Section 4: CTO REB Qualification Checklist

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

#	Criteria	CGSB	TCPS2	HC	GCP	FDA	DHHS	PHIPA
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.	4.2.1.1 4.2.4.1 4.2.2.1 4.2.2.2	6.1 6.2 6.3		3.3.1		45 CFR 46.103(b)(1)	
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.	4.2.2.2	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.	4.2.2.5				21 CFR 56.112 21 CFR 312.66 21 CFR 812.60	45 CFR 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 interest that could influence the REB's	4.2.2.6 4.3.2.8 4.4.4.4.9	7.1 7.2 7.3	FDR C.05.010,	3.2.1	21 CFR 56.107(e) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.107(e)	O.Reg.329/ 04 s.15.(2)

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	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.		7.4	NHRP part 4, s.74				
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.	4.2.2.3 4.2.3.3 4.2.3.4	8.1			21 CFR 56.114 21 CFR 312.66 21 CFR 812.60	45 CFR 46.114	
A6	The REB Chair and administrators should assess the educational and training needs of REB members and address any knowledge gaps.	4.2.4.2 (a–c)						
REB authority								
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.	4.2.3.2	6.3	FDR C.05.001, NHRP part 4, s.74	3.1.2	21 CFR 56.109(a) 21 CFR 56.113 21 CFR 312.66 21 CFR 812.60	45 CFR 46.109(a) 45 CFR 46.113	
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 trial.	4.2.3.1						
A9	An REB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the REB's requirements or that has been associated with unexpected serious harm to participants. Any suspension or termination of approval shall include a statement of the reasons for the REB's action and shall be reported promptly to the researcher, appropriate institutional officials, and the relevant regulatory authorities.	4.2.3.2(d)	6.3		3.1.2	21 CFR 56.113 21 CFR 312.66 21 CFR 812.60	45 CFR 46.113	
SECTION B - REB Composition, appointment, and administrative support								
General								
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.	4.2.2.4	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	4.3.1.1	6.4 6.7	FDR C.05.001	3.2.1	21 CFR 56.107(a) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.107(a)	

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	evaluate the science, medical aspects, and ethics of the proposed research.			NHRP part 4, s.74				
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.	4.3.1.1	6.4		3.2.1	21 CFR 56.107(a) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.107(a)	
REB members								
See **Table 1** for REB Membership requirements								
B4	A member of the REB may not fulfil more than two representative capacities and disciplines.	4.3.2.2	6.4					
B5	An REB may appoint alternate members with qualifications comparable to the primary member for whom they serve as an alternate.	4.3.2.4	6.4					
B6	In appointing alternate, additional REB members, organizations should consider the qualifications and expertise their REBs require.	4.3.2.4 4.3.2.5	6.4			21 CFR 56.107(f) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.107(f)	
B7	When the REB lacks the experience or expertise to conduct competent ethics review of a particular biomedical clinical trial, the REB shall seek the assistance of one or more ad hoc advisors. Ad hoc advisors shall not be voting members or participate in the decisions of the REB. An REB which regularly seeks recourse to ad hoc advisors in the same or similar disciplines should re-examine its composition.	4.3.2.6	6.5					
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.	4.3.2.7	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.	4.3.2.9						
REB Chair and Vice-Chair or equivalent								
B10	The REB Chair is responsible for ensuring that the REB review process conforms to all applicable regulatory requirements. The Chair should have at least two years of experience on an REB and knowledge of international and national regulations along with local policies.	4.3.3.1	6.8		3.3 3.3.1			
B11	The REB Chair, in collaboration with administrative staff, as appropriate, shall advise the organization on policies and procedures related to the ethical conduct of research involving human subjects. The Chair shall advise the organization on the evaluation of performance of REB members and administrative staff.	4.3.3.2						

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B12	The REB Vice-Chair or equivalent shall: a) discharge the responsibilities of the Chair when the Chair is unable to do so; b) discharge the responsibilities assigned by the Chair; and c) assist in the overall operation of the REB, as requested.	4.3.3.4						
REB administrative staff								
B13	The organization with an REB should have established policies and procedures that define administrative staff roles and responsibilities, and the appointment of administrative staff as REB members.	4.3.4.1 4.3.4.2						
B14	REB administrative staff responsibilities may include a) pre-review of submissions and requests to the REB; b) quality management activities (see Quality Management Checklist, if applicable); c) management of administrative issues involving REB research ethics oversight; d) implementation of REB directives; and e) provision of advice and information to the REB.	4.3.4.3						
B15	When administrative staff serve as REB members, it should be ensured that they: a) have the necessary expertise and experience; b) can fulfill their responsibilities independently; c) are not counted towards quorum and do not vote; d) perform delegated reviews according to requirements for normal REB members as indicated in Sec. D of this checklist.	4.3.4.4 4.3.4.5 4.3.4.6						
B16	REB administrative staff shall be subject to privacy and confidentiality policies of the organization and the REB.	4.3.4.7						
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).	4.4.1.1 4.5.2.1			3.2.2 3.3	21 CFR 56.108(a) and 108(b) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.103(b)(4) and 103(b)(5)	
C2	When there are discrepancies among regulations, the REB/organization shall establish procedures to document the rationale for its decisions that attempts to strike a balance between the compliance with applicable regulatory and ethical requirements.	4.4.1.2						
C3	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								

