable time and document its views in writing, clearly identifying the study, the documents reviewed and the dates for the following: a) approval/favourable opinion; b) modifications required prior to its approval/favourable opinion; c) disapproval/negative opinion; and d) termination/suspension of any prior approval/favourable opinion.	4.4.4.4.10	6.13	FDR C.05.010(c), NHRP part 4, s.74	3.1.2	21 CFR 56.109(e), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.109(d)		
25	REB meeting dates and submission deadlines should be published in such a way as to give sufficient notice to members and applicants.	4.4.4.4.1			3.3.2				
26	Remote participation during convened meetings is allowed during emergencies and when necessary.	4.4.4.4.3	6.10						
27	An REB should make its decisions at announced meetings at which at least a quorum, as stipulated in its written operating procedures, is present. An REB must have quorum rules that meet the minimum requirements of membership representation.	4.4.4.4.5	6.9	FDR C.05.010(c), NHRP part 4, s.74	3.2.3	21 CFR 56.108(c), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.108(b)		
28	When there is less than full attendance, decisions requiring full review should be adopted only when the members in attendance at that meeting have the specific expertise, relevant competence and knowledge necessary to provide an adequate research ethics review of the proposals under consideration.	4.4.4.4.4	6.9						
29	Only members who participate in the REB review and discussion should vote/provide their opinion and/or advice.	4.4.4.4.5			3.2.4				
30	Written comments from absent members shall be allowed to inform the consideration of an application.	4.4.4.4.7		FDR C.05.010(c), NHRP part 4, s.74					
31	Applicants or qualified researchers are allowed to attend REB meetings or provide information for the purpose of helping its members understand the application. They must not be present when the REB discusses its decision, reaches consensus or votes on the application.	4.4.4.4.8	6.13	FDR C.05.010, NHRP part 4, s.74	3.2.5	21 CFR 56.107(f), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.107(f)		
32	An REB may invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the REB. These individuals may not vote with the REB.	4.3.2.6, 4.4.4.4.6	6.5		3.2.6	21 CFR 56.107(f), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.107(f)		
33	REBs may allow observers to attend meetings. Observers: a) shall not participate when the REB discusses its decision, reaches consensus or votes on the application; b) shall agree in writing to maintain the confidentiality of the REB proceedings; and c) where the REB finds that an observer otherwise qualifies as an expert in relation to the research under consideration, the observer may be allowed to contribute input if it is relevant and significant to discussion. However the observer shall not participate when the REB discusses its decision, reaches consensus or votes on the application. The minutes shall reflect the expertise and contributions of any observer.	4.4.4.4.12							

CTO REB Qualification Checklist

#	Criteria	CGSB	TCPS2	HC	GCP	FDA	DHHS	PHIPA	Comments
Delegated review									
34	REB shall have delegated review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.	4.4.4.5.1, 4.4.4.5.2, 4.4.4.5.3, 4.4.7.4, 4.4.7.5	6.12	FDR C.05.010, NHRP part 4, s.74	3.3.5	21 CFR 56.110 (a) and 110(b) (1) and 110(b)(2) , 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.110 (a) and 110(b)(1,2)		
35	An REB may use the delegated review procedure to review either or both of the following: a) Some or all of the research is a type of research which is approved by authorities to be reviewed through delegated review, and found by the reviewer(s) to involve no more than minimal risk;and/or b) minor changes in previously approved research during the period (of 1 year or less) for which approval is authorized.	4.4.4.5.1	6.12	FDR C.05.010, NHRP part 4, s.74	3.1.4, 3.3.5	21 CFR 56.110(b) , 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.110(b)		
36	Under a delegated review procedure, the review may be carried out by the REB chairperson or by one or more experienced reviewers designated by the REB chairperson from among the members of the REB. In reviewing the research, the reviewers may exercise all of the authorities of the REB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with a non-delegated review procedure.	4.4.4.5.1	6.12	FDR C.05.010, NHRP part 4, s.74	3.3.5	21 CFR 56.110(b), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.110(b)		
37	The delegated reviewer(s) shall be authorized to approve the applications, require modification, request clarification or further information, or refer the application for review at the convened meeting. The reviewers may not disapprove research by the delegated process.	4.4.4.5.2, 4.4.4.5.3				21 CFR 56.110(b), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.110(b)		
38	Each REB which uses a delegated review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.	4.4.4.5.4				21 CFR 56.110(c), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.110(c)		
Notification of REB decision									
39	REB has a procedure to promptly notify in writing the researcher/organization concerning: a) Its study-related decisions/opinions; b) The reasons for its decisions/opinions; c) Procedures for appeal of its decisions/opinions; and d) Suspension or termination.	4.4.5.1, 4.4.5.2, 4.4.5.3, 4.4.5.4, 4.4.5.5, 4.4.5.7	6.13	FDR C.05.010, NHRP part 4, s.74	3.3.9	21 CFR 56.108(b)(3), 21 CFR 56.109(e) , 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.103(b)(5) (ii), 45 CFR 46.109(d)	2004, c. 3, Sched. A, s.44(4)	
40	Communications about REB decisions made at convened meetings should include, or the REB should provide at the request of the applicant: a) a copy of the REB membership roster in effect on the date of the meeting, and a statement confirming that quorum was present during the REB decision regarding the applicant's study; and b) each member's academic qualifications, affiliation, gender, and status (regular or alternate member).	4.4.5.6			8.2.8				
SECTION E - Ongoing review									
1	The REB of Record shall, subject to jurisdictional or collaboration agreements, ensure ongoing review of the studies that it has reviewed and approved in accordance with applicable regulations.	4.4.6.1	6.15, 6.16		3.1.4, 3.3.3	21 CFR 56.108(a)(1), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.103(b)(4)		
2	The REB shall have authority to review any study documentation for compliance and observe or have a third party observe the consent process and the research.	4.4.6.9				21 CFR 56.109(f), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.109(e)		

