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Observational Health Research REB Qualification Manual

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

Acknowledgements

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Contents

Introduction

This CTO Observational Health Research (OHR) REB Qualification Manual is intended as a guide for the review and Qualification of REBs that review observational health and other non-regulated research. The requirements for Qualification reflected in the Manual have been informed by numerous sources including the Tri-Council Policy Statement 2 (TCPS2), and applicable US regulations (for a full list please see Section 1).

A REB that is Qualified by CTO will be compliant with the CTO OHR 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 OHR 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 OHR 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 normally 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 and A REB operations representative).

A A 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 OHR 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 OHR 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 Observational Health Research Qualification Review Process

OBJECTIVES

The CTO OHR 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 OHR 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:

- US Code of Federal Regulations: 45 Part 46
- 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)
- Freedom of Information and Protection of Privacy Act, 2021
- Ontario Regulations 366/19 Section 41

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 OHR REB Qualification Checklist (Section 4)** prior to requesting a Qualification review.

Please also note:

a. The right-hand columns of the OHR 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 subject to US regulations).

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 (SOPs)
   b. Current REB membership list
   c. Terms of Reference and organizational chart(s) depicting the reporting relationships of the REB and the REB office (if available)
   d. Annual Report (if available)
   e. Application Forms and consent templates
   f. Copy of the OHR REB Qualification Checklist where the REB has filled out the "Comments" column referencing where documentation of compliance with each element can be found (Example: SOP 102, 5.2.1, Terms of Reference, 2.1, ICF template etc.)

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 at the visit by the CTO Qualification Team.
    a. REB application forms
    b. Templates such as the informed consent template/checklist, REB member appointment letter(s) and confidentiality agreements/conflict of interest disclosures
    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 agendas 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 the 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** the Chair(s) and/or Vice-Chair(s) at the arranged time(s).

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 OHR 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 OHR 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 OHR 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 undergoing qualification**
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 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) What percentage of these were reviewed at full board? _____ (ii) How many studies are multi-centre projects? _____
c) Please provide a brief description of the types of studies reviewed by the REB (e.g. surveys, focus groups and interviews, observation, secondary data analysis, etc..):
d) How often does your REB/panels meet?
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.):
g) Does the REB review US-funded research? If so, please provide the FWA number and IRB registration numbers.
SECTION 7 - REB Records
a) Are REB records (minutes, correspondence, REB review files, 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:

Are there archiving schedules for REB files? Please provide if available.

SECTION 8 - REB Application Forms and Consent Templates

a) Please select one of the following options to submit your REB Application forms to CTO (Initial submission, Amendments, Continuing Review, Unanticipated Problems):

☐ Option 1: Copy of REB Application forms enclosed

☐ Option 2: REB Application forms are publicly available. Please provide website link:

Click to enter link to online version if applicable.

b) Please select one of the following options to submit your Informed Consent form templates to CTO

☐ Option 1: Enclosed

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

N/A We use Consent Guidelines only (please provide website link)

Click to enter link to online version if applicable.

SECTION 9 – 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 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 OHR 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 Observational Health Research REB Qualification Checklist

- **TCPS2**: Tri Council Policy Statement: Ethical Conduct for Research Involving Humans
- **DHHS**: US Code of Federal Regulations: 45 Part 46 (applicable to institutions reviewing US agency-funded research)
- **PHIPA**: Personal Health Information Protection Act, 2004 Chapter 3 Schedule A, and Ontario Regulation 329/04 Section 15 and 16
- **FIPPA**: Freedom of Information and Protection of Privacy Act, 2021 and Ontario Regulations 366/19 Section 41

#	Criteria	TCPS2	DHHS	PHIPA	FIPPA
SECTION A – Governance, mandate, authority and resources					
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	6.1 6.2 6.3	45CFR46.103(b)(1)		

	to fulfill their duties.				
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.	6.3	46.112		
A4	The organization with an REB shall have policies and procedures to declare and manage conflicts of interest situations within the REB and other conflicts of	7.1 7.2 7.3 7.4	46.107(e)	O.Reg. 329/04 s.15(2)	

	interest that could influence the REB's mandate, operations and/or jurisdiction. 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.				
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	46.114		