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C4	In collaboration with their researchers, organizations and their REBs should develop preparedness plans for emergency research ethics review. Research ethics review during publicly declared emergencies may follow modified procedures and practices.	4.4.2.2 4.4.2.3 4.4.2.4 4.5.2.1(p)	6.21					
C5	REBs should give special care to requests for exceptions during publicly declared emergencies.	4.4.2.1	6.23					
C6	Research ethics policies and procedures for emergencies take effect once an emergency has been publicly declared. They should cease to apply as soon as is feasible after the end of the publicly declared emergency.	4.4.2.3	6.22					
Application procedures								
See **Table 3** for Submission requirements								
C7	Clear written requirements for submission of an application are required. These requirements shall include, but are not limited to: a) the name and address of the REB office where application materials are to be submitted; b) the format for submission, including provisions for electronic submission (if any); c) deadlines for submission in relation to review dates; and d) the means by which an application will be acknowledged, including notification when the application is incomplete.	4.4.3.1						
C8	The REB may request more information than is outlined in **Table 2 and Table 3** be given to participants when, in the judgment of the REB, the additional information would add meaningfully to the protection of the rights, safety and/or well-being of the participants.	4.4.3.4		FDR C.05.010(d) NHPR Part 4, s.74(d)	3.1.2 3.1.5	21 CFR 56.109(b) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.109(b)	
SECTION D - Ethics review processes								
Requirements and criteria for ethics review								
See **Table 2** for Informed Consent Elements								
D1	A signed and dated copy of informed consent should be given to participants.	4.4.4.2.10	3.12	FDR C.05.010 (h) NHRP part 4, s.74	4.8.11	21 CFR 50.27(a) 21 CFR 56.109(c) 21 CFR 312.66 21 CFR 812.6	45 CFR 46.117(a)	
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).	4.4.4.2.13 4.4.4.2.15	3.2 3.7A 3.8 (a-f) 3.9 (a,b, e) 3.10 10.3	FDR C.05.010 NHRP part 4, s.74	2.9 3.1.6 3.1.7 4.8.12 4.8.13 4.8.14(e) 4.8.15	21 CFR 50.20 21 CFR 50.23 21 CFR 50.24 21 CFR 50.27 21 CFR 56.109(b) and 109(c) 21 CFR 56.111(a)(4) 21 CFR 312.66	45 CFR 46.101(i) 45 CFR 46.109(b) and 109(c) 45 CFR 46.111(a)(4) 45 CFR 46.116(c)(1) and 116(c)(2) 116(d)(1-4)	2004, c. 3, Sched. A s.18(1)(a), 2004, c. 3, Sched. A, s.44 (3) (d)

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						21 CFR 812.60		
D3	Waivers, deferred or verbal consent, and use of substitute decision makers or translation, can only be approved by the REB.	4.4.4.2.12 4.4.4.2.13 4.4.4.2.15	3.7A			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 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).	4.4.4.2.13 4.4.4.2.15	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(c) and 116(d)	
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	4.4.4.2.6 4.4.4.2.7	3.8		2.2	21 CFR 56.109(c) and 109(d) 21 CFR 50.24 21 CFR 312.66 21 CFR 812.60		

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	emergencies to be carried out without the consent of participants, or of their authorized third party, if all of the 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.	4.4.4.1.1 4.4.6.4 4.4.7.4 4.4.7.5	6.12	FDR C.05.010 (c) NHRP part 4, s.74	3.2.2 3.3.3 3.3.5	21 CFR 56.108(a) and 108(b) 21 CFR 56.110(a) and 110(b)(1) and 110(b)(2) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.103(b)(4) and 103(b)(5) 45 CFR 46.110(a) and (b)(1) and 110(b)(2)	
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.	4.4.4.2.4 (c)			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 b) whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.	4.4.4.2.5 4.4.4.2.6			2.2	21 CFR 56.111(a)(1) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.111(a)(1)	
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.	4.4.4.2.5 4.4.4.2.6			2.2	21 CFR 56.111(a)(2) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.111(a)(2)	
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 and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons.	4.4.4.2.14	4.1		3.1.1	21 CFR 56.111(a)(3) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.111(b)	
D12	Informed consent will be sought from each prospective participant or the participant's appropriate representative, in accordance with applicable regulations.	4.4.4.2.8	3.2			21 CFR 56.111(a)(4) 50 Subpart B 21 CFR 312.66	45 CFR 46.111(a)(4)	