CTO REB Qualification Checklist

#	Criteria	CGSB	TCPS2	HC	GCP	FDA	DHHS	PHIPA	Comments
3	The REB should have a procedure for ensuring the prompt reporting of changes in research activity. Changes in approved research, during the period for which REB approval has already been given, may not be initiated without REB review and approval, except where necessary to eliminate apparent immediate hazards to the human participants, or change(s) involving only logistical or administrative aspects of the study (e.g., change of monitor(s), telephone number(s)).	4.4.5.3, 4.4.6.2, 4.4.6.5			3.3.7	21 CFR 56.108(a)(3) and 108(a)(4), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.103(b)(4) (iii)		
4	Any changes that affect the rights, safety, or well-being of the research participants or the integrity of the study shall be reviewed at a convened meeting of the REB, including but not limited to changes that: a) affect the selection, monitoring or withdrawal of research participants; b) significantly increase the risk to the health of a research participant; c) extend the duration of participation in the study; d) affect the evaluation of the clinical efficacy of the investigational product(s); and e) affect the safety evaluation of the investigational product(s).	4.4.6.3, 4.4.6.2	6.16	FDR C.05.012 (g)					
5	REB shall have a procedure to provide delegated review and approval/favourable opinion of minor change(s) in ongoing studies that have the approval/favourable opinion of the REB.	4.4.6.4	6.12		3.3.5				
6	REB should have procedures for specifying that the researcher should promptly report to the REB, and if applicable, organization and agencies: a) Deviations from, or changes of, the protocol to eliminate immediate hazards to the research participants; b) Changes increasing the risk to participants and/or affecting significantly the conduct of the study; c) All adverse drug reactions (ADRs) that are both serious and unexpected; d) New information that may affect adversely the safety of the participants or the conduct of the study; e) Any unanticipated problems involving risks to human participants or others; f) Any instance of serious or continuing noncompliance with these regulations or the requirements or determinations of the REB; g) Any suspension or termination of REB approval; h) Any discontinuation of the study.	4.4.6.6, 4.4.5.7	6.15		3.3.8	21 CFR 56.108(b), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.103(b)(5)		
7	Researchers shall report to the REB any unanticipated issue or event that may increase the level of risk to participants, or has other ethical implications that may affect participants' welfare.	4.4.6.7, 4.5.2.1(n)	6.15, 11.9			21 CFR 56.108(b)(1), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.103(b)(5) (i)		
8	Correspondence with REB (emails, faxes, amendments, notifications, AE reporting forms and responses, and submissions) and copies of all correspondence between the REB and the researchers are on file.				4.4, 8.2.7, 8.3.17, 8.3.19, 8.4.7	21 CFR 56.115(a)(4), 21 CFR 312.66, 21 CFR 812.60			
SECTION F - Continuing review									
1	The REB should conduct continuing review of each ongoing study at intervals appropriate to the degree of risk to human participants, but at least once per year. At minimum, continuing research ethics review shall consist of an annual status report (for multi-year research projects), and an end-of-study report (projects lasting less than one year).	4.4.7.1	6.14		3.1.4, 4.10	21 CFR 56.109(f), 21 CFR 56.115(a)(3), 21 CFR 312.66, 21 CFR 812.60			

CTO REB Qualification Checklist

#	Criteria	CGSB	TCPS2	HC	GCP	FDA	DHHS	PHIPA	Comments
2	REB shall have procedures for conducting initial and continuing review, determining the frequency of review, identifying which projects need verification from sources other than the researcher that no material changes have occurred since previous REB review, and for reporting its findings and actions to the researcher and the organization. This includes review of proposed research at convened meetings achieving quorum and receiving the approval of a majority of those members present at the meeting.	4.4.7.2, 4.4.7.3, 4.4.7.4			3.3.3, 3.3.4	21 CFR 56.108(a)(1) and 108(a)(2)and 108(c), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.103(b)(4) (ii)		

SECTION G – Reconsideration, appeals and study completion

1	REB shall have an established mechanism and a procedure in place for promptly handling appeals from researchers when, after reconsideration, the REB has refused ethics approval of the research. Researchers have the right to request, and REBs have an obligation to provide, prompt reconsideration of decisions affecting a research project.	4.4.8.1, 4.4.8.2, 4.4.8.3	6.18, 6.19, 6.20						
2	The appeal committee shall have the authority to review negative decisions made by an REB. In so doing, it may approve, reject or request modifications to the research. Its decision on behalf of the organization shall be final.	4.4.8.3	6.20						
3	When a study is completed or terminated, the REB should require that reporting of this event be done promptly and that a completion report be provided.	4.4.9.1, 4.4.6.6							

