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Research Ethics Board Qualification Manual

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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 original CTO Qualification Manual. CTO is greatly indebted to TAHSN and to Ms. Anita Sengar and Mr. Nicholas Stavrinou, the original authors of the Manual.

CTO also acknowledges and thanks all those who have contributed their advice and expertise in the development of the original CTO REB Qualification Manual. The collaborative efforts of the REB community in Ontario are reflected in this first significant revision of the Qualification Checklist and Manual. We especially acknowledge the following members who participated on a sub-committee of the CTO REB Council: Anita Sengar, Jennifer Couture, Erika Basile, Sheri Webb, and David Kenney, all of whom contributed significantly to the development of these revised documents.

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

Contents

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 portal for research ethics review (CTO Stream), and policies, procedures, tools and education to support a province-wide REB of Record review model.

The CTO Streamlined System supports any single *CTO Qualified* REB in providing ethical review and continuing ethics 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 REB 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 Tri-Council Policy Statement 2 (TCPS2), the Canadian Food and Drugs Act and applicable Regulations, the International Council for Harmonization Good Clinical Practice guidelines (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 Qualification Team. The Qualification Team will generally consist of an Auditor with specific training in reviewing REBs, a CTO Program Manager, and two experienced

members from the research ethics community (e.g., REB Chair/Vice-Chair and an REB operations representative).

An REB must have written REB Standard Operating Procedures (SOPs) 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 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 and lead REB operations person
    - 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 Qualification Team will review the CAP and, upon acceptance of the plan, the REB will be designated as a *CTO Qualified REB*.

The 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 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

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 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).

Requesting Qualification

1. Please contact CTO when the REB is ready to undergo the Qualification process, ideally at least 8 weeks prior to the desired dates for the on-site visit.

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), lead REB operations person, 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 Qualification Team for the duration of the visit.

3. The REB Operations Personnel will be asked to complete the **Preliminary Questionnaire (Section 2)** and provide the following materials (or links if the materials are publicly 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 Qualification Team as needed during the Qualification Review period.

2. The Qualification Team will hold an **entrance meeting** with the REB Operations Personnel (and others as determined by the REB/institution). During this meeting, the Qualification Team will provide an overview of the REB Qualification process and answer any questions. The REB Operations Personnel will be asked to provide the 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 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. 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 Qualification Team during the on-site review period. Assistance from the REB Operations Personnel may be required to aid with navigation of the REB's electronic systems. While on-site, the Qualification Team may request that a limited selection of the electronic documents be provided in paper format to facilitate their review.

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 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. This report will be provided to the REB Chair(s) and the REB contact person.

2. If the Qualification Report does not contain any findings, the REB will be designated as a *CTO Qualified REB* and the designated institutional contact(s) will be copied on the official Qualification letter.

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.

4. Once the CAP has been reviewed by CTO and all findings have been resolved, the REB will be designated as a *CTO Qualified REB*. Confirmation of this designation will be provided to the REB Chair(s), the REB contact person, and the designated institutional contact(s).

5. Depending on the nature or extent of Findings identified during the review, CTO may conduct a follow-up visit at a later date to ensure that the corrective action has been successfully implemented. CTO will inform the REB if this is the case.

6. *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.

7. A list of *CTO Qualified REB*s will be posted publicly 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 ☐ No ☐ If yes, please provide the purpose and focus of review for each subcommittee or panel:	
d) Please describe any affiliated institutions or external sites for which the REB is a Board of Record:	
e) Are there formal agreements covering the Board of Record arrangements with each of the affiliated institutions or external sites? Yes ☐ No ☐	
f) Is there an Annual Report available either electronically or in hard copy? Yes ☐ No ☐ 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: ☐ Option 1: Copy of REB SOPs enclosed ☐ Option 2: REB SOPs are publicly available. Please provide website link:	

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) along with descriptions of their roles and responsibilities:

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 publicly posted? Yes ☐ No ☐ 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 ☐ No ☐
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:
d) Please provide the following documents as part of the Qualification package:

1. REB Application forms (Initial submission, Amendments, Continuing Review, Unanticipated Problems):

☐ Option 1: Enclosed

☐ Option 2: Publicly available. Please provide website link:

Click to enter link to online version if applicable.