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						21 CFR 812.60		
D13	Informed consent will be appropriately documented, in accordance with and to the extent required by applicable regulations.	4.4.4.2.12 4.4.4.2.13 4.4.4.2.15				21 CFR 56.111(a)(5) 21 CFR 50.27 21 CFR 312.66 21 CFR 812.60	45 CFR 46.111(a)(5)	
D14	The REB shall determine that the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.	4.4.6.8	11.7			21 CFR 56.111(a)(6) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.111(a)(6)	
D15	The REB shall determine that there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.	4.4.4.2.4(f) 4.4.4.2.16	5.2 5.3			21 CFR 56.111(a)(7) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.111(a)(7)	
D16	When some or all of the participants, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons, are likely to be vulnerable to coercion or undue influence additional safeguards have been included in the study to protect the rights and welfare of these participants.	4.4.4.2.7 4.4.4.2.14	4.6 4.7		3.1.1	21 CFR 56.111(b)	45 CFR 46.111(b)	
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.	4.4.4.2.7 4.4.4.2.15	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 50 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;	4.4.4.2.9 (u)			3.1.2 3.1.8 3.1.9			

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	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.							
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).	4.4.4.2.16	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.	4.4.4.3.1 4.4.4.4.2	6.10	FDR C.05.010(c) NHPR Part 4, s.74	3.3.2 3.3.3 3.3.5	21 CFR 56.108(c) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.108(b)	
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.	4.4.4.3.2 4.4.4.5.1 4.4.4.5.2 4.4.4.5.3	6.12	FDR C.05.010(c) NHPR Part 4, s.74	3.3.5	21 CFR 56.108(c) 21 CFR 56.110(a) and 110(b) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.108(b) 45 CFR 46.110(a) and 110(b)	
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.	4.4.4.4.10	6.13	FDR C.05.010(c) NHRP part 4, s.74	3.1.2	21 CFR 56.109(e) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.109(d)	
D24	REB meeting dates and submission deadlines should be published in such a way as to give sufficient notice to members and applicants.	4.4.4.4.1			3.3.2			
D25	Remote participation during convened meetings is allowed during emergencies and when necessary.	4.4.4.4.3	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.	4.4.4.4.5	6.9	FDR C.05.010(c) NHRP part 4, s.74	3.2.3	21 CFR 56.108(c) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.108(b)	
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 knowledge necessary to provide an adequate research ethics review of the proposals under consideration.	4.4.4.4.4	6.9					

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D28	Only members who participate in the REB review and discussion should vote/provide their opinion and/or advice.	4.4.4.4.5			3.2.4			
D29	Written comments from absent members shall be allowed to inform the consideration of an application.	4.4.4.4.7		FDR C.05.010(c) NHRP part 4, s.74				
D30	Applicants or qualified researchers are allowed to attend REB meetings or provide information for the purpose of helping its members understand the application. They must not be present when the REB discusses its decision, reaches consensus or votes on the application.	4.4.4.4.8	6.13	FDR C.05.010 NHRP part 4, s.74	3.2.5	21 CFR 56.107(f) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.107(f)	
D31	An REB may invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the REB. These individuals may not vote with the REB.	4.3.2.6 4.4.4.4.6	6.5		3.2.6	21 CFR 56.107(f) 21 CFR 312.66 21 CFR 812.	45 CFR 46.107(f)	
D32	REBs may allow observers to attend meetings. Observers: a) shall not participate when the REB discusses its decision, reaches consensus or votes on the application; b) shall agree in writing to maintain the confidentiality of the REB proceedings; and c) where the REB finds that an observer otherwise qualifies as an expert in relation to the research under consideration, the observer may be allowed to contribute input if it is relevant and significant to discussion. However the observer shall not participate when the REB discusses its decision, reaches consensus or votes on the application. The minutes shall reflect the expertise and contributions of any observer.	4.4.4.4.12						
D33	REB shall have delegated review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.	4.4.4.5.1 4.4.4.5.2 4.4.4.5.3 4.4.7.4 4.4.7.5	6.12	FDR C.05.010 NHRP part 4, s.74	3.3.5	21 CFR 56.110 (a) and 110(b) (1) and 110(b)(2) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.110 (a) and 110(b)(1,2)	
D34	An REB may use the delegated review procedure to review either or both of the following: a) Some or all of the research is a type of research which is approved by authorities to be reviewed through delegated review, and found by the reviewer(s) to involve no more than minimal risk; and/or b) minor changes in previously approved research during the period (of 1 year or less) for which approval is authorized.	4.4.4.5.1	6.12	FDR C.05.010 NHRP part 4, s.74	3.1.4 3.3.5	21 CFR 56.110(b) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.110(b)	
D35	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	4.4.4.5.1	6.12	FDR C.05.010	3.3.5	21 CFR 56.110(b) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.110(b)	