A6	The REB Chair and administrators should assess the educational and training needs of REB members and address any knowledge gaps.	6.2			
A7	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	46.109(e) 46.113		
A8	When an application is submitted, the REB requires the applicant to comply with all REB decisions with respect to the ethical conduct of the study.	2.1			
A9	An REB shall have authority to suspend or terminate	6.3	46.113		

	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.				

#	Criteria	TCPS2	DHHS	PHIPA	FIPPA
SECTION B – REB Composition, appointment and administrative support					
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			
B2	The REB should consist of a reasonable number of members, who collectively have the qualifications and experience in the relevant research disciplines, fields, and methodologies to evaluate the proposed research.	6.4	45CFR46.107(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		46.107(e)		

	promote respect for its advice and counsel in safeguarding the rights and welfare of human participants.				
REB Members					
See **Table 1** for REB Membership requirements.					
B4	Where the size of the REB meets the minimum requirement, each member may only fulfill one position. Where the size of the REB exceeds the minimum requirements, members may fulfill more than one capacity.	6.4			
B5	An REB may appoint alternate members with qualifications comparable to the primary member for whom they serve as an alternate.	6.4			
B6	In appointing alternate, additional REB members, organizations should consider the qualifications and expertise their REBs require.	6.4	46.107(f)		
B7	When the REB lacks the experience or expertise to conduct competent ethics review of a particular research study, the REB	6.5			

	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.				
B8	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			
B9	REB members and ad hoc advisors shall maintain the confidentiality of the documents submitted for ethics review and of the REB discussions.				O.Reg. 366/19 s.41(1)
B10	The organization with an REB should have established policies and procedures that define administrative staff roles and responsibilities, and the appointment of	6.4 6.9			

	administrative staff as REB members.				
B11	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;	6.4 6.9			
REB Chair					
B12	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.	6.8			
B13	REB administrative staff shall be subject to privacy and confidentiality policies of the organization and the REB.				S.41(1)

#	Criteria	TCPS2	DHHS	PHIPA	FIPPA
SECTION C – REB operating procedures					
REB Standard operating procedures					
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).	6.17	45 CFR 46.103(b)(4) and 103(b)(5)		
C2	The REB should establish a procedure which specifies that no participant should be recruited to a study before the REB issues its approval of the research.	2.1			
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	6.23			

	care to requests for exceptions during publicly declared emergencies.				
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 judgement of the REB, the additional information would add meaningfully to the protection of the rights, safety and/or well-being of participants.	3.2	45CFR46.109(b)		

#	Criteria	TCPS2	DHHS	PHIPA	FIPPA
SECTION D – Ethics review processes					
Requirements and criteria for ethics review					
See **Table 2** for Informed Consent Elements.					
D1	Documentation of informed consent, appropriate to the study and population, should be given to participants.	3.12	45CFR46.117(a)		
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	46.101(i) 46.109(b) and (c) 46.111(a)(4) 46.116(c)(1) and (2) 116(d)(1-4)	2004, c.3, Sched. A s.18(1)(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	46.109(c)		
D4	The REB may approve research that involves an alteration to the requirements of written	3.7A 3.9 5.5A 5.5B 12.3A	46.116(c) and 116(d)		

	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 e) the plan to provide a debriefing (if any) which may also offer participants the possibility of refusing	12.3B			