2. Informed Consent form templates

☐ Option 1: Enclosed

☐ Option 2: Publicly available. Please provide website link:

Click to enter link to online version if applicable.

SECTION 8 - REB Compliance Inspections

a) Has the REB been inspected by a regulatory agency such as the Food and Drug Administration 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		☐	☐	Yes ☐ No ☐
2		☐	☐	Yes ☐ No ☐
3		☐	☐	Yes ☐ No ☐

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 Food and Drugs Act and applicable Regulations	Yes ☐	No ☐
US Code of Federal Regulations	Yes ☐	No ☐

ICH GCP	Yes ☐	No ☐
PHIPA and Ontario Regulation 329/04	Yes ☐	No ☐
Tri-Council Policy Statement (TCPS 2)	Yes ☐	No ☐
Other (Please specify):		

SECTION 10 – Institutional Contacts

a) Please provide the name of the institutional contact(s) for the REB (such as the Vice-President, Research), for the institution hosting the REB and institution(s) the REB serves:

Contact Name	Contact Role	Contact Email	Institution Name

SECTION 11 - 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:

Minor:	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.
Major	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

- **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 (E6 R2)
- **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

The "Notes" column may be used by REB staff or by the qualification team for the purposes of recording their own notes when preparing for a Qualification review

#	Criteria	TCPS2	HC	GCP	FDA	DHHS	PHIPA	Notes
SECTION A - Governance, mandate, authority, and resources								
Governance and mandate of the REB								
A1	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; 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.	6.1 6.2 6.3		3.3.1		45 CFR 46.103((a)		
A2	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.	6.2 6.13						
A3	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.				21 CFR 56.112 21 CFR 312.66 21 CFR 812.60	45 CFR 46.112		
A4	The organization shall have conflict of interest (COI) policies and procedures to identify, eliminate, minimize, or otherwise manage COI that may affect research. These policies should address the following:	7.1 7.2 7.3 7.4	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(d)	O.Reg.329/ 04 s.15.(2)	

#	Criteria	TCPS2	HC	GCP	FDA	DHHS	PHIPA	Notes
	a) Institutional Conflicts of Interest Real, potential or perceived institutional COI that affect research should be reported to the REB; the REB will consider whether the institutional COI should be disclosed as part of the consent process b) Researchers Conflicts of Interest Researchers shall disclose to the REB any real, potential, or perceived individual COI, as well as any institutional COI of which they are aware that may have an impact on their research. Upon discussion with the researcher, the REB shall determine the appropriate steps to manage the COI. c) REB Members Conflicts of Interest REB members shall disclose real, potential, or perceived COI to the REB. When necessary, the REB may decide that some of its members must withdraw from REB deliberations and decisions. Only those REB members who are independent of the researcher and the sponsor of the research should vote/provide opinion on a study-related matter. No REB member will participate in the REB's initial or continuing review of any research in which the member has a conflicting interest, except to provide information requested by the REB							
A5	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.	8.1			21 CFR 56.114 21 CFR 312.66 21 CFR 812.60	45 CFR 46.114(c)		
REB authority								
A6	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.	6.3	FDR C.05.001, NHPR 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		
A7	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.	6.3		3.1.2	21 CFR 56.113 21 CFR 312.66 21 CFR 812.60	45 CFR 46.113		

#	Criteria	TCPS2	HC	GCP	FDA	DHHS	PHIPA	Notes
SECTION B - REB Composition, appointment, and administrative support								
General								
B1	The REB should establish, document in writing, and follow its procedures when determining its composition (names and qualifications of the members). In appointing REB members, organizations shall establish their terms to allow for continuity of the research ethics review process.	6.4 6.6		3.3.1				
B2	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.	6.4 6.7	FDR C.05.001 NHPR 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)		
B3	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.	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								
B4	An REB may appoint alternate members with qualifications comparable to the primary member for whom they serve as an alternate.	6.4						
B5	In appointing alternate, additional REB members, organizations should consider the qualifications and expertise their REBs require.	6.4			21 CFR 56.107(f) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.107(e)		
B6	When the REB lacks the experience or expertise to conduct competent ethics review of a particular research project, 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.	6.5						
B7	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.	6.7						
REB Chair and Vice-Chair or equivalent								
B8	The REB Chair is responsible for ensuring that the REB review process conforms to all applicable regulatory requirements.	6.8		3.3 3.3.1				
SECTION C - REB operating procedures								
REB standard operating procedures								

