Competency Framework - Webinar 1 – REB Governance, Resourcing, Reporting and Authority

(Certification topic Alignment: 2 a i, 4a,b,c,d,e,i to v.

Audience: New administrators, members, chairs who require a broad overview of how REBs are structured, resourced and governed and the issues which might arise.

Duration: One hour –learning objectives covered at a basic level to build general familiarity

Webinar Objective	Learning Outcomes	Assessment Criteria	TCPS2(2014) & Applicable Regulatory, Policy, Standard and Guideline Alignment[1]	Webinar Participation Assessment Question(s)
Critically assess an REB in order to identify issues and opportunities for improvement relating to its governance, reporting relationships, structure, resourcing and auditing of its operations.	By the end of this webinar, the research ethics professional should be able to: • Describe some common models used to characterize REBs • Assess the implications of various governance and reporting structures	The participant shall demonstrate the ability to: Describe the mandate and characteristics of the range of common types of REBs which exist in Canada e.g., clinical, first nation, social science and humanities, regional, private "for profit", delegated board of record, appointed under provincial legislation to service a geographic area, specific disease focused, course based research Contrast and compare the governance structures which are common within academic institutions to those found in other research environments/contexts e.g., bi-cameral systems, board of directors, owners Assess the impact of various reporting structures (e.g. senate and board of governors in academia) on REB operations – i.e., resourcing versus decision making, potential benefits and challenges including managing conflict of	**TCPS2 (2014**): 2.1, 6.1, 6.3, 6.5, 6.12, 8.1, 8.2, 8.3, 8.4, 9.1, 9.2, 11.1, 11.4 **TCPS2 (2014):** 6.1, 7.1 **TCPS2 (2014)**: 6.2, 6.6, 6.13, 7.3, 7.4, 11.10	When considering a bi-cameral (or various) reporting structures such as a senate with a board of governors, how could this structure impact the functioning of an REB? a) no impact – REB is to work independently of these bodies b) the senate and board of governors control the resources available therefore may influence (intentionally or unintentionally) the decision making by the REB c) The REB is to make decisions on applications independently, and will need to contact the senate and/or b of g for resources d) The REB is a subcommittee of the senate or b of g. When a submission is made to the REB, the following are responsible for completing the ethical review: a)REB chair b) REB board members c) a and b

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		interest Contrast the role and reporting implications of the REB within the organization e.g., REC Chair and members, as compared to the role of the research office administrative staff, e.g., research ethics officer Discuss the challenges which can exist when resource allocation/ employee management structures/compliance happen through one channel and decision making may happen through another Differentiate between organizational responsibilities/approvals and ethical clearance/approvals. Discuss the role of institutional legal advisors, institutional insurance advisors, institutional research risk managers, for example. Clarify how and why these two approval processes should be kept separate , i.e., a protocol may be deemed to be ethically acceptable but the organization may decide to not provide approval for the research to proceed for institutional strategy/resource utilization/risk/liability reasons Indicate COI which can arise based on differences in reporting structures. Discuss how to manage COI when it arises.	**TCPS2 (2014)**: 6.2, 6.4, 6.7 **TCPS2 (2014)**: 6.3, 6.16, 6.18, 6.19, 6.20 **TCPS2 (2014)**: 6.3 **TCPS2 (2014)**: 6.2, 7.1, 7.2, 7.3, 7.4	d) the research office administrator Describe how oversight bodies may be separated or combined in various types of organizations that require an REB. Describe how the roles of various organizational bodies could be defined to ensure effective functioning of the REB? a) Create/Maintain guidelines (preferably written) such as Terms of reference, SOP b) Follow local, provincial and national mandates Provide an example whereby an REB application may be deemed ethically acceptable but the institution chooses not to approve the application. If an application is ethically sound, a university might not grant approval because: a) they have it out for the individual b) they have reached their quota of positive applications c) there may be insurance and or other risks that prohibit the application d) the REB might deny the application based on the lack of funding for the project.
	By the end of this webinar, the research ethics	The participant shall demonstrate the ability to:		The jurisdiction of the institution can include (choose all that apply):