	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	3.8			

	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 requirements apply.				
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	46.103(b)(4) and (5) 46.110(a) 46.110 (b)(1) and(2)		
D8	During their review, the REB determines that the	2.10			

	proposed study will protect participants from any unnecessary or avoidable risks and that the potential research outcomes and potential benefits merit the risks.				
D9	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	Ch2 Part B	46.111(a)(2)		

	that fall within the purview of its responsibilities.				
D10	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 and should consider added protections required for research involving populations in vulnerable circumstances, such as children, prisoners, people with physical or cognitive challenges, or people who are economically or educationally disadvantaged.	4.1	46.111(b)		
D11	Informed consent will be sought from each prospective participant or the participant's appropriate representative, in accordance with applicable regulations or requirements.	3.2	46.111(a)(4)		
D12	Informed consent will be appropriately documented, in accordance with applicable regulations and	3.12	46.111(a)(5)		

	requirements.				
D13	The REB shall determine that the research plan makes adequate provision for monitoring the safety, efficacy/effectiveness (where feasible) and validity of the study.	11.6	46.111(a)(6)		
D14	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	46.111(a)(7)		
D15	When some or all of the participants, such as children, prisoners, people with physical or cognitive challenges, or people who are economically or educationally disadvantaged, 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.	4.6 4.7	46.111(b)		
D16	For research involving participants who lack decision-making capacity: a) The research question	4.6 3.9			

	can be addressed only with participants within the identified group; and the research does not expose participants to more than minimal risk without the prospect of direct benefits for them; or where the research entails only minimal risk, it should provide direct benefits to participants or to a group that is the focus of the research aand to which participants belong. 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.				
D17	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	3.9	21CFR50 Subpart D		

	with applicable regulations and ethical and legal requirements.				
D18	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.	3.1			
D19	The confidentiality of records that could identify participants should be protected, respecting the privacy and confidentiality	5.7	46.111(a)(7)	2004, c.3, Sched. A., s.44(3)	

	rules in accordance with the applicable regulatory requirement(s).				
Review at a convened meeting of the REB					
D20	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	46.108(b)		
D21	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	46.108(b) 46.110(a) and (b)		

D22	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; b) modifications required prior to its approval; c) disapproval/rejection; and d) termination or suspension of any prior approval.				
D23	Remote participation during convened meetings is allowed in accordance with institutional support and established policies and procedures.	6.10 9-Feb-2022 PRE guidance			
D24	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	46.108(b)		
D25	When there is less than full	6.9			

	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.				
D26	Researchers or applicants (e.g. supervisors) 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	46.107(f)		
D27	An REB may invite individuals with expert knowledge 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	46.107(f)		

D28	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.	6.9			O.Reg. 366/19 s.41(1)
D29	REB shall have delegated review procedures for certain kinds of research involving no more than	6.12	46.110(a) 46.110(b)(1) and (2)		

	minimal risk, and for minor changes in approved research.				
D30	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	46.110(b)		
D31	Under a delegated review procedure, the review may be carried out by the REB Chair or by one or more experienced reviewers designated by the REB Chair from among the members of the REB. In reviewing the research, the reviewers may exercise all authorities of the REB except that the	6.12	46.110(b)		

	reviewers may not disapprove/reject the research. A research activity may be disapproved/ rejected only after review in accordance with a non-delegated review procedure.				
D32	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/reject research by the delegated process.	6.12	46.110(b)		
D33	Each REB which uses a delegated review procedure shall adopt a method for keeping all members apprised of research proposals which have been approved under the procedure.	6.12	46.110(c)		
Notification of REB decision					
D34	REB has a procedure to promptly notify in writing the researcher/organization concerning: a) Its study-related	6.13	46.103(b)(5)(iii) 46.109(d)	s.44(4)	

	decisions/opinions; b) The reasons for its decisions/opinions; c) Procedures for appeal of its decisions/opinions; and d) Suspension or termination of a study and/or its approval.				