#	Criteria	TCPS2	HC	GCP	FDA	DHHS	PHIPA	Notes
C1	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). REB policies and procedures should be documented and inclusive of the following: a) composition of the REB; b) selection, appointment, renewal and removal of REB members, including the Chair c) the process for decision making at REB meetings; d) 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; e) communication with qualified researchers, research staff and other individuals as applicable f) reporting of non-compliance of qualified researchers; g) document management and retention; h) requirements for handling unanticipated problems; i) requirements for reporting protocol deviations; and j) emergency preparedness.	6.2 6.6 6.10 6.12 6.17 6.21 7.3		3.2.2 3.3 3.3.1 3.3.3 3.3.8(a) 3.3.9 (c)	21 CFR 56.108(a), 108(b) and 108(c) 21 CFR 56.115(a)(2) 21 CFR 56.115(a)(5) 21 CFR 312.66 21 CFR 812.60	45 CFR 46. 108(a)(2), (3), (4) and 108(b) 45 CFR 46.115(a)(2)		
C2	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								
C3	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.	6.21						
C4	REBs should give special care to requests for exceptions during publicly declared emergencies.	6.23						
C5	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.	6.22						
Application procedures								
See **Table 3** for Submission requirements								
C6	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.		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)		

#	Criteria	TCPS2	HC	GCP	FDA	DHHS	PHIPA	Notes
SECTION D - Ethics review processes								
Requirements and criteria for ethics review								
See **Table 2** for Informed Consent Elements								
D1	As appropriate to the study and population, a letter of information or consent form should be provided/made available to all participants. Written consent in a signed statement from the participant is a common means of demonstrating consent and in some instances is mandatory. The procedures used to document/capture informed consent should be documented unless rationale has been provided by the researcher and REB approval granted for a waiver/alteration in documenting active consent. Where there are valid reasons for not recording consent in writing, the procedures used to seek consent must be documented.	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 812.60	45 CFR 46.117(a) 45 CFR 46.117(c)(2)		
D2	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).	3.2 3.7A 3.8 (a-f) 3.9 (a,b, e) 3.10 10.3	FDR C.05.010 NHPR 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(e) and 116(f)	2004, c. 3, Sched. A s.18(1)(a), 2004, c. 3, Sched. A, s.44 (3) (d)	
D3	Waivers, deferred or verbal consent, and use of substitute decision makers or translation, can only be approved by the REB.	3.7A			21 CFR 56.109(c) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.109(c)		
D4	The REB may approve research that involves an alteration to the requirements of written informed consent (e.g., research that waives the requirement to 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 alteration to consent requirements 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) in the case of a proposed alteration, the precise nature and extent of any proposed alteration is defined, and	3.7A 3.9 5.5A 5.5B 12.3A 12.3B			21 CFR 56.109(c) and 109(d) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.116(d), 116(e) and 116(f)		

#	Criteria	TCPS2	HC	GCP	FDA	DHHS	PHIPA	Notes
	e) the plan to provide a debriefing (if any) which may also offer participants the possibility of refusing consent and/or withdrawing data and/or biological specimens is in accordance with the requirements The REB shall be satisfied that the necessary criteria have been met when consent is waived for the secondary use of identifiable information, and secondary use of identifiable biological specimens (consent is not required for research that relies exclusively on secondary use of non-identifiable information).							
D5	Debriefing must be part of all research involving an alteration to consent requirements whenever it is possible, practicable and appropriate. Participants in such research must have the opportunity to refuse consent and request the withdrawal of their data and/or biological specimens whenever possible, practicable and appropriate	3.7B						
D6	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.	3.8		2.2	21 CFR 56.109(c) and 109(d) 21 CFR 50.24 21 CFR 312.66 21 CFR 812.60			
D7	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.	6.12	FDR C.05.010 (c) NHPR 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 46.108(a)(3) and 108(b) 45 CFR 46.110(a) and (b)(1) and 110(b)(2)		
D8	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.			3.1.3				
D9	During their review, the REB determines that 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			2.2	21 CFR 56.111(a)(1) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.111(a)(1)		