Webinar Objective	Learning Outcomes	Assessment Criteria	TCPS2(2014) & Applicable Regulatory, Policy, Standard and Guideline Alignment[1]	Webinar Participation Assessment Question(s)
	professional should be able to: • Provide an overview of various approaches used to delegate responsibility and authority to an REB	Assess the relative advantages and disadvantages of various models e.g. REB specific terms of reference, pan-institutional human research guidelines Discuss the pros and cons associated with various methods used to define an REBs jurisdiction and what elements should be considered e.g., scope, types of protocols, review processes, ability to delegate Discuss the differences between the formal delegation of responsibility to an REB and the day to day working relationships which are required to support the REBs work. Discuss the challenges which can exist when resource allocation/ employee management structures/compliance happen through one channel and decision making may happen through another	**TCPS2 (2014)**: 6.1, 6.2, 6.3 **TCPS2 (2014)**: 6.2 **TCPS2 (2014)**: 6.1, 6.2, 6.3	a) Physical space – all on campus facilities b) Geographic area – local municipality or province c) People involved – faculty, staff, or students d) Resources – listservs, laboratories, meeting rooms e) All of the above REBs can be: a) Part of the institution they serve b) External to the institution REBs must be established by (indicate all that apply): a) The President or CEO of an institution b) The highest body in charge of the research program in an institution c) The highest body of the institution d) The Director or Manager of the REB The Director/Manager of an REB often reports to a different body than does the REB. This duality can lead to (choose all that apply): a) Conflicts of interest between the REB and the institution b) Conflicts of interest between the Ethics Administration and the REB c) Lack of funds for the Ethics Administration d) Conflicts of interest between the Ethics Administration and the body to whom they report e) Lack of institutional support for the REB.

Webinar Objective	Learning Outcomes	Assessment Criteria	TCPS2(2014) & Applicable Regulatory, Policy, Standard and Guideline Alignment[1]	Webinar Participation Assessment Question(s)
				Specific REBs can be created to review: a) Social science and humanities research b) Research on specific diseases c) Undergraduate and course based research d) Clinical trials e) Community liaison research projects f) All of the above g) None of the above The key factor determining whether an specific type of REB (such as an REB for clinical trials) is appropriate is: a) Availability of specific expertise b) Sufficient submissions to ensure experience with review c) Resources (financial and personnel) to support the REB d) All of the above e) None of the above
	By the end of this webinar, the research ethics professional should be able to: • Describe specific resourcing considerations and needs for a range of different types of REBs	The participant shall demonstrate the ability to: Identify common budgetary considerations and resourcing challenges for various types of REBs (e.g. REBs in colleges, independent REBs, REBs in universities, remote REBs, large REBs, REBs reviewing clinical trials etc., REBs which charge a fee for review, and those which do not, for example REBS which primarily review funded/contract research and REBs which primarily review unfunded/student research) Discuss various approaches REB use to deal with risk assessment, privacy, data safety monitoring board with a focus on identifying how	**TCPS2 (2014)**: 6.2 **TCPS2 (2014)**: 6.5, 11.4, 11.5, 11.7	The REB of XYZ institution charges REB administration fees from the sponsor for review of industry funded protocol. The REB reviewed the protocol and found that it was not ethically appropriate and therefore did not approve it. The sponsor refused to pay the REB fees as they did not get the result they were looking for. a) How would you approach this scenario if you were an REB administrator? b) In your opinion, who should be responsible for collecting fees for REB protocol review? c) What are the other ways/ideas for offsetting REB administration fees you have come across? d) Can the REB charge fees for non-

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		different REBs handle risk assessment activities. Describe differences in resourcing considerations between independent/private REB vs institutionally associated REBs		industry sponsored studies?
	By the end of this webinar, the research ethics professional should be able to: • Identify relevant REB stakeholders, both within and outside the organization	The participant shall demonstrate the ability to: Identify the units with whom REBs typically work within the organization and the nature of these relationships e.g., lawyers, insurance, grants facilitators, faculty unions, VPs Research/Grad Studies/Academic, etc., research risk managers Identify the units with whom REBs typically work which are external to the organization and the nature of these relationships e.g., federal secretariat, Tri-agencies, research funders, CAREB, industry associations, ACAHO, N2, OHRP, AAHRP Identify the types of resources and networking or advocacy opportunities available to the REB from internal and external sources, and also those which are available to the ethics office from internal and external sources Clarify methods which can be used to manage dual reporting relationships and responsibilities e.g., matrix structures, coordinating bodies such as research committees or operations committees	**TCPS2 (2014)**: 6.2, 6.5, 6.7, 6.12, 11.4	REBs often work with other areas and units within their organization. List 2 such areas or units with whom REBs work with internally and describe the nature of these relationships. Explain one method REBs can use to manage dual reporting challenges.