SECTION H - Documents and record keeping

General

1	The REB (or if appropriate, its organization) shall prepare and maintain comprehensive records which shall be kept confidential to the greatest extent possible.	4.5.1.1, 4.5.3.1	6.17	FDR C.05.010, NHRP part 4, s.74	3.2.2, 3.4	21 CFR 56.115(a), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.115(a)		
2	REB policies and procedures should be documented and inclusive of the following: a) managing conflicts of interest for REB members, ad hoc advisors, and REB administrative staff; b) composition of the REB; c) selection, appointment terms, duties, and performance evaluations of REB members, including the Chair and Vice-Chair or equivalent; d) training and education of REB members and REB administrative staff; e) delegation of signing authority; f) confidentiality of information on studies submitted for review; g) REB application/submission procedures; h) the process for decision making at REB meetings; i) procedures for initial review, ongoing review, and continuing review and criteria for REB ethical acceptability, including review at a convened meeting of the REB and delegated review; j) communication with qualified researchers and qualified researchers staff, with research participants and with other individuals or organizations; k) guidelines on informed consent processes; l) management of non-compliance of qualified researchers; m) document management and retention; n) requirements for handling unanticipated problems; o) requirements for reporting protocol deviations; and p) emergency preparedness.	4.5.2.1			3.2.2				

CTO REB Qualification Checklist

#	Criteria	CGSB	TCPS2	HC	GCP	FDA	DHHS	PHIPA	Comments
Documents related to ethics review									
3	Submission: a) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by researchers, and reports of injuries to participants; b) All documentation related to the projects submitted to the REB for review.	4.5.3.2	6.17	FDR C.05.010, NHRP part 4, s.74	3.1.2, 3.2.2, 3.4	21 CFR 56.115(a)(1), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.115(a)(1)		
4	Attendance at all REB meetings.	4.5.3.3	6.17						
5	The REB should have in documentation, a list of REB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to REB deliberations; and any employment or other relationship between each member and the organization; for example: full-time employee, part-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant.				3.2.1	21 CFR 56.115(a)(5), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.115(a)(5)		
6	Minutes of REB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the REB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.	4.5.3.3	6.17	FDR C.05.010, NHRP part 4, s.74	3.4	21 CFR 56.115(a)(2), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.115(a)(2)		
7	Where the REB denies ethics approval for a research proposal, the minutes shall include the reasons for this decision.	4.5.3.3	6.17						
8	The REB may be asked by researchers, sponsors or regulatory authorities to provide its written procedures and membership lists.				3.4				
Retention of REB documents									
9	Documentation is stored in a secure location with restricted access.								
10	Long term record retention plans are outlined (e.g., archive procedures).	4.5.4.1		FDR C.05.010, NHRP part 4, s.74	3.4, 4.9.5				
11	When deciding the retention period for their files, REBs should be guided by their organizations record-keeping policies and other relevant legal or regulatory requirements. Files, minutes and other relevant documentation shall be accessible to authorized representatives of the organization, researchers, sponsors and funders when necessary to assist internal and external audits, or research monitoring, and to facilitate reconsideration or appeals.	4.5.4.1	6.17	FDR C.05.012(4)					
12	The REB Records shall be retained for the maximum amount of time stipulated in any applicable regulations. The retention period shall begin on the date of when the REB accepts the study completion report or REB approval expires. In the absence of a regulatory requirement for the REB record retention, the REB records shall be retained for a period of at least three years and shall be accessible at reasonable times and in a reasonable manner. Records include (e.g., written procedures, membership lists, lists of occupations/affiliations of members, submitted documents, minutes of meetings, and correspondence).	4.5.4.1		FDR C.05.010, NHRP part 4, s.74	3.4	21 CFR 56.115(b), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.115(b)		