#	Criteria	CGSB	TCPS2	HC	GCP	FDA	DHHS	PHIPA
	REB. In reviewing the research, the reviewers may exercise all of the authorities of the REB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with a non-delegated review procedure.			NHRP part 4, s.74				
D36	The delegated reviewer(s) shall be authorized to approve the applications, require modification, request clarification or further information, or refer the application for review at the convened meeting. The reviewers may not disapprove research by the delegated process.	4.4.4.5.2 4.4.4.5.3	6.12			21 CFR 56.110(b) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.110(b)	
D37	Each REB which uses a delegated review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.	4.4.4.5.4				21 CFR 56.110(c) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.110(c)	
Notification of REB decision								
D38	REB has a procedure to promptly notify in writing the researcher/organization concerning: a) Its study-related decisions/opinions; b) The reasons for its decisions/opinions; c) Procedures for appeal of its decisions/opinions; and d) Suspension or termination.	4.4.5.1 4.4.5.2 4.4.5.3 4.4.5.4 4.4.5.5 4.4.5.7	6.13	FDR C.05.010 NHRP part 4, s.74	3.3.9	21 CFR 56.108(b)(3) 21 CFR 56.109(e) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.103(b)(5)(ii) 45 CFR 46.109(d)	2004, c. 3, Sched. A, s.44(4)
D39	All REB decisions concerning an application shall be communicated in writing to the applicant in a timely manner and shall contain the following information: a) unambiguous identification of the application reviewed b) whether the application was reviewed at a convened meeting of the REB and, if so, the date of that meeting c) a statement of the decision reached by the REB, and d) A statement that the REB meets the requirements of this Standard and is in compliance with the applicable statutes and regulations.	4.4.5.2(a-d)						
D40	Communications about REB decisions made at convened meetings should include, or the REB should provide at the request of the applicant: a) a copy of the REB membership roster in effect on the date of the meeting, and a statement confirming that quorum was present during the REB decision regarding the applicant's study; and b) each member's academic qualifications, affiliation, gender, and status (regular or alternate member).	4.4.5.6			8.2.8			
SECTION E - Ongoing review								
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.	4.4.6.1	6.15 6.16		3.1.4 3.3.3	21 CFR 56.108(a)(1) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.103(b)(4)	

#	Criteria	CGSB	TCPS2	HC	GCP	FDA	DHHS	PHIPA
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.	4.4.6.9				21 CFR 56.109(f) 21 CFR 312.66 21 CFR 812.60	45 CFR 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 aspects of the study (e.g., change of monitor(s), telephone number(s)).	4.4.5.3 4.4.6.2 4.4.6.5			3.3.7	21 CFR 56.108(a)(3) and 108(a)(4) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.103(b)(4)(iii)	
E4	Any changes that affect the rights, safety, or well-being of the research participants or the integrity of the study shall be reviewed at a convened meeting of the REB, including but not limited to changes that: a) affect the selection, monitoring or withdrawal of research participants; b) significantly increase the risk to the health of a research participant; c) extend the duration of participation in the study; d) affect the evaluation of the clinical efficacy of the investigational product(s); and e) affect the safety evaluation of the investigational product(s).	4.4.6.3 4.4.6.2						
E5	REB shall have a procedure to provide delegated review and approval/favourable opinion of minor change(s) in ongoing studies that have the approval/favourable opinion of the REB.	4.4.6.4	6.12		3.3.5			
E6	REB should have procedures for specifying that the researcher should promptly report to the REB, and if applicable, organization and agencies: a) Deviations from, or changes of, the protocol to eliminate immediate hazards to the research participants; b) Changes increasing the risk to participants and/or affecting significantly the conduct of the study; c) All adverse drug reactions (ADRs) that are both serious and unexpected; d) New information that may affect adversely the safety of the participants or the conduct of the study; e) Any unanticipated problems involving risks to human participants or others; f) Any instance of serious or continuing noncompliance with these regulations or the requirements or determinations of the REB; g) Any suspension or termination of REB approval;	4.4.6.6 4.4.5.7	6.15		3.3.8	21 CFR 56.108(b) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.103(b)(5)	

#	Criteria	CGSB	TCPS2	HC	GCP	FDA	DHHS	PHIPA
	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.	4.4.6.7 4.5.2.1(n)	6.15 11.9			21 CFR 56.108(b)(1) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.103(b)(5)(i)	
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).	4.4.7.1	6.14		3.1.4 4.10	21 CFR 56.109(f) 21 CFR 56.115(a)(3) 21 CFR 312.66 21 CFR 812.60		
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 at convened meetings achieving quorum and receiving the approval of a majority of those members present at the meeting.	4.4.7.2 4.4.7.3 4.4.7.4			3.3.3 3.3.4	21 CFR 56.108(a)(1) and 108(a)(2)and 108(c) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.103(b)(4)(ii)	
SECTION G – Reconsideration, appeals and study completion								
G1	Researchers have the right to request, and REBs have an obligation to provide, prompt reconsideration of decisions affecting a research project.	4.4.8.1	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.	4.4.8.1 4.4.8.2 4.4.8.3	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.	4.4.9.1 4.4.6.6						
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.	4.5.1.1 4.5.3.1	6.17	FDR C.05.010 NHRP part 4, s.74	3.2.2 3.4	21 CFR 56.115(a) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.115(a)	