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	By the end of this webinar, the research ethics professional should be able to: • Describe the range of oversight mechanisms, both mandatory and voluntary, with which REBs may need to comply	The participant shall demonstrate the ability to: Identify specific registration and reporting obligations which exist in both Canadian and US contexts e.g. (Health Canada, provincially mandated REBs in Quebec and Newfoundland, Northern Canada) Identify specific registration and reporting obligations which exist in US and other specialized contexts e.g. FWA for OHRP in the US, FDA, ORI, clinicaltrials.gov Identify specific registration and reporting obligations arising from harmonized REB initiatives e.g., CTO for clinical trials in Ontario, disease specific REBs e.g. OCREB, university driven harmonized REBs in BC, Alberta and Saskatchewan	**TCPS2 (2014)**: page 10, p. 154, 11.3, **TCPS2 (2014):** 11.3 **TCPS2 (2014)**: 8.1, 8.2, 8.4	When conducting research within Canada, identify which provinces and/or regions require specific registration and reporting obligations: a) Quebec b) Newfoundland and Labrador c) Northern Canada d) All of the above Does Health Canada have specific reporting obligations, which researchers must follow? If so, why? When working outside of Canada, for example the United States, name four organizations who would require specific registration and reporting obligations? Dr. R has just developed a new and improved diet pill, she plans to market it in the US and Canada. What approvals will she need prior to the product being sold?
	By the end of this webinar, the research ethics	The participant shall demonstrate the ability to:		Contrast between various types of internal audits/quality improvement processes REB can

Webinar Objective	Learning Outcomes	Assessment Criteria	TCPS2(2014) & Applicable Regulatory, Policy, Standard and Guideline Alignment[1]	Webinar Participation Assessment Question(s)
	professional should be able to: • Describe the range of both internal and external audit and compliance review mechanisms which may affect REBs. • Describe various models which might be used to appeal REB decisions.	Describe the types of internal and external audits REBs may need to undergo. Explain the common impacts of internal audits, e.g. quality improvement, on REB operations. Explain how certain types of Internal audits e.g., post-approval or continuous monitoring can involve review of REB processes, study protocols and the consent process. Describe how a non–routine review can be triggered by a whistleblower complaint, protocol deviation leading to new concerns for research integrity Describe various types of external accreditation audits REBs may encounter. Explain how to prepare for external oversight reviews e.g., Tri-agency, US oversight reviews such as FDA OR OHRP audits Identify stakeholder, process and expectations in the auditing process. Explain how to make the audit process educational and inclusive of all stakeholder interests.	**TCPS2 (2014)**: 2.8, 6.14, 6.15, **TCPS2 (2014)**: 6.18, 11.8, 11.9	develop: 1) For cause – as a response to a complaint/issue 2) Not for cause –proactive for internal QI Describe common issues which might arise in these areas that could be audited: 1) REB processes – submission, approval, communication with various stakeholders 2) People – REB staff, REB member, REB Chair 3) PI and study related processes – Informed consent management, adverse event reporting, document management 4) Educational needs and assessment –all stakeholders What is a Corrective Action Plan (CAP)?

Note: If this webinar is to be used for certification credit, the professional development subcommittee suggests that candidates be given a case study to analyze. The objective would be to have the candidate assess the internal and external situational context of a specific REB, identify issues it faces regarding its structure, governance, reporting and resourcing, and make recommendations for improvement. Alternatively the questions provided in the right hand column could be used to assess learning and provided on-line.