Table 1: REB Membership

#	Criteria	CGSB	TCPS2	HC	GCP	FDA	DHHS	PHIPA	Comments
The REB membership shall include, but not be limited to:									
1	At least five members.	4.3.2.1	6.4	FDR C.05.001, NHPR part 4, s.63, MDR Part 3, s.81(h)	3.2.1(a)	21 CFR 56.107(a), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.107(a)	O.Reg.32 9/04 s.15(1)	
2	Composed of both men and women.	4.3.2.1	6.4	FDR C.05.001, NHPR part 4, s.63, MDR Part 3, s.81(h)		21 CFR 56.107(b), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.107(b)		
3	Has a majority of members who are Canadian citizens or permanent residents under the Immigration Act.	4.3.2.3		FDR C.05.001, NHPR part 4, s.63					
4	At least one member whose primary area of interest is in a non-scientific area.	4.3.2.1(d)		FDR C.05.001, NHPR part 4 s.63	3.2.1(b)	21 CFR 56.107(c), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.107(c)		
5	At least one member who is independent of the organization /research site. Only those REB members who are free of conflict of interest and independent of the researcher and the sponsor of the research should vote/provide opinion on a study-related matter.	4.4.4.4.9	7.1, 7.3		3.2.1 (c)	21 CFR 56.107(d) and 107(e), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.107(d) and (e)		
6	One member knowledgeable in Canadian laws relevant to the biomedical research to be approved (but that member should not be the institution's legal counsel or risk manager).	4.3.2.1(e)	6.4(c)	FDR C.05.001, NHPR part 4, s.63, MDR Part 3, s.81(h)					
7	One member knowledgeable in ethics relevant to research.	4.3.2.1(f)	6.4(b)	FDR C.05.001, NHPR part 4, s.63, MDR Part 3, s.81(h)				O.Reg. 329/04 s. 15(1)(ii)	
8	At least one member knowledgeable in considering privacy issues.	4.3.2.1 (j)						O.Reg. 329/04 s. 15.1.iv	
9	One (or two*) members whose primary experience and expertise are in a scientific discipline, who have broad experience in the methods and areas of research to be approved.	4.3.2.1 (a)*	6.4(a)*	FDR C.05.001, NHPR part 4, s.63, MDR Part 3, s.81(h)		21 CFR 56.107(c), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.107(c)	O.Reg. 329/04 s. 15(1) (iii)	
10	One member from a medical discipline or, if the research is in respect of a drug to be used for dental purposes, is from a dental discipline.	4.3.2.1(b)		FDR C.05.001, NHPR part 4, s.63					
11	One member who is from the community or is a representative of an organization interested in the areas of research to be approved and who is not affiliated with the sponsor or the site (organization) where the research is to be conducted and who is not part of the immediate family of a person who is affiliated with the organization.	4.3.2.1(c)	6.4(d)	FDR C.05.001, NHPR part 4, s.63, MDR Part 3, s.81(h)	3.2.1(c)	21 CFR 56.107(d), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.107(d)	O.Reg. 329/04 s.15(1)(i)	
When applicable to the research being reviewed, the REB should additionally include (as applicable):									
12	When the research involves specific populations the board should reflect the population with a designated member e.g., aboriginal, pediatrics, or knowledgeable in complementary and/or alternative healthcare.	4.3.2.1(g) (h)(i)	6.4	NHPR, Part 4, s.63					
The REB membership shall address the following restrictions, as applicable:									
13	No REB may consist of members entirely of one profession.					21 CFR 56.107(b), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.107(b)		
14	Senior administrators of the organization do not serve on the REB.		6.4						

Table 2: Informed Consent Elements

#	Criteria	CGSB	TCPS2	HC	GCP	FDA	DHHS	PHIPA	Comments
1	Statement indicating that the study involves research.	4.4.4.2.9 (a)	3.2(a)	FDR C.05.010(h)(ii), NHPR Part 4, s. 74(h)(ii)	4.8.10(a)	21 CFR 50.25(a)(1)	45 CFR 46.116(a)(1)		
2	The purpose of the research.	4.4.4.2.9 (b)	3.2(b)	FDR C.05.010(h)(ii), NHPR Part 4, s. 74(h)(ii)	4.8.10(b)	21 CFR 50.25(a)(1)	45 CFR 46.116(a)(1)	2004, c. 3, Sched. A s.18(1)(b) and 18(5)(a)	
3	The study treatment(s) and the probability for random assignment to each treatment.	4.4.4.2.9 (d)		FDR C.05.010(h)(ii), NHPR Part 4, s. 74(h)(ii)	4.8.10(c)				
4	The study procedures to be followed, including all invasive procedures.	4.4.4.2.9 (e)	3.2(b)	FDR C.05.010(h)(ii), NHPR Part 4, s. 74(h)(ii)	4.8.10(d)	21 CFR 50.25(a)(1)	45 CFR 46.116(a)(1)		
5	The participant's responsibilities.	4.4.4.2.9 (s)	3.2(b)	FDR C.05.010(h)(ii), NHPR Part 4, s. 74(h)(ii)	4.8.10(e)				
6	Those aspects of the study that are experimental.	4.4.4.2.9 (e)		FDR C.05.010(h)(ii), NHPR Part 4, s. 74(h)(ii)	4.8.10(f)	21 CFR 50.25(a)(1)	45 CFR 46.116(a)(1)		
7	The reasonably foreseeable risks or inconveniences to the participant and, when applicable, to an embryo, fetus, or nursing infant.	4.4.4.2.9 (g)	3.2(c)	FDR C.05.010(h)(ii), NHPR Part 4, s. 74(h)(i)	4.8.10(g)	21 CFR 50.25(a)(2)	45 CFR 46.116(a)(2)		
8	A statement that the research may involve risks to the participant (or embryo or fetus, if the participant may become pregnant) which are unforeseeable.	4.4.4.2.9 (h)				21 CFR 50.25(b)(1)	45 CFR 46.116(b)(1)		
9	The reasonably expected benefits. When there is no intended clinical benefit to the participant, the participant should be made aware of this.	4.4.4.2.9 (i)	3.2(c)	FDR C.05.010(h)(i), NHPR Part 4, s.74(h)(i)	4.8.10(h)	21 CFR 50.25(a)(3)	45 CFR 46.116(a)(3)		
10	The alternative procedure(s) or course(s) of treatment that may be available to the participant, and their important potential benefits and risks.	4.4.4.2.9 (f)		FDR C.05.010(h)(ii), NHPR Part 4, s. 74(h)(ii)	4.8.10(i)	21 CFR 50.25(a)(4)	45 CFR 46.116(a)(4)		
11	The compensation and/or treatment available to the participant in the event of a study-related injury.	4.4.4.2.9 (l), 4.4.4.2.9 (n)		FDR C.05.010(h)(ii), NHPR Part 4, s. 74(h)(ii)	4.8.10(j)	21 CFR 50.25(a)(6)	45 CFR 46.116(a)(6)		
12	The anticipated prorated payment, if any, to the participant for participating in the study.	4.4.4.2.9 (u)	3.2(j)	FDR C.05.010(h)(ii), NHPR Part 4, s. 74(h)(ii)	3.1.9, 4.8.10(k)				
13	The anticipated expenses, if any, to the participant for participating in the study.	4.4.4.2.9 (t)	3.2(j)	FDR C.05.010(h)(ii), NHPR Part 4, s. 74(h)(ii)	4.8.10(l)	21 CFR 50.25(b)(3)	45 CFR 46.116(b)(3)		
14	That the participant's participation in the study is voluntary and that the participant may refuse to participate or withdraw from the study, at any time, without penalty or loss of benefits to which the participant is otherwise entitled.	4.4.4.2.9 (o)	3.2(d)	FDR C.05.010(h)(ii), NHPR Part 4, s. 74(h)(ii)	4.8.10(m)	21 CFR 50.25(a)(8)	45 CFR 46.116(a)(8)	2004, c. 3, Sched. A s.18(5)(b)	
15	That the monitor(s), the auditor(s), the REB, and the regulatory authority(ies) will be granted direct access to the participant's original medical records for verification of study procedures and/or data without violating the confidentiality of the participant, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the participant or the participant's appropriate representative is authorizing such access.	4.4.4.2.9 (k)	3.2(i)	FDR C.05.010(h)(ii), NHPR Part 4, s. 74(h)(ii)	4.8.10(n)	21 CFR 50.25(a)(5)	45 CFR 46.116(a)(5)		