#	Criteria	TCPS2	HC	GCP	FDA	DHHS	PHIPA	Notes
	b) whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.							
D10	During their review, the REB determines that 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.			2.2	21 CFR 56.111(a)(2) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.111(a)(2)		
D11	During their review, the REB determines that 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. REBs should be particularly cognizant when circumstances may lead to vulnerability in the context of research, as outlined in the applicable regulations.	4.1		3.1.1	21 CFR 56.111(a)(3) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.111(a)(3)		
D12	Informed consent will be sought from each prospective participant or the participant's appropriate representative, in accordance with applicable regulations.	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)		
D13	Informed consent will be appropriately documented, in accordance with and to the extent required by applicable regulations.				21 CFR 56.111(a)(5) 21 CFR 50.27 21 CFR 312.66 21 CFR 812.60	45 CFR 46.111(a)(5)		
D14	The REB shall determine that the research plan makes adequate provision for monitoring safety, efficacy/effectiveness (where feasible) and validity) including: a) how participant safety will be monitored and what actions will be taken in the event of a threat to participant safety; b) how intervention efficacy will be monitored (where feasible) and what actions will be taken if efficacy is found to be greater than expected; c) the criteria by which participants may be removed from a study for safety reasons; d) the study-wide stopping rules (if any) by which studies may be stopped or amended due to evidence of inferior safety, superior efficacy or futility; and	11.6			21 CFR 56.111(a)(6) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.111(a)(6)		

#	Criteria	TCPS2	HC	GCP	FDA	DHHS	PHIPA	Notes
	e) the reporting procedure that will be followed to ensure any information relevant to participant welfare or consent is reported clearly and in a timely fashion to the REB. A data and safety monitoring plan may (but need not) include the establishment of an independent DSMB.							
D15	The REB shall determine that there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.	5.2 5.3			21 CFR 56.111(a)(7) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.111(a)(7)		
D16	When some or all of the participants, are likely to be vulnerable to coercion or undue influence in the context of research, additional safeguards have been included in the study to protect the rights and welfare of these participants.	4.6 4.7		3.1.1	21 CFR 56.111(b)	45 CFR 46.111(b)		
D17	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.	3.9 4.6		3.1.1				
D18	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	21 CFR 46 Subpart D		
D19	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			3.1.2 3.1.8 3.1.9				

#	Criteria	TCPS2	HC	GCP	FDA	DHHS	PHIPA	Notes
	form and any other written information to be provided to participants; and d) The way payment will be prorated should be specified.							
D20	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).	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								
D21	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.	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)		
D22	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.	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)		
D23	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.	6.13	FDR C.05.010(c) NHPR 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)		
D24	REB meeting dates and submission deadlines should be published in such a way as to give sufficient notice to members and applicants.			3.3.2				
D25	Remote participation during convened meetings is allowed during emergencies and when necessary.	6.10						
D26	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.	6.9	FDR C.05.010(c) NHPR 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)		
D27	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	6.9						

#	Criteria	TCPS2	HC	GCP	FDA	DHHS	PHIPA	Notes
	knowledge necessary to provide an adequate research ethics review of the proposals under consideration.							
D28	Only members who participate in the REB review and discussion should vote/provide their opinion and/or advice.			3.2.4				
D29	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.	6.13	FDR C.05.010 NHPR part 4, s.74	3.2.5	21 CFR 56.107(f) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.107(e)		
D30	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.	6.5		3.2.6	21 CFR 56.107(f) 21 CFR 312.66 21 CFR 812.	45 CFR 46.107(e)		
D31	REB shall have delegated review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.	6.12	FDR C.05.010 NHPR 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)		
D32	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.	6.12	FDR C.05.010 NHPR 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)		
D33	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 (approve the applications, require modification, request clarification or further information, or refer the application for review at the convened meeting) 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.	6.12	FDR C.05.010 NHPR 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)		
D34	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.	6.12			21 CFR 56.110(c) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.110(c)		
Notification of REB decision								