#	Criteria	CGSB	TCPS2	HC	GCP	FDA	DHHS	PHIPA
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, duties, and performance evaluations of REB members, including the Chair and Vice-Chair or equivalent; d) training and education of REB members and REB administrative staff; e) delegation of signing authority; f) confidentiality of information on studies submitted for review; g) REB application/submission procedures; h) the process for decision making at REB meetings; i) procedures for initial review, ongoing review, and continuing review and criteria for REB ethical acceptability, including review at a convened meeting of the REB and delegated review; j) communication with qualified researchers and qualified researchers staff, with research participants and with other individuals or organizations; k) guidelines on informed consent processes; l) management of non-compliance of qualified researchers; m) document management and retention; n) requirements for handling unanticipated problems; o) requirements for reporting protocol deviations; and p) emergency preparedness.	4.5.2.1			3.2.2			
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.	4.5.3.2	6.17	FDR C.05.010 NHRP part 4, s.74	3.1.2 3.2.2 3.4	21 CFR 56.115(a)(1) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.115(a)(1)	
H4	Attendance at all REB meetings.	4.5.3.3	6.17					
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 to REB deliberations; and any employment or other relationship between each member and the organization; for example: full-time employee, part-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant.				3.2.1	21 CFR 56.115(a)(5) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.115(a)(5)	

#	Criteria	CGSB	TCPS2	HC	GCP	FDA	DHHS	PHIPA
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 including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.	4.5.3.3	6.17	FDR C.05.010 NHRP part 4, s.74	3.4	21 CFR 56.115(a)(2) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.115(a)(2)	
H7	Where the REB denies ethics approval for a research proposal, the minutes shall include the reasons for this decision.	4.5.3.3	6.17					
H8	The REB may be asked by researchers, sponsors or regulatory authorities to provide its written procedures and membership lists.				3.4			
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.							
H11	Long term record retention plans are outlined (e.g., archive procedures).	4.5.4.1		FDR C.05.010 NHRP part 4, s.74	3.4 4.9.5			
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.	4.5.4.1	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. The retention period shall begin on the date of when the REB accepts the study completion report or REB approval expires. In the absence of a regulatory requirement for the REB record retention, the REB records shall be retained for a period of at least three years and shall be accessible at reasonable times and in a reasonable manner. Records include (e.g., written procedures, membership lists, lists of occupations/affiliations of members, submitted documents, minutes of meetings, and correspondence).	4.5.4.1		FDR C.05.010 NHRP part 4, s.74	3.4	21 CFR 56.115(b) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.115(b)	

Table 1: REB Membership

#	Criteria	CGSB	TCPS 2	HC	GCP	FDA	DHHS	PHIPA
The REB membership shall include, but not be limited to:								
1.1	At least five members.	4.3.2.1	6.4	FDR C.05.001 NHPR part 4, s.63 MDR Part 3, s.81(h)	3.2.1(a)	21 CFR 56.107(a) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.107(a)	O.Reg.329/04 s.15(1)
1.2	Composed of both men and women.	4.3.2.1	6.4	FDR C.05.001 NHPR part 4, s.63 MDR Part 3, s.81(h)		21 CFR 56.107(b) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.107(b)	
1.3	Has a majority of members who are Canadian citizens or permanent residents under the Immigration Act.	4.3.2.3		FDR C.05.001 NHPR part 4, s.63				
1.4	At least one member whose primary area of interest is in a non-scientific area.	4.3.2.1(d)		FDR C.05.001 NHPR part 4 s.63	3.2.1(b)	21 CFR 56.107(c) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.107(c)	
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.	4.4.4.4.9	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(d) and (e)	O.Reg. 329/04 s. 15(1)(i)
1.6	One member knowledgeable in Canadian laws relevant to the biomedical research to be approved (but that member should not be the institution's legal counsel or risk manager).	4.3.2.1(e)	6.4(c)	FDR C.05.001 NHPR part 4, s.63 MDR Part 3, s.81(h)				
1.7	One member knowledgeable in ethics relevant to research.	4.3.2.1(f)	6.4(b)	FDR C.05.001 NHPR part 4, s.63 MDR Part 3, s.81(h)				O.Reg. 329/04 s. 15(1)(ii)
1.8	At least one member knowledgeable in considering privacy issues.	4.3.2.1 (j)						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 approved.	4.3.2.1(a)*	6.4(a)*	FDR C.05.001 NHPR part 4, s.63 MDR Part 3, s.81(h)		21 CFR 56.107(c) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.107(c)	O.Reg. 329/04 s. 15(1) (iii)*
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.	4.3.2.1(b)		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	4.3.2.1(c)	6.4(d)	FDR C.05.001	3.2.1(c)	21 CFR 56.107(d)	45 CFR 46.107(d)	

Table 1: REB Membership

#	Criteria	CGSB	TCPS 2	HC	GCP	FDA	DHHS	PHIPA
	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.			NHPR part 4, s.63 MDR Part 3, s.81(h)		21 CFR 312.66 21 CFR 812.60		
When applicable to the research being reviewed, the REB should additionally include (as applicable):								
1.12	When the research involves specific populations the board should reflect the population with a designated member e.g., aboriginal, pediatrics, or knowledgeable in complementary and/or alternative healthcare.	4.3.2.1(g) (h)(i)	6.4	NHPR, Part 4, s.63				
The REB membership shall address the following restrictions, as applicable:								
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	45 CFR 46.107(b)	
1.14	Senior administrators of the organization do not serve on the REB.		6.4					