Table 2: Informed Consent Elements

#	Criteria	CGSB	TCPS2	HC	GCP	FDA	DHHS	PHIPA	Comments
16	That records identifying the participant will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the study are published, the participant's identity will remain confidential.	4.4.4.2.9 (j)	3.2(i), 3.2(f)	FDR C.05.010(h)(ii), NHPR Part 4, s. 74(h)(ii)	4.8.10(o)	21 CFR 50.25(a)(5)	45 CFR 46.116(a)(5)		
17	That the participant or the participant's appropriate representative will be informed in a timely manner if information becomes available that may be relevant to the participant's willingness to continue participation in the study.	4.4.4.2.9 (r)	3.2(d)	FDR C.05.010(h)(ii), NHPR Part 4, s. 74(h)(ii)	4.8.10(p)	21 CFR 50.25(b)(5)	45 CFR 46.116(b)(5)		
18	The person(s) to contact for further information regarding the study and the right of research participants, and whom to contact in the event of a study-related injury.	4.4.4.2.9 (x),(y),(z)	3.2(g), (h)	FDR C.05.010(h)(ii), NHPR Part 4, s. 74(h)(ii)	4.8.10(q)	21 CFR 50.25(a)(7)	45 CFR 46.116(a)(7)		
19	The foreseeable circumstances and/or reasons under which the participant's participation in the study may be terminated without the participants consent.	4.4.4.2.9 (q)	3.2(l)	FDR C.05.010(h)(ii), NHPR Part 4, s. 74(h)(ii)	4.8.10(r)	21 CFR 50.25(b)(2)	45 CFR 46.116(b)(2)		
20	The process involved for termination of participation.	4.4.4.2.9 (p)				21 CFR 50.25(b)(4)	45 CFR 46.116(b)(4)		
21	The expected duration of the participant's participation in the study.	4.4.4.2.9 (c)	3.2(b)	FDR C.05.010(h)(ii), NHPR Part 4, s. 74(h)(ii)	4.8.10(s)	21 CFR 50.25(a)(1)	45 CFR 46.116(a)(1)		
22	The approximate number of participants involved in the study.	4.4.4.2.9 (w)		FDR C.05.010(h)(ii), NHPR Part 4, s. 74(h)(ii)	4.8.10(t)	21 CFR 50.25(b)(6)	45 CFR 46.116(b)(6)		
23	A statement to the effect that, by consenting, participants have not waived any rights to legal recourse in the event of research-related harm.	4.4.4.2.9 (m)	3.2(k)		4.8.4				
24	If deemed suitable by the REB, information regarding the registration of the clinical trial in an internationally recognized clinical trial registry (e.g. name of registry, identifying code etc.) should be included. For clinical trials conducted in the U.S. there should be the following statement of online registry: "description of this clinical trial will be available on http://www.ClinicalTrials.gov , as required by U.S. Law. This website will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."*	4.4.4.2.11				21 CFR 50.25(6)(c)*			
25	Information concerning the possibility of commercialization of research findings, and the potential or perceived conflicts of interest on the part of the researchers, their organizations or the research sponsors.	4.4.4.2.9 (aa)	3.2 (e)						
26	The identity of the sponsors and qualified investigators.	4.4.4.2.9 (v)	3.2(b)						
27	Information on the participant's right to request the withdrawal of information or specimens, and any limits on the feasibility of that withdrawal.		3.2(d)						
28	An indication of what information will be collected about participants and for what purposes; a description of the anticipated uses of data; and information indicating who may have a duty to disclose information collected, and to whom such disclosures could be made.		3.2(i)						