#	Criteria	TCPS2	HC	GCP	FDA	DHHS	PHIPA	Notes
D35	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.	6.13	FDR C.05.010 NHPR 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 46.108(a)(3)(i) and 108(a)(4)(ii)) 45 CFR 46.109(d)	2004, c. 3, Sched. A, s.44(4)	
D36	At the request of the applicant, the REB should provide a copy of the REB membership roster documenting that the REB is constituted in agreement with applicable regulations.			3.4 8.2.8				
SECTION E - Ongoing review								
E1	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.	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 46.108(a)(3)(i)		
E2	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.			4.9.7	21 CFR 56.109(f) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.109(g)		
E3	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)).	6.16		3.3.7	21 CFR 56.108(a)(3) and 108(a)(4) 21 CFR 312.66 21 CFR 812.60	45 CFR 46. 108(a)(3)(iii)		
E4	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.	6.12		3.3.5				
E5	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;	6.15 11.8		3.3.8 4.12.1 4.12.2	21 CFR 56.108(b) 21 CFR 312.66 21 CFR 812.60	45 CFR 46. 108(a)(3)(iii) and 108)(a)(4)		

#	Criteria	TCPS2	HC	GCP	FDA	DHHS	PHIPA	Notes
	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, termination or suspension of the study.							
E6	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.	6.15 11.9			21 CFR 56.108(b)(1) 21 CFR 312.66 21 CFR 812.60	45 CFR 46. 108(a)(4)(i)		
SECTION F - Continuing review								
F1	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).	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			
F2	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 through delegated review or at convened meetings achieving quorum and receiving the approval of a majority of those members present at the meeting, in accordance with applicable regulations.			3.3.3 3.3.4 3.3.9(a)	21 CFR 56.108(a)(1) and 108(a)(2)and 108(c) 21 CFR 312.66 21 CFR 812.60	45 CFR 46. 108(a)(3) and 108(a)(4)		
SECTION G – Reconsideration, appeals and study completion								
G1	Researchers have the right to request, and REBs have an obligation to provide, prompt reconsideration of decisions affecting a research project.	6.18						
G2	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.	6.19		3.3.9(c)				
G3	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.	6.20						

#	Criteria	TCPS2	HC	GCP	FDA	DHHS	PHIPA	Notes
G4	When a study is completed, terminated or suspended, the REB should require that reporting of this event be done promptly and that a completion report be provided.	6.14		4.12.1 4.12.2 4.13				
SECTION H - Documents and record keeping								
General								
H1	The REB (or if appropriate, its organization) shall prepare and maintain comprehensive records which shall be kept confidential to the greatest extent possible.	6.17	FDR C.05.010 NHPR 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)		
H2	REB policies and procedures should be documented and inclusive of the following: a) composition of the REB; b) selection, appointment, renewal and removal of REB members, including the Chair c) the process for decision making at REB meetings; d) 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; e) communication with qualified researchers and qualified research staff, f) reporting non-compliance of qualified researchers; g) document management and retention; h) requirements for handling unanticipated problems; i) requirements for reporting protocol deviations; and j) emergency preparedness.	6.2 6.6 6.10 6.12 6.17 6.21 7.3		3.2.2 3.3.1 3.3.3 3.3.8(a) 3.3.9 (c)	21 CFR 56.108(a)(1), (2) 56.108(c) 21 CFR 56.115(a)(5) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.108(a)(2), (3), (4) 46.108(b)		
H3	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.	6.17	FDR C.05.010 NHPR 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)		
H4	Attendance at all REB meetings.	6.17			21 CFR 56.115(a)(2) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.115(a)(2)		
H5	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			3.2.1	21 CFR 56.115(a)(5) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.108(a)(2)		

#	Criteria	TCPS2	HC	GCP	FDA	DHHS	PHIPA	Notes
	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.							
H6	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 (when applicable), including the number of members voting for, against, and abstaining or consensus decisions (for research without US regulatory compliance requirements); the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.	6.17	FDR C.05.010 NHPR 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)		
H7	Where the REB denies ethics approval for a research proposal, the minutes shall include the reasons for this decision.	6.17			21 CFR 56.115(a)(2)	45 CFR 46.115(a)(2)		
H8	The REB may be asked by researchers, sponsors or regulatory authorities to provide its written procedures and membership lists.			3.4	21 CFR 56.115(b)	45 CRF 46.115(b)		
H9	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	45 CFR 46.115(a)(4)		
Retention of REB documents								
H10	Documentation is stored in a secure location with restricted access.	6.17	FDR C.05.012 NHPR part 4, s.74					
H11	Long term record retention plans are outlined (e.g., archive procedures).		FDR C.05.010 NHPR part 4, s.74	3.4 4.9.5				
H12	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.	6.17	FDR C.05.012(4)					
H13	The REB Records shall be retained for the maximum amount of time stipulated in any applicable regulations or guidance documents and shall be accessible at reasonable times and in a reasonable manner. Records include (e.g., written procedures, membership lists, lists of		FDR C.05.010 NHPR part 4, s.74	3.4	21 CFR 56.115(b) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.115(b)		