Table 2: Informed Consent Elements

#	Criteria	CGSB	TCPS 2	HC	GCP	FDA	DHHA	PHIPA
2.1	Statement indicating that the study involves research.	4.4.4.2.9(a)	3.2(a)	FDR C.05.010(h)(ii) NHPR Part 4 s.74(h)(ii)	4.8.10(a)	21 CFR 50.25(a)(1)	45 CFR 46.116(a)(1)	
2.2	The purpose of the research.	4.4.4.2.9(b)	3.2(b)	FDR C.05.010(h)(ii) NHPR Part 4, s. 74(h)(ii)	4.8.10(b)	21 CFR 50.25(a)(1)	45 CFR 46.116(a)(1)	2004, c. 3, Sched. A s.18(1)(b) and 18(5)(a)
2.3	The study treatment(s) and the probability for random assignment to each treatment.	4.4.4.2.9(d)		FDR C.05.010(h)(ii) NHPR Part 4, s. 74(h)(ii)	4.8.10(c)			
2.4	The study procedures to be followed, including all invasive procedures.	4.4.4.2.9(e)	3.2(b)	FDR C.05.010(h)(ii) NHPR Part 4, s. 74(h)(ii)	4.8.10(d)	21 CFR 50.25(a)(1)	45 CFR 46.116(a)(1)	
2.5	The participant's responsibilities.	4.4.4.2.9(s)	3.2(b)	FDR C.05.010(h)(ii) NHPR Part 4, s. 74(h)(ii)	4.8.10(e)			
2.6	Those aspects of the study that are experimental.	4.4.4.2.9(e)		FDR C.05.010(h)(ii) NHPR Part 4, s. 74(h)(ii)	4.8.10(f)	21 CFR 50.25(a)(1)	45 CFR 46.116(a)(1)	
2.7	The reasonably foreseeable risks or inconveniences to the participant and, when applicable, to an embryo, fetus, or nursing infant.	4.4.4.2.9(g)	3.2(c)	FDR C.05.010(h)(ii) NHPR Part 4, s. 74(h)(i)	4.8.10(g)	21 CFR 50.25(a)(2)	45 CFR 46.116(a)(2)	
2.8	A statement that the research may involve risks to the participant (or embryo or fetus, if the participant may become pregnant) which are unforeseeable.	4.4.4.2.9(h)				21 CFR 50.25(b)(1)	45 CFR 46.116(b)(1)	
2.9	The reasonably expected benefits. When there is no intended clinical benefit to the participant, the participant should be made aware of this.	4.4.4.2.9(i)	3.2(c)	FDR C.05.010(h)(i) NHPR Part 4, s.74(h)(i)	4.8.10(h)	21 CFR 50.25(a)(3)	45 CFR 46.116(a)(3)	
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.	4.4.4.2.9(f)		FDR C.05.010(h)(ii) NHPR Part 4, s. 74(h)(ii)	4.8.10(i)	21 CFR 50.25(a)(4)	45 CFR 46.116(a)(4)	
2.11	The compensation and/or treatment available to the participant in the event of a study-related injury.	4.4.4.2.9(l) 4.4.4.2.9(n)		FDR C.05.010(h)(ii) NHPR Part 4, s. 74(h)(ii)	4.8.10(j)	21 CFR 50.25(a)(6)	45 CFR 46.116(a)(6)	
2.12	The anticipated prorated payment, if any, to the participant for participating in the study.	4.4.4.2.9(u)	3.2(j)	FDR C.05.010(h)(ii) NHPR Part 4, s. 74(h)(ii)	3.1.9, 4.8.10(k)			