Table 3: Materials Required for Submission to the REB

#	Criteria	CGSB	TCPS2	HC	GCP	FDA	DHHS	PHIPA	Comments
Initial REB submission requirements									
1	Research protocol	4.4.3.2(b)	6.11		3.1.2, 4.4.1	21 CFR 56.115(a)(1), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.115(a)(1)		
2	Protocol amendments	4.4.6.2	6.16		3.1.2, 4.4.3	21 CFR 56.115(a)(1), 21 CFR 56.108(a)(3), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.115(a)(1)		
3	Informed Consent Form(s) - Original Submission	4.4.3.2(j)	3.2		3.1.2, 4.4.1, 4.8.1, 4.8.2	21 CFR 50.27(a), 21 CFR 56.115(a)(1), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.117(a), 45 CFR 46.115(a)(1)		
4	Informed Consent Form(s) - Revised and Amended	4.4.3.2(j)	3.2		3.1.2, 4.4.1, 4.8.1, 4.8.2	21 CFR 50.27(a), 21 CFR 56.115(a)(1), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.117(a), 45 CFR 46.115(a)(1)		
5	Consent form updates that the researcher proposes for use in the study	4.4.3.2(j)	3.2		3.1.2, 4.4.1, 4.8.1, 4.8.2	21 CFR 50.27(a), 21 CFR 56.115(a)(1), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.117(a), 45 CFR 46.115(a)(1)		
6	Participant recruitment procedures (e.g. advertisements)	4.4.3.2(e) (f)			3.1.2, 4.4.1				
7	Written information to be provided to participant (such as diaries, contact cards, study process)	4.4.3.2(j)			3.1.2, 4.4.1, 4.8.1, 4.8.2				
8	Investigator's Brochure (IB), Product Monograph, Device manual	4.4.3.2(c)			3.1.2, 4.4.2				
9	Available safety information	4.4.3.2(c)			3.1.2	CFR 56.111(a)(1), and 111(a)(2), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.111(a)(1) and 111(a)(2)		
10	Information about payments and compensation available to participants	4.4.3.2(k)	3.1(a)		3.1.2, 3.1.8				
11	Researcher's current CV and/or other documentation evidencing qualifications, including a written attestation that the qualified investigator is entitled to provide health care under the applicable laws, and that he/she is a member in good standing with his/her respective regulatory authority*	4.4.3.2 (d)*			3.1.2, 3.1.3, 4.1.1				
12	Other documents that the REB may need to fulfill its responsibilities	4.4.3.4			3.1.2				
13	Attestation by Department Head /Division Chief, responsible organizational official or sponsor that the available facilities at the research site are suitable and feasible and that there is available care in case of an emergency	4.4.4.2.4 (d)							
14	Disclosure of any financial interest or other potential conflict of interest that the research has in relation to the research, or any real, potential, or perceived institutional conflicts that may affect their research*	4.4.3.2(l)	7.2, 7.4*						
15	An application, authenticated and dated	4.4.3.2(a)							
16	A description of all processes used to obtain informed consent and assent (if applicable)	4.4.3.2(g)							

Table 3: Materials Required for Submission to the REB

#	Criteria	CGSB	TCPS2	HC	GCP	FDA	DHHS	PHIPA	Comments
17	The process whereby research subjects may withdraw their consent, if given, and associated documentation	4.4.3.2(h)							
18	A description of the processes used to provide research subjects with new information which may affect their willingness to participate, and to obtain their ongoing consent	4.4.3.2(i)							
19	A statement and description of any safety monitoring process provided by the sponsor or qualified investigator, such as data and safety monitoring board (DSMB)	4.4.3.2(n)	11.7			21 CFR 56.111(a)(6), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.111(a)(6)		
20	If the trial has been registered in an internationally recognized clinical trial registry, the name of the clinical trial registry, the unique identifying code assigned to the clinical trial by the registry, and information regarding where the results of the clinical trial will be made publically available	4.4.3.3							
21	If the research involves (optional*) genetic testing, a description of the separate processes used for obtaining and documenting informed consent and assent for such genetic testing. In addition, a plan for managing information that may be revealed through genetic research should be submitted to the REB*	4.4.3.2(a)	13.2*						
22	A statement by the qualified investigator that he/she is aware of and shall make all reasonable efforts to comply with the applicable laws, guidelines, policies, and professional obligations	4.4.3.2(p)							
23	All previous decisions, if known, by other REBs or Regulatory Authorities for the proposed biomedical clinical trial (whether in the same location or elsewhere), and indication of modification(s) to the protocol made on that account, and the reasons for previous negative decisions	4.4.3.2(o)							
24	Clinical trial budget, in sufficient detail to ensure that conflicts of interest are identified, minimized, or otherwise managed	4.4.3.2 (m)	11.11, 11.10						
25	Measures for meeting confidentiality obligations and explanation of any reasonably foreseeable disclosure requirements, and proposed measures for safeguarding information, for the full life cycle of information: its collection, use, dissemination, retention and/or disposal		5.2(a), 5.3			21 CFR 56.111(a)(7), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.111(a)(7)	2004, c.3, Sched. A. s.44(3)(b)	
26	If material incidental findings are likely, a plan indicating how researchers will disclose such findings to participants		3.4						
27	Unless otherwise exempt from REB review, researchers who propose to engage in data linkage describe the data that will be linked and the likelihood that identifiable data will be created through the linkage		5.7						
28	When proposing research expected to involve First Nations, Inuit or Métis participants, an explanation as to how the researchers have engaged, or intend to engage, the relevant community, or a request for an exception to the requirement for community engagement		9.10						
29	Justification for the choice of a placebo control arm, as opposed to the other possible choices of control group, is provided to the REB (as applicable)		11.2 (a-c)						