Webinar Topic Title: Establishing and Maintaining Effective REB Standard Operating Procedures

Target Audience: REB Members, REB Chairs, REB Administrators, Learners, Institutional Administrators, Legal/Lawyers, Risk Managers, Policy Advisors

Length of Session: One hour

Webinar Objective	**Learning Outcomes**	**Assessment Criteria**	**TCPS2 (2014) & Applicable Regulatory, Policy, Standard and Guideline Alignment[1]**	**Webinar Participant Assessment Questions**
To provide a detailed overview of the processes and activities required to develop and maintain appropriate REB standard operating procedures (SOPs) .	**By the end of this Webinar Participants should be able to:** *1.* Describe the processes necessary to establish and maintain written standard operating procedures to facilitate compliance with principles, guidelines and regulations regarding the ethical review and oversight of research involving human participants or human materials. *2.* Describe some of the circumstances which might precipitate the need for creating a new SOP or revising an existing one (e.g. changes to applicable regulations or guidance documents, implementation of new policies, changes to a research ethics office's administrative practices). *3.* Describe the components of an SOP, including each component's use and application. • Policy Statement/Purpose • Definitions/Glossary of Key Terms • Responsibility • Procedures	*The participant shall demonstrate the ability to:* 1. Explain how REB SOPs are developed, reviewed, revised, approved and distributed 2. List and highlight the purpose of each component of an SOP a. Policy statement/purpose b. definitions/glossary of key terms c. responsibility d. procedure e. reference 3. Identify key considerations and issues in the development and management of REB SOPs 4. Describe the role of appropriate REB SOPs in facilitating compliance and consistent ethical standards	**TCPS2 (2014):** Articles 6.2; 6.10; 6.12; 6.13; 6.14; 6.17; 6.21; 6.22 Canadian General Standards Board (CGSB): Research Ethics Oversight of Biomedical Clinical Trials (CAN/CGSB-191.1-2013 Clinical Trials Ontario REB Qualification Manual	*Base questions on the content covered during the webinar.* *Require Participant responses to the following questions:* 1. What are the necessary processes for establishing and maintaining written REB SOPs? 2. What circumstances might precipitate the need for creating a new SOP or revising an existing SOP? 3. What are the core components of an REB SOP document? 4. What are the key considerations and issues involved in REB SOP development and management? 5. What do appropriate REB SOPs enable?

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	• Reference *4.* Discuss some of the key considerations and issues involved when developing and implementing SOPs including: • consistent systems for content development, approval, storage, revision, archiving • Adopting terminology which is e consistent with existing terminology in procedures/SOPs, (i.e., recognizable and searchable terms) • Ensuring appropriate authorship and content expertise • Ensuring appropriate sign-offs and approvals/authorization for documents • Developing tracking mechanisms to monitor progress of the SOP and authorship *5.* Discuss the role of SOPs in creating a framework to promote consistent ethical standards in the review, oversight and conduct of research involving human research participants or human materials.			

Competency Framework – Webinar 3 (Parts a,b,c,d) – How to review a protocol in the social sciences and humanities (SSH) domain

Certification topic Alignment:

Audience: New administrators, new REB members, new REB chairs who need to develop a basic understanding of the most common types of ethical issues which need to be considered when reviewing a social science and humanities protocol. The webinars will also include some possible solutions or approaches which might be considered by the REB.

Duration: (As indicated). This is a series of inter-related webinars. The introductory webinar is designed to build general familiarity with the primary responsibilities of the REB. Subsequent webinars will explore the most common ethical issues SSHR REBs encounter and need to consider by focusing on more nuanced discussion of the issues raised in the first webinar as well as specific issues and best practices which emerge either from the application of the core principles in the SSH domain or from common SSH methodologies.

Webinar Objective	Learning Outcomes	Examples of typical issues or factors to be considered	TCPS 2 (2014) & Applicable Regulatory, Policy, Standard and Guideline Alignment[1]	Webinar Participation Assessment Question(s)
(Overview) Webinar 3a (1 hour)				
Describe the five overarching responsibilities of an REB when conducting an ethical review	By the end of this webinar participants should be able to: 1. Adopt a participant based perspective 2. Ensure favorable risk benefit ratio 3. Conduct proportionate review	• Difference in risk perception between researchers and participants (Mis)use of technical language/grant language • Higher the risk = higher the benefits • REBs may conduct scientific review for above minimal risk research • Generalizable benefits to society or group vs individual benefits • Degree of prior peer review already conducted – not replicate efforts • Effort and reward ratio – wordsmithing of information and consent letters • Degree of serial review for minimal risk multi-jurisdictional research required and incremental benefit likely to occur • Use of ad hoc experts	**TCPS2 (2014):** Article 2.9, 1.1c	Case study