#	Criteria	CGSB	TCPS 2	HC	GCP	FDA	DHHA	PHIPA
2.13	The anticipated expenses, if any, to the participant for participating in the study.	4.4.4.2.9(t)	3.2(j)	FDR C.05.010(h)(ii) NHPR Part 4, s. 74(h)(ii)	4.8.10(l)	21 CFR 50.25(b)(3)	45 CFR 46.116(b)(3)	
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.	4.4.4.2.9(o)	3.2(d)	FDR C.05.010(h)(ii) NHPR Part 4, s. 74(h)(ii)	4.8.10(m)	21 CFR 50.25(a)(8)	45 CFR 46.116(a)(8)	2004, c. 3, Sched. A s.18(5)(b)
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.	4.4.4.2.9(k)	3.2(i)	FDR C.05.010(h)(ii) NHPR Part 4, s. 74(h)(ii)	4.8.10(n)	21 CFR 50.25(a)(5)	45 CFR 46.116(a)(5)	
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.	4.4.4.2.9 (j)	3.2(i), 3.2(f)	FDR C.05.010(h)(ii) NHPR Part 4, s. 74(h)(ii)	4.8.10(o)	21 CFR 50.25(a)(5)	45 CFR 46.116(a)(5)	
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.	4.4.4.2.9(r)	3.2(d)	FDR C.05.010(h)(ii) NHPR Part 4, s. 74(h)(ii)	4.8.10(p)	21 CFR 50.25(b)(5)	45 CFR 46.116(b)(5)	
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.	4.4.4.2.9 (x),(y),(z)	3.2(g), (h)	FDR C.05.010(h)(ii) NHPR Part 4, s. 74(h)(ii)	4.8.10(q)	21 CFR 50.25(a)(7)	45 CFR 46.116(a)(7)	
2.19	The foreseeable circumstances and/or reasons under which the participant's participation in the study may be terminated without the participants consent.	4.4.4.2.9(q)	3.2(l)	FDR C.05.010(h)(ii) NHPR Part 4, s. 74(h)(ii)	4.8.10(r)	21 CFR 50.25(b)(2)	45 CFR 46.116(b)(2)	
2.20	A statement that outlines the process involved for termination of participation.	4.4.4.2.9(p)				21 CFR 50.25(b)(4)	45 CFR 46.116(b)(4)	
2.21	The expected duration of the participant's participation in the study.	4.4.4.2.9(c)	3.2(b)	FDR C.05.010(h)(ii) NHPR Part 4, s. 74(h)(ii)	4.8.10(s)	21 CFR 50.25(a)(1)	45 CFR 46.116(a)(1)	
2.22	The approximate number of participants involved in the study.	4.4.4.2.9(w)		FDR C.05.010(h)(ii)	4.8.10(t)	21 CFR 50.25(b)(6)	45 CFR 46.116(b)(6)	

Table 2: Informed Consent Elements

#	Criteria	CGSB	TCPS 2	HC	GCP	FDA	DHHA	PHIPA
				NHPR Part 4, s. 74(h)(ii)				
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.	4.4.4.2.9(m)	3.2(k)		4.8.4			
2.24	If deemed suitable by the REB, information regarding the registration of the clinical trial in an internationally recognized clinical trial registry (e.g. name of registry, identifying code etc.) should be included. For clinical trials conducted in the U.S. there should be the following statement of online registry: “description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."*	4.4.4.2.11				21 CFR 50.25(6)(c)*		
2.25	Information concerning the possibility of commercialization of research findings, and the potential or perceived conflicts of interest on the part of the researchers, their organizations or the research sponsors.	4.4.4.2.9(aa)	3.2 (e)					
2.26	The identity of the sponsors and qualified investigators.	4.4.4.2.9(v)	3.2(b)					
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)					

Table 3: Materials Required for Submission to the REB

#	Criteria	CGSB	TCPS 2	HC	GCP	FDA	DHHS	PHIPA
Initial REB submission requirements								
3.1	Research protocol	4.4.3.2(b)	6.11		3.1.2 4.4.1	21 CFR 56.115(a)(1) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.115(a)(1)	
3.2	Informed Consent Form(s)	4.4.3.2(j)	3.2		3.1.2 4.4.1 4.8.1 4.8.2	21 CFR 50.27(a) 21 CFR 56.115(a)(1) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.117(a) 45 CFR 46.115(a)(1)	
3.3	Participant recruitment procedures (e.g. advertisements)	4.4.3.2(e),(f)			3.1.2 4.4.1			
3.4	Written information to be provided to participant (such as diaries, contact cards, study process)	4.4.3.2(j)			3.1.2 4.4.1 4.8.1 4.8.2			
3.5	Investigator's Brochure (IB), Product Monograph, Device manual	4.4.3.2(c)			3.1.2 4.4.2			
3.6	Available safety information	4.4.3.2(c)			3.1.2	CFR 56.111(a)(1), and 111(a)(2) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.111(a)(1) and 111(a)(2)	
3.7	Information about payments and compensation available to participants	4.4.3.2(k)	3.1(a)		3.1.2 3.1.8			
3.8	Researcher's current CV and/or other documentation evidencing qualifications	4.4.3.2(d)			3.1.2 3.1.3 4.1.1			
3.9	Written attestation that the Qualified Investigator is entitled to provide health care under the applicable laws and that he/she is a member in good standing with the respective regulatory authority.	4.4.3.2(d)						
3.10	Other documents that the REB may need to fulfill its responsibilities	4.4.3.4			3.1.2			
3.11	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*	4.4.3.2(l)	7.2 7.4*					
3.12	An application, authenticated and dated	4.4.3.2(a)						
3.13	A description of all processes used to obtain informed consent and assent (if applicable)	4.4.3.2(g)						