Table 3: Materials Required for Submission to the REB

#	Criteria	CGSB	TCPS2	HC	GCP	FDA	DHHS	PHIPA	Comments
Submission requirements during ongoing trial conduct may include, but are not limited to:									
30	Consent form updates that the researcher proposes for use in the study	4.4.6.2	3.3, 6.16	FDR C.05.012(3)(g)	3.1.2, 4.4.1, 4.8.2	21 CFR 56.115 (a)(1) and 115(a)(7), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.115 (a)(1) and 115(a)(7)		
31	Any revisions to written information provided to participants (not including consent form revisions, as noted above)	4.4.6.2		FDR C.05.012(3)(g)	3.1.2, 4.4.3, 4.8.2				
32	Written summaries of trial status/progress reports/continuing review reports, including DSMB reports*	4.4.7.3*	6.14, 6.17, 11.7*	FDR C.05.012(3)(g)	4.10.1	21 CFR 56.115(a)(1), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.115(a)(1)		
33	Written reports on any changes significantly affecting the conduct of the trial, and/or increasing the risk to subjects, including: a) deviations from, or changes of, the protocol to eliminate immediate hazards to trial subjects; b) changes increasing the risks and/or affecting significantly the conduct of the trial; c) all adverse drug reactions that are serious and unexpected; d) new information that may affect adversely the safety of the subjects or the conduct of the study.	4.4.6.6 (b), 4.4.6.6(e) 4.4.7.3(d) (3)	6.15, 10.5, 11.8	FDR C.05.012(3)(g)	3.3.8, 4.5.4(a), 4.10.2	21 CFR 56.108(a)(3), 21 CFR 56.115(a)(1), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.108(a), 45 CFR 46.115(a)(1)		
34	Unanticipated problems, including serious unexpected adverse events/reactions	4.4.6.6(c), 4.4.6.7, 4.4.7.3(d) (3)	6.15, 11.8		4.11.1	21 CFR 56.115(a)(1), 21 CFR 56.108(b)(1), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.115(a)(1)		
35	Serious or continuing non-compliance with organizational policy or REB requirements and determinations, or the regulations	4.4.6.6(d)	6.15			21 CFR 56.108(b)(2), 21 CFR 312.66, 21 CFR 812.60			
36	Updates to the Investigator's Brochure (IB), product monograph (PM), device manual	4.4.7.3(c)			4.4.2				
37	Changes to measures to protect privacy and confidentiality					21 CFR 56.111(a)(7), 21 CFR 312.66, 21 CFR 812.60	45 CFR 46.111(a)(7)		
38	Discontinuation of the clinical trial at the local site and the reasons for it	4.4.6.6 (a)			4.12.1, 4.12.2	21 CFR 56.108(a)(3), 21 CFR 312.66, 21 CFR 812.60			
39	Summary of trial outcome/study completion report	4.4.9.1			4.13				
40	Changes in any additional documents subject to review	4.4.6.2		FDR C.05.012(3)(g)	4.4.3				

Table 3: Materials Required for Submission to the REB

#	Criteria	CGSB	TCPS2	HC	GCP	FDA	DHHS	PHIPA	Comments	
Privacy requirements for research plans:										
41	<p>The following are prescribed as additional requirements that must be set out in research plans:</p> <p>a) a description of the research proposed to be conducted and the duration of the research;</p> <p>b) a description of the personal health information required and the potential sources;</p> <p>c) a description of how the personal health information will be used in the research, and if it will be linked to other information, a description of the other information as well as how the linkage will be done;</p> <p>d) an explanation as to why the research cannot reasonably be accomplished without the personal health information and, if it is to be linked to other information, an explanation as to why this linkage is required;</p> <p>e) an explanation as to why consent to the disclosure of the personal health information is not being sought from the individuals to whom the information relates;</p> <p>f) a description of the reasonably foreseeable harms and benefits that may arise from the use of the personal health information and how the researchers intend to address those harms;</p> <p>g) a description of all persons who will have access to the information, why their access is necessary, their roles in relation to the research, and their related qualifications;</p> <p>h) the safeguards that the researcher will impose to protect the confidentiality and security of the personal health information, including an estimate of how long information will be retained in an identifiable form and why;</p> <p>i) information as to how and when the personal health information will be disposed of or returned to the health information custodian;</p> <p>j) the funding source of the research;</p> <p>k) whether the researcher has applied for the approval of another research ethics board and, if so the response to or status of the application;</p> <p>l) whether the researcher's interest in the disclosure of the personal health information or the performance of the research would likely result in an actual or perceived conflict of interest with other duties of the researcher.</p>	4.4.4.2.16							O.Reg 329/04 s.16	