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(Overview) Webinar 3a (1 hour)				
	with appropriate expertise 4. Assess ethical appropriateness i.e., not provide institutional approval for research to proceed 5. View TCPS 2 as a minimum	• May be ethically sound but not institutionally supported • Other approvals/regulations may apply before research can proceed • Institution may ask REB to do more than what TCPS2 requires through their internal policies/procedures e.g. review QA or vocational skill acquisition if involves human participants		
Apply the three key factors which are relevant to determining whether an application requires review by the institutional REB	1. Does it fall under the institutional auspices? 2. Is it research? 3. Does it involve human participants or their data or	• Use of institutional resources or proprietorial information; involve institutional employees, students or members • TCPS 2 definition of research • Applicability of generalizability principle in SSH • Disciplinary norms • Special types of research e.g. Applied research, Course based research, Thesis research • TCPS2 definition of human participant • Required to answer question • Staged interventions	**TCPS2 (2014):** Article 2.1, 5.5 A	

Webinar Objective	Learning Outcomes	Examples of typical issues or factors to be considered	TCPS 2 (2014) & Applicable Regulatory, Policy, Standard and Guideline Alignment[1]	Webinar Participation Assessment Question(s)
(Overview) Webinar 3a (1 hour)				
	biological material?	• Expectation of privacy • Identification via dissemination • Living participants • Deceased participants • Use of participant data • Secondary use of data		
	Identify specific situations in which an REB review is not required by TCPS 2	• Quality assurance • Publicly available information • Secondary use of anonymous information • Creative practice • Observation in public spaces if no intervention, no expectation of privacy and non-identifiable data	**TCPS2 (2014):** Article 2.2, 2.3, 2.4,2.5,2.6	
	Discuss how and why an REB may wish to use checklist templates to guide the ethical review	• Review samples of various checklist templates		
	Describe some of the REB behaviours which may cause REB feedback and deliberations to be less than effective	• Feedback not linked to ethical principles • No mitigation mechanisms provided • Inconsistent feedback • Lack of proportionate review		

Webinar Objective	Learning Outcomes	Examples of typical issues or factors to be considered	TCPS2 (2014) & Applicable Regulatory, Policy, Standard and Guideline Alignment[2]	Webinar Participant Assessment Question(s)
(Supplementary) Webinar 3 b – Conducting a Risk/Benefit Analysis (1 hour)				
Assess the risks and benefits associated with a SSH protocol to ensure a favourable balance exists	By the end of this webinar participants should be able to: Differentiate between the concepts of minimal risk and above minimal risk and what that means in terms of review (i.e. delegated vs full board)	• Review TCPS2 definition • Consider types of risks encountered every day by various participant groups e.g. children, geriatrics, first nations, prisoners, differently abled • Clarify that minimal risk does not mean no risk • Clarify the link which should exist between ongoing risk assessment and the need for ongoing consent e.g., adverse events, incidental findings • Note that sometimes full board review is appropriate for 'difficult questions' for which there is little precedent	**TCPS2 (2014):** Article 2.8	
	Differentiate between the concepts of probability of harm and magnitude of harm	• Examples of high probability of harm and low magnitude of harm versus low probability of harm and high magnitude of harm • Example of use of risk matrix to determine when above minimal risk review is required		
	Apply participant perspective to assess risks	• Examples of daily risks regularly faced by vulnerable participants • Notion that need to respect autonomy of participants when conducting risk assessment i.e. not assume that all research involving vulnerable participants is above minimal risk • Individual well being maintained • Impact of research on all to be considered – even those not directly involved • Relative risks and potential benefits for individual to be assessed versus relative risks and benefits for other groups not directly		