#	Criteria	TCPS2	HC	GCP	FDA	DHHS	PHIPA	Notes
	occupations/affiliations of members, submitted documents, minutes of meetings, and correspondence).							

Table 1: REB Membership

#	Criteria	TCPS 2	HC	GCP	FDA	DHHS	PHIPA	Notes
The REB membership shall include, but not be limited to:								
1.1	At least five members.	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.329/04 s.15(1)	
1.2	Composed of both men and women.	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	45CFR 46.107(a)		
1.3	Has a majority of members who are Canadian citizens or permanent residents under the Immigration Act.		FDR C.05.001 NHPR part 4, s.63					
1.4	At least one member whose primary area of interest is in a non-scientific area.		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(b)		
1.5	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.	6.4(d) 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(c) and (e)	O.Reg. 329/04 s. 15(1)(i)	
1.6	One member knowledgeable in laws relevant to the research to be reviewed (but that member should not be the institution's legal counsel or risk manager).	6.4(c)	FDR C.05.001 NHPR part 4, s.63			45 CFR 46 107(a)		
1.7	One member knowledgeable in ethics relevant to research.	6.4(b)	FDR C.05.001 NHPR part 4, s.63				O.Reg. 329/04 s. 15(1)(ii)	
1.8	At least one member knowledgeable in considering privacy issues.						O.Reg. 329/04 s. 15(1)(iv)	
1.9	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 reviewed.	6.4(a)*	FDR C.05.001* NHPR part 4, s.63*		21 CFR 56.107(c) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.107(b)	O.Reg. 329/04 s. 15(1) (iii)*	
1.10	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.		FDR C.05.001 NHPR part 4, s.63					
1.11	One member who is from the community or is a representative of an organization interested in the areas of research to be approved	6.4(d)	FDR C.05.001 NHPR part 4, s.63	3.2.1(c)	21 CFR 56.107(d)	45 CFR 46.107(c)		

#	Criteria	TCPS 2	HC	GCP	FDA	DHHS	PHIPA	Notes
	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.				21 CFR 312.66 21 CFR 812.60			
1.12	When the research involves specific populations, the board should reflect the population with a designated member	6.4 9.4	NHPR, Part 4, s.63					
The REB membership shall address the following restrictions, as applicable:								
1.13	No REB may consist of members entirely of one profession.				21 CFR 56.107(b) 21 CFR 312.66 21 CFR 812.60			
1.14	Senior administrators of the organization do not serve on the REB.	6.4						

Table 2: Informed Consent Elements

#	Criteria	TCPS 2	HC	GCP	FDA	DHHS	PHIPA	Notes
2.1	Statement indicating that the study involves research.	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(b)(1)		
2.2	The purpose of the research.	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(b)(1)	2004, c. 3, Sched. A s.18(1)(b) and 18(5)(a)	
2.3	The study treatment(s) and the probability for random assignment to each treatment.		FDR C.05.010(h)(ii) NHPR Part 4, s. 74(h)(ii)	4.8.10(c)				
2.4	The study procedures to be followed, including all invasive procedures.	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(b)(1)		
2.5	The participant's responsibilities.	3.2(b)	FDR C.05.010(h)(ii) NHPR Part 4, s. 74(h)(ii)	4.8.10(e)				
2.6	Those aspects of the study that are experimental.		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(b)(1)		
2.7	The reasonably foreseeable risks or inconveniences to the participant and, when applicable, to an embryo, fetus, or nursing infant.	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(b)(2)		
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.				21 CFR 50.25(b)(1)	45 CFR 46.116(c)(1)		
2.9	The reasonably expected benefits. When there is no intended clinical benefit to the participant, the participant should be made aware of this.	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(b)(3)		
2.10	The alternative procedure(s) or course(s) of treatment that may be available to the participant, and their important potential benefits and risks.		FDR C.05.010(h)(ii)	4.8.10(i)	21 CFR 50.25(a)(4)	45 CFR 46.116(b)(4)		