#	Criteria	TCPS2	DHHS	PHIPA	FIPPA
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 and ethical requirements.	6.15 6.16	45CFR46.103(b)(4)		
E2	The REB shall have authority to review all study documentation for compliance and observe or have a third party observe the consent process and the research.	6.14	46.109(e)		
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	6.16	46.103(b)(4)(iii)		

	aspects of the study (e.g., researcher contact information).				
E4	Any changes that affect the rights, safety, or well-being of the research participants or the integrity of the study shall be reviewed by a member of or the full REB, dependent on the change to risk. Changes include but are not limited to those that: a) affect the selection, monitoring or withdrawal of research participants; b) significantly increase the risk to the health or welfare of a research participant; and c) extend the duration of participation in the study.	6.16			
E5	REB shall have a procedure to provide delegated review and approval of minor change(s) in ongoing studies that have the approval of the REB.	6.12			
E6	REB should have procedures for specifying that the researcher should promptly report to the REB, and if applicable, organization and agencies:	6.15	46.103(b)(5)		

	a) Deviations from, or changes of, the protocol to eliminate immediate hazards to research participants; b) Changes increasing the risk to participants and/or affecting significantly the conduct of the study; c) All adverse events 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.				
E7	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	46.103(b)(5)		

#	Criteria	TCPS2	DHHS	PHIPA	FIPPA
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			
F2	REB shall have procedures for conducting initial and continuing review, determining the frequency of 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, or through delegated review, for minimal risk research.	6.14	45CFR46.103(b)(4)(ii)		

#	Criteria	TCPS2	DHHS	PHIPA	FIPPA
SECTION G – Reconsiderations, 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			
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			
G4	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.	6.14			

#	Criteria	TCPS2	DHHS	PHIPA	FIPPA
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	45CFR46.115(a)		O.Reg. 366/19 s.41(1)
H2	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 and duties of REB members, including the Chair; 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;	6.17			

	h) 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 research 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.				

H3	All documentation related to the project submitted to the REB for review shall be retained including research proposals approved consent documents, and progress reports.	6.17	46.115(a)(1)		
H4	Attendance records for all REB meetings must be retained.	6.17			
H5	The REB should have in documentation a list of REB members identified by name; earned degrees; representative capacity; indications of experience (e.g. CV) sufficient to describe each member's chief anticipated contributions to REB deliberations; and any employment or other relationship between each member and the organization.	6.17	46.115(a)(5)		
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	6.17	46.115(a)(2)		

	for, against, and abstaining or consensus decisions; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.				
H7	Where the REB denies ethics approval for a research proposal, the minutes shall include the reasons for this decision.	6.17			
H8	Correspondence with REB (emails, amendments, notifications, AE reporting forms and responses, and submissions) and copies of all correspondence between the REB and the researchers are on file.	6.17	46.115(a)(4)		
Retention of REB documents					
H9	Documentation is stored in a secure location with restricted access.				S.41(1)
H10	Long term record retention plans are outlined (e.g., archive procedures).	6.17			S.41(1)
H11	When deciding the retention period for their files, REBs should be guided by their organizations record-keeping policies and other	6.17			

	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.				
H12	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/	6.17	46.115(b)		S.41(4)

	affiliations of members, submitted documents, minutes of meetings, and correspondence).				

Table 1: REB Membership

#	Criteria	TCPS2	DHHS	PHIPA	FIPPA
1.1	At least five members.	6.4	45CFR46.107(a)	O.Reg.329/0 4 s.15(1)	
1.2	Composed of both men and women.	6.4	46.107(b)		
1.3	At least one member whose primary area of interest is in a non- scientific area.		46.107(c)		
1.4	Only 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	46.107(d)	s.15(1)(i)	
1.5	One member knowledgeable in Canadian laws relevant to the research to be approved (but that member should not be the institution's legal counsel or risk manager).	6.4(c)			
1.6	One member knowledgeable in ethics relevant to research.	6.4(b)		s.15(1)(ii)	
1.7	At least one member knowledgeable in considering privacy issues.			s.15(1)(iv)	