#	Criteria	CGSB	TCPS 2	HC	GCP	FDA	DHHS	PHIPA
3.14	The process whereby research subjects may withdraw their consent, if given, and associated documentation	4.4.3.2(h)						
3.15	A description of the processes used to provide research subjects with new information which may affect their willingness to participate, and to obtain their ongoing consent	4.4.3.2(i)						
3.16	A statement and description of any safety monitoring process provided by the sponsor or qualified investigator, such as data and safety monitoring board (DSMB)	4.4.3.2(n)	11.7			21 CFR 56.111(a)(6) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.111(a)(6)	
3.17	If the trial has been registered in an internationally recognized clinical trial registry, the name of the clinical trial registry, the unique identifying code assigned to the clinical trial by the registry, and information regarding where the results of the clinical trial will be made publically available	4.4.3.3						
3.18	If the research involves (optional*) genetic testing, a description of the separate processes used for obtaining and documenting informed consent and assent for such genetic testing. In addition, a plan for managing information that may be revealed through genetic research should be submitted to the REB**	4.4.3.2(q)*	13.2**					
3.19	A statement by the qualified investigator that he/she is aware of and shall make all reasonable efforts to comply with the applicable laws, guidelines, policies, and professional obligations	4.4.3.2(p)						
3.20	All previous decisions, if known, by other REBs or Regulatory Authorities for the proposed biomedical clinical trial (whether in the same location or elsewhere), and indication of modification(s) to the protocol made on that account, and the reasons for previous negative decisions	4.4.3.2(o)						
3.21	Clinical trial budget, in sufficient detail to ensure that conflicts of interest are identified, minimized, or otherwise managed	4.4.3.2 (m)	11.11					
3.22	Measures for meeting confidentiality obligations and explanation of any reasonably foreseeable disclosure requirements, and proposed measures for safeguarding information, for the full life cycle of information: its collection, use, dissemination, retention and/or disposal		5.2(a) 5.3			21 CFR 56.111(a)(7) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.111(a)(7)	2004, c.3, Sched. A. s.44(3)(b)
3.23	If material incidental findings are likely, a plan indicating how researchers will disclose such findings to participants		3.4					

Table 3: Materials Required for Submission to the REB

#	Criteria	CGSB	TCPS 2	HC	GCP	FDA	DHHS	PHIPA
3.24	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					
3.25	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					
3.26	Justification for the choice of a placebo control arm, as opposed to the other possible choices of control group, is provided to the REB (as applicable)		11.2 (a-c)					
Submission requirements during ongoing trial conduct may include, but are not limited to:								
3.27	Protocol amendments	4.4.6.2	6.16		3.1.2, 4.4.3	21 CFR 56.115(a)(1) 21 CFR 56.108(a)(3) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.115(a)(1)	
3.28	Consent form updates that the researcher proposes for use in the study	4.4.6.2	3.3 6.16	FDR C.05.012(3)(g)	3.1.2 4.4.1 4.8.2	21 CFR 56.115 (a)(1) and 115(a)(7) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.115 (a)(1) and 115(a)(7)	
3.29	Any revisions to written information provided to participants (not including consent form revisions, as noted above)	4.4.6.2		FDR C.05.012(3)(g)	3.1.2 4.4.3 4.8.2			
3.30	Written summaries of trial status/progress reports/continuing review reports, including DSMB reports*	4.4.7.3*	6.14 11.7*	FDR C.05.012(3)(g)	4.10.1	21 CFR 56.115(a)(1) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.115(a)(1)	
3.31	Written reports on any changes significantly affecting the conduct of the trial, and/or increasing the risk to subjects, including: a) deviations from, or changes of, the protocol to eliminate immediate hazards to trial subjects; b) changes increasing the risks and/or affecting significantly the conduct of the trial; c) all adverse drug reactions that are serious and unexpected; d) new information that may affect adversely the safety of the subjects or the conduct of the study.	4.4.6.6 (b), 4.4.6.6(e) 4.4.7.3(d)(3)	6.15 10.5 11.8	FDR C.05.012(3)(g)	3.3.8 4.5.4(a) 4.10.2	21 CFR 56.108(a)(3) 21 CFR 56.115(a)(1) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.108(a) 45 CFR 46.115(a)(1)	

Table 3: Materials Required for Submission to the REB

#	Criteria	CGSB	TCPS 2	HC	GCP	FDA	DHHS	PHIPA
3.32	Unanticipated problems, including serious unexpected adverse events/reactions	4.4.6.6(c) 4.4.6.7 4.4.7.3(d)(3)	6.15 11.8		4.11.1	21 CFR 56.115(a)(1) 21 CFR 56.108(b)(1) 21 CFR 312.66 21 CFR 812.60	45 CFR 46.115(a)(1)	
3.33	Serious or continuing non-compliance with organizational policy or REB requirements and determinations, or the regulations	4.4.6.6(d)	6.15			21 CFR 56.108(b)(2) 21 CFR 312.66 21 CFR 812.60		
3.34	Updates to the Investigator's Brochure (IB), product monograph (PM), device manual	4.4.7.3(c)			4.4.2			
3.35	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)	
3.36	Discontinuation of the clinical trial at the local site and the reasons for it	4.4.6.6 (a)			4.12.1 4.12.2	21 CFR 56.108(a)(3) 21 CFR 312.66 21 CFR 812.60		
3.37	Summary of trial outcome/study completion report	4.4.9.1			4.13			
3.38	Changes in any additional documents subject to review.	4.4.6.2		FDR C.05.012(3)(g)	4.4.3			