#	Criteria	TCPS 2	HC	GCP	FDA	DHHS	PHIPA	Notes
			NHPR Part 4, s. 74(h)(ii)					
2.11	The compensation and/or treatment available to the participant in the event of a study-related injury.		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(b)(6)		
2.12	The anticipated prorated payment, if any, to the participant for participating in the study.	3.2(j)	FDR C.05.010(h)(ii) NHPR Part 4, s. 74(h)(ii)	3.1.9, 4.8.10(k)				
2.13	The anticipated expenses, if any, to the participant for participating in the study.	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(c)(3)		
2.14	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.	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(b)(8)	2004, c. 3, Sched. A s.18(5)(b)	
2.15	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.	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(b)(5)		
2.16	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.	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(b)(5)		
2.17	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.	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(c)(5)		

Table 2: Informed Consent Elements

#	Criteria	TCPS 2	HC	GCP	FDA	DHHS	PHIPA	Notes
2.18	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.	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(b)(7)		
2.19	The foreseeable circumstances and/or reasons under which the participant's participation in the study may be terminated without the participants consent.	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(c)(2)		
2.20	The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant.				21 CFR 50.25(b)(4)	45 CFR 46.116(c)(4)		
2.21	The expected duration of the participant's participation in the study.	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(b)(1)		
2.22	The approximate number of participants involved in the study.		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(c)(6)		
2.23	A statement to the effect that, by consenting, participants have not waived any rights to legal recourse in the event of research-related harm.	3.2(k)		4.8.4				
2.24	For clinical trials conducted in the U.S. there should be the following statement of online registry: "A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site 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."*				21 CFR 50.25(c)*			
2.25	Information concerning the possibility of commercialization of research findings, and the presence of any real, potential or perceived conflicts of interest on the part of the researchers, their organizations or the research sponsors.	3.2 (e)						
2.26	The identity of the researcher and funder or sponsor.	3.2(b)						

#	Criteria	TCPS 2	HC	GCP	FDA	DHHS	PHIPA	Notes
2.27	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)						
2.28	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)						
2.29	Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective participant or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.					45 CFR 46.116(a)(5)(i)		
2.30	One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens: (a) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the participant or the legally authorized representative, if this might be a possibility; or (b) A statement that the participant's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.					45 CFR 46.116(b)(9)(i),(ii)		
2.31	If applicable, a statement that the participant's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the participant will or will not share in this commercial profit					45 CFR 46.116(c)(7)		

#	Criteria	TCPS 2	HC	GCP	FDA	DHHS	PHIPA	Notes
2.32	If applicable, a statement regarding whether clinically relevant research results, including individual research results, will be disclosed to participants, and if so, under what conditions					45 CFR 46.116(c)(8)		
2.33	If applicable, for research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)					45 CFR 46.116(c)(9)		

Table 3: Materials Required for Submission to the REB

#	Criteria	TCPS 2	HC	GCP	FDA	DHHS	PHIPA	Notes
Initial REB submission requirements								
3.1	Research protocol	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)		
3.2	Informed Consent Form(s)	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)		
3.3	Participant recruitment procedures (e.g. advertisements)			3.1.2 4.4.1				
3.4	Written information to be provided to participant (such as diaries, contact cards, study process)			3.1.2 4.4.1 4.8.1 4.8.2				
3.5	Investigator's Brochure (IB), Product Monograph or equivalent documentation (e.g. Device manual)			3.1.2 4.4.2				
3.6	Available safety information			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)		
3.7	Information about payments and compensation available to participants	3.1(a)		3.1.2 3.1.8				
3.8	Researcher's current CV and/or other documentation evidencing qualifications			3.1.2 3.1.3 4.1.1				
3.9	Other documents that the REB may need to fulfill its responsibilities			3.1.2				
3.10	Disclosure of any financial interest or other real, potential or perceived conflicts of interest that the researcher has in relation to the research, or any real, potential, or perceived institutional conflicts that may affect the research.	7.2 7.4*						
3.11	A description of all processes used to obtain informed consent and assent (if applicable)	3.2						