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(Supplementary) Webinar 3 b – Conducting a Risk/Benefit Analysis (1 hour)				
		involved with research • Harms minimized and benefits maximized • Follow up with participants and access to results to ensure benefits maximized		
Differentiate between the types of risks commonly found in biomedical/clinical protocols and those typically found in SSH protocols.	Assess the range of common risks which need to be assessed relevant to a specific SSH application	• Physical risks (administration of a substance, bodily contact) • Psychological risks (embarrassment, upset, demeaned) • Social risks (loss of status, reputation, privacy) • Economic risks (increased costs) • Stigmatization risks • Loss of privacy risks		
	Discuss the role of the REB when risks for researchers have been identified as part of the REB review	• Link with institutional risk management personnel	**TCPS2 (2014):** Article 2.9, 4.7	
	Discuss how and why institutions interpret level of risk differently	• Review examples of various differences in risk definitions and interpretations		
	Assess the range of benefits which may occur as a result of the research	• Participant benefits • Disciplinary benefits • Societal benefits • Reciprocity requirements • Minimal risk unless potential direct benefits to individual or group • Equitable distribution of research benefits		
	Describe the situations in which the REB may decide to conduct a scientific/scholarly review.	• Identify situations in which there may be a need for replication of previous professional peer-review • Factors which should be considered in order to conduct a scientific review of above minimal risk research.	**TCPS2 (2014):** Article 2.7	

Webinar Objective	Learning Outcomes	Examples of typical issues or factors to be considered	TCPS2 (2014) & Applicable Regulatory, Policy, Standard and Guideline Alignment[3]	Webinar Participant Assessment Question(s)
Supplementary Webinar 3 c – Applying the key ethical principles and ensure respect for persons (1 hour)				
	By the end of this webinar participants should be able to: Define the three fundamental ethical principles which need to be assessed during the review process.	• Respect for persons • Concern for welfare • Justice	**TCPS2 (2014):** Article 1.1	
	Assess the application for ethical issues associated with the principle of: "Respect for persons"	• Twin responsibilities – protect autonomy and protect those with diminished autonomy • Maintain ability to choose without interference e.g. connections to family and community to be considered • Need for transparency and complete information • Assess impact of controlling influences, power imbalances and coercion on autonomy to make decision about participation • Identify barriers to accessing resources or knowledge outside the research context • Identify specific barriers to exercising autonomy (youth, cognitive impairment, mental health issues, illness, relationships)		
	Ensure free and informed consent is obtained	• Define the concept of free, informed and ongoing consent • Identify specific conditions for secondary use of identifiable without consent	**TCPS2 (2014):** 3.1, 5.5 A	
	Identify situations which may inhibit the provision of free and informed consent	• Undue influence • Coercion • Excessive incentives • Conflict of interest	**TCPS2 (2014):** 3.1	

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Supplementary Webinar 3 c – Applying the key ethical principles and ensure respect for persons (1 hour)				
		• Not provide to guardians or authorized third parties for arranging participation		
	Ensure consent is fully informed and precedes participation	• Review the contents which should be provided at a minimum in an information and consent letter	**TCPS2 (2014):** 3.2, 3.5	
	Describe the limitations to consent	• Can be withdrawn at any time • Can also request data be withdrawn • Need to refresh consent if risks or other material conditions change • Consent viewed as a process considering incidental findings, adverse events	**TCPS2 (2014):** 3.1 , 3.3,	
	Define the specific conditions which allow for departures from general principles of consent	• Conditions include: the research is minimal risk, waiving consent is essential to research, unlikely to affect welfare, protect privacy, comply with known preferences, impossible or impracticable, all other necessary permissions obtained	**TCPS2 (2014):** 3.7a, 5.5a	
	Define situations which may require alternative process to be employed to obtain consent	• Critical inquiry • Consent shall be documented • Other forms of consent e.g. waiver of consent, oral, assumed (surveys), • Partial Disclosure and Deception • Individual medical emergencies • Secondary use of non-identifying information	**TCPS2 (2014):** 3.6, 3.12, 3.7A, 3.7B, 3.8, 5.5b	
	Describe the requirement for researchers to ensure participants have appropriate decision making capacity	Identify considerations for those lacking capacity • Determination of capacity • Use of authorized third parties • Assent versus consent • Prohibition against above minimal risk research with no direct benefit to participant • Revoking third party authorizations • Use of research directives	**TCPS2 (2014):** 3.9, 3.10, 3.11, 4.6	

Webinar Objective	Learning Outcomes	Examples of typical issues or factors to be considered	TCPS2 (2014) & Applicable Regulatory, Policy, Standard and Guideline Alignment[3]	Webinar Participant Assessment Question(s)
Supplementary Webinar 3 c – Applying the key ethical principles and ensure respect for persons (1 hour)				
	Discuss best practices and other considerations for obtaining consent	Discuss practices involving time of day, level of understanding, language