1.8	At least two members with the relevant knowledge and expertise to understand the content area and methodology of the proposed or ongoing research, and to assess the risks and potential benefits that may be associated with the research.	6.4(a)	46.107(d)	s.15(1)(iii)	
1.9	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.	6.4(d)	46.107(d)		
1.10	When the research often involves specific communities, the board should include members representing or with expertise of the experiences of those communities whenever possible (e.g., Indigenous,	6.4			

	pediatric, HIV/AIDS).				
1.11	No REB may consist of members entirely of one profession.	6.4	46.107(b)		
1.12	Senior administrators of the organization may not serve on the REB.	6.4			

Table 2: Informed Consent Elements

#	Criteria	TCPS2	DHHS*	PHIPA	FIPPA
2.1	Information that the individual is being invited to participate in a research study.	3.2(a)	45CFR46.116(a)(1)		
2.2	The purpose of the research.	3.2(b)	46.116(a)(1)	2004, c.3, Sched. A s.18(1)(b) and 18(5)(a)	
2.3	The identity of the researchers, including principal investigator and co-investigators.	3.2(b)			
2.4	The identity of the funder or sponsor.	3.2(b)			
2.5	The expected duration of the participation.	3.2(b)			
2.6	The study procedures to be followed.	3.2(b)	46.116(a)(1)		
2.7	The participant's responsibilities.	3.2(b)			
2.8	Those aspects of the study that are experimental.		46.116(a)(1)		
2.9	Description of all foreseeable risks to participant and in general that may arise from research participation.	3.2(c)			
2.10	A statement that the		46.116(b)(1)		

	research may involve risks to the participant which are unforeseeable.				
2.11	Description of all potential benefits to participant and in general that may arise from research participation. When there is no intended benefit to the participant, they should be made aware of this.	3.2(c)	46.116(a)(3)		
2.12	Assurance that prospective participants are under no obligation to participate and are free to withdraw at any time without penalty.	3.2(d)	46.116(a)(8)	s.18(5)(b)	
2.13	Assurance that prospective participants will be given in a timely manner throughout the research project, information that is relevant to their decision to continue or withdraw from participation.	3.2(d)	46.116(b)(5)		
2.14	Assurance that prospective participants will be given information on their right to request the withdrawal of data or human biological materials, including any limitations on the feasibility of that withdrawal.	3.2(d)			
2.15	Information on the	3.2(e)			

	possibility of commercialization of research findings .				
2.16	Information on the presence of any real, potential or perceived conflicts of interest on the part of the researcher, the institution or research sponsors.	3.2(e)			
2.17	Measures to be undertaken for dissemination of research results.	3.2(f)			
2.18	Whether participants will be identified directly or indirectly.	3.2(f)			
2.19	Identity and contact information of a qualified designated representative who can explain scientific or scholarly aspects to participants.	3.2(g)			
2.20	Identity and contact information of appropriate individual(s) outside the research team whom participants may contact regarding possible ethical issues in the research.	3.2(h)			
2.21	What information will be collected about participants and for what purposes; who will have access to the information collected about	3.2(i) 5.2	46.116(a)(5)		

	the identity of participants; a description of how confidentiality will be protected; a description of the anticipated uses of data; and information indicating who may have a duty to disclose information collected, and to whom.				
2.22	Individuals responsible for overseeing the integrity and compliance of the research will have direct access to the participant's data without violating the confidentiality of the participant.	3.2(j)	46.116(a)(5)		
2.23	Information about any payments, including incentives for participants, reimbursements for participation-related expenses and compensation for injury.	3.2(j)	46.116(b)(3)		
2.24	Anticipated expenses, if any, to the participant for participating in the study that will not be reimbursed.		46.116(b)(3)		
2.25	Statement that by consenting, participants have not waived any rights to legal recourse in the event of research-related harm.	3.2(k)			

2.26	Alternative procedure(s) that may be available to the participant and their foreseeable risks and potential benefits.		46.116(a)(4)		
2.27	Approximate number of participants involved in the study.		46.116(b)(6)		

*For clauses only identified as DHHS-specific, required if US-funded research; otherwise a recommendation.