Section 5: Quality Management

This section is meant as a development exercise and is voluntary. Prior to Qualification review Institutions/REBs can indicate if they would like the Review to include this section; it will not impact the Qualification review outcome.

#	Criteria	CGSB	TCPS2	HC	GCP	FDA	DHHS	PHIPA	Comments
Quality management									
General									
1	As appropriate to the nature and volume of the studies that the REB reviews, the REB shall collaborate with the highest body within the organization to identify appropriate levels of quality management and shall establish policies and procedures for evaluating and assessing performance. Such policies and procedures shall include both quality control and quality improvement processes. NOTE: The scale and comprehensive nature of the quality management level may differ from one organization to another due to the size of the organization, type of activities and complexity of their processes and interactions. For example, quality management processes may be the responsibility of the REB Chair and REB administrative staff or may be the responsibility of a distinct entity within the organization.	4.6.1.1							
2	The quality management activities for the REB should promote the quality and effectiveness of the processes and activities of the REB.	4.6.1.2							
3	The quality management activities for the REB should consist of initiatives designed to operationalize the ethical oversight of research involving research participants through the review, evaluation, performance measurement, control of deviations, and continuous improvement for REB activities as set out in criteria 4 through 9.	4.6.1.3							
Quality management review									
4	The quality management review of the REB should consist of a review of the following at planned intervals: a) existence, completeness, and status of the REB's written policies and SOPs; b) results of routine evaluations of the REB and the REB administration c) REB performance metrics and annual reports; d) feedback from applicants, qualified researchers, sponsors, funders, and public outreach to research participants; e) feedback from regulators relevant to the protection of the rights, safety and well-being of research participants; f) continuous improvement activities; g) new requirements (ethical, statutory or regulatory); h) status of any deviations as specified in 8; i) status of action items from previous reviews; and j) compliance with the applicable regulatory requirements.	4.6.2.1							

Quality Management

#	Criteria	CGSB	TCP52	HC	GCP	FDA	DHHS	PHIPA	Comments
5	<p>Recommendations for improvements to the REB and related processes resulting from the quality management review should consist of the following:</p> <p>a) new policies and/or SOPs or modification of existing policies or SOPs;</p> <p>b) additional training or educational activities or modifications to existing activities; and</p> <p>c) additional resources or modifications to existing resources.</p>	4.6.2.2							
Evaluation of the REB									
6	<p>The REB shall, in collaboration with the highest body within the organization, plan and implement a routine or directed evaluation of the REB to assure the organization that the REB is complying with the requirements of this Standard.</p> <p>NOTE: An organization with an REB may choose to implement a more formal audit program which is independent of the REB and reports to the highest level of the organization. The defined responsibilities and requirements for planning and conducting audits, and reporting, recording, and storing the results should be described in documented procedures.</p>	4.6.3.1							
Performance measurement of ongoing REB activities									
7	<p>The REB should, in collaboration with the highest body within the organization, identify meaningful indicators of the performance of the REB such as:</p> <p>a) the REB workload (e.g., volume of research reviewed, specifying any research that it considers to be high risk or involving vulnerable persons);</p> <p>b) the timeline REB metrics (turnaround time from submission of an application for ethics review to REB decision);</p> <p>c) the number of research participants participating in research under the ethics oversight of the REB;</p> <p>d) the nature and status of training and educational activities;</p> <p>e) the stakeholder satisfaction surveys.</p>	4.6.4.1							
Control of deviations									
8	<p>The REB shall, in collaboration with the highest body within the organization, take remedial action where a deviation from this Standard or from ethical, statutory or regulatory requirements, or from the organization's policies, where applicable, has been identified. Such actions shall include measures implemented to determine the cause of the deviation, and any corrective and preventative actions taken. The REB should assess whether re-review of the study is required. All decisions and actions shall be documented and reported in accordance with the policies of the organization.</p>	4.6.5.1							
Continuous improvement									
9	<p>Continuous improvement of the REB is achieved through an ongoing program consisting of the review of the following in order to implement corrective actions and preventative actions:</p> <p>a) routine or directed evaluations of the REB;</p> <p>b) routine or directed evaluations of the research, which may include evaluation of consent processes, safety monitoring, and data integrity;</p> <p>c) any feedback from researchers, sponsors, funders, and research participants; and</p> <p>d) any feedback from regulators relevant to the protection of the rights, safety, and well-being of research participants.</p>	4.6.6.1							