#	Criteria	TCPS 2	HC	GCP	FDA	DHHS	PHIPA	Notes
3.12	The process whereby research participants may withdraw their consent, if given, and associated data or biological materials.	3.1						
3.13	A description of the processes used to provide participants with all information relevant to their ongoing consent to participate in the research	3.3						
3.14	A statement and description of any safety monitoring process provided by the sponsor or qualified investigator, such as data and safety monitoring board (DSMB)	11.6 11.7			21 CFR 56.111(a)(6) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.111(a)(6)		
3.15	Evidence of clinical trial registration in a publicly accessible registry that is acceptable to the World Health Organization (WHO) or the International Committee of Medical Journal Editors (ICMJE). and information regarding where the results of the clinical trial will be made publically available	11.10						
3.16	If the research involves genetic research, a description of the plan for managing information that may be revealed through genetic research and the procedures for managing information and communicating findings in accordance with the participant's preferences.	13.2 13.3						
3.17	Clinical trial budget, in sufficient detail to ensure that conflicts of interest are identified, minimized, or otherwise managed. Specifically, for research conforming to TCPS2: Chapter 12 (Section F: research involving human pluripotent stem cells), copies of contracts between researchers, institutions and industry sponsors and any relevant budgetary information required to examine and evaluate any potential or actual conflicts of interest and to ensure the right to publish in a timely manner without undue restriction.	12.20						
3.18	Measures for meeting confidentiality obligations and explanation of any reasonably foreseeable disclosure requirements, and proposed measures	5.2(a) 5.3			21 CFR 56.111(a)(7) 21 CFR 312.66	45 CFR 46.111(a)(7)	2004, c.3, Sched. A. s.44(3)(b)	

#	Criteria	TCPS 2	HC	GCP	FDA	DHHS	PHIPA	Notes
	for safeguarding information, for the full life cycle of information: its collection, use, dissemination, retention and/or disposal				21 CFR 812.60			
3.19	If material incidental findings are likely, a plan indicating how the researcher will determine materiality, the likelihood of discovery of material incidental findings, how the findings will be managed and assessed for validity, how such findings will be disclosed to participants and how communication will be managed.	3.4						
3.20	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						
3.21	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						
3.22	Justification for the choice of a placebo (or other) control group, as opposed to the other possible choices of control group, is provided to the REB (as applicable)	11.3 11.4 (a-c)						
Submission requirements during ongoing trial conduct may include, but are not limited to:								
3.23	Protocol amendments	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)		
3.24	Consent form updates that the researcher proposes for use in the study	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)		
3.25	Any revisions to written information provided to participants (not including consent form revisions, as noted above)		FDR C.05.012(3)(g)	3.1.2 4.4.3 4.8.2				

#	Criteria	TCPS 2	HC	GCP	FDA	DHHS	PHIPA	Notes
3.26	Written summaries of trial status/progress reports/continuing review reports, including DSMB reports	6.14 11.6	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)		
3.27	Written reports on any changes significantly affecting the conduct of the trial, and/or increasing the risk to participants, including: a) deviations from, or changes of, the protocol to eliminate immediate hazards to trial participants; 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 participants or the conduct of the study.	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)(3)(iii) 45 CFR 46.115(a)(1)		
3.28	Unanticipated problems, including serious unexpected adverse events/reactions	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)		
3.29	Serious or continuing non-compliance with organizational policy or REB requirements and determinations, or the regulations	6.15			21 CFR 56.108(b)(2) 21 CFR 312.66 21 CFR 812.60			
3.30	Updates to the Investigator's Brochure (IB), product monograph (PM) or equivalent documentation (e.g. device manual)			4.4.2				
3.31	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)		
3.32	Discontinuation of the clinical trial at the local site and the reasons for it			4.12.1 4.12.2	21 CFR 56.108(a)(3) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.108(a)(3)(iii)		
3.33	Summary of trial outcome/study completion report			4.13				
3.34	Changes in any additional documents subject to review.		FDR C.05.012(3)(g)	4.4.3				