Table 3: Materials Required* for Submission to the REB

*Some criteria may not be appropriate for research in certain disciplines, methods or with certain research populations. If not provided, a rationale for omitting them should be provided.

#	Criteria	TCPS2	DHHS	PHIPA	FIPPA
3.1	Research protocol (information may be included in the ethics application form)	6.11	45CFR46.115(a)(1)		
3.2	Informed consent form(s), script or description of process/rationale for waiver	3.2	46.117(a) 46.115(a)(1)		
3.3	Participant recruitment procedures (e.g. email scripts, social media posts, flyers)	3.1			
3.4	Written information to be provided to participants (e.g. procedure schedules, mental health or other resources)	3.2			
3.5	Information about payments and compensation available to participants (if separate from ICF)	3.1(a)			
3.6	Other documents that the REB may need to fulfill its responsibilities (e.g. measures, surveys, draft interview questions)	6.11			

3.7	Disclosure of any financial interest or other potential conflict of interest that the researcher has in relation to the research, or any real, potential, or perceived institutional conflicts that may affect their research	7.2 7.4			
3.8	Ethics application form, authenticated and dated. The form and/or research protocol should contain the following information, as per applicable details in Section D and Table 2 of the Checklist: a) Scientific/scholarly rationale b) Methods to be used c) Details about prospective participant population, including vulnerable. circumstances if applicable; inclusion and exclusion criteria; any role-based COIs and how they will be managed. d) Recruitment process e) Process to obtain informed consent and assent (if applicable) or	6.11 11.7 11.11 5.2(a) 5.3 7.4	46.111(a)(7)	s.44(3)(b)	O.Reg. 366/19 s.41(1)

	justification to alter or waive consent. f) Process to provide participants with new information and process to obtain ongoing consent. g) Description of any safety monitoring process, if applicable. h) If defined as a clinical trial under ICMJE definition, clinical trial registry number in a recognized clinical trials registry, or indication that the study will be registered. i) Measures for meeting confidentiality obligations and explanation of reasonably foreseeable disclosure requirements, and proposed measures for safeguarding information for the full life cycle of information: collection, use, dissemination, retention and/or disposal.				
3.9	If the research involves (optional) genetic testing, a	13.2			

	description of the separate processes used for obtaining and documenting informed consent and assent and a plan for managing information that may be revealed through genetic research.				
3.10	A statement by the principal investigator that he/she is aware of and shall make all reasonable efforts to comply with the applicable laws, guidelines, and policies.	Chapter 1			
3.11	Study budget, if requested by the REB, in sufficient detail to ensure that conflicts of interest are identified, and that sufficient funds are available to conduct the research.	11.11			
3.12	If material incidental findings are likely, a plan indicating how researchers will disclose such findings to participants.	3.4			
3.13	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	5.7			

	will be created through the linkage.				
3.14	When proposing research expected to involve First Nations, Inuit or Métis participants, a process to describe and assess how the researchers have engaged, or intend to engage, the relevant community, or a justification to request for an exception to the requirement for community engagement.	9.10			
3.15	Justification for the choice of a placebo/no treatment control arm, as opposed to the other possible choices of control group (as applicable).	11.2 (a-c)			
3.16	Amendments which involve a substantive change to the study as per items listed in 3.8.	6.16	46.115(a)(1) and (7)		
3.17	Revised/updated consent forms.	3.3			
3.18	Revised/updated materials to replace what participants have already or will receive.	3.3			
3.19	Continuing review reports	6.14	46.115(a)(1)		
3.20	Written reports on any changes significantly affecting the conduct of the	6.15 10.5	46.108(a) 46.115(a)(1)		

	trial, and/or increasing the risk to participants, as per Section E6.				
3.21	Unanticipated issue or event that may increase the level of risk to participants or that has other ethical implications that may affect participants' welfare.	6.15	46.115(a)(1)		
3.22	Serious or continuing non-compliance with organizational policy or REB requirements and determinations, or regulatory requirements.	6.15			
3.23	Study completion report	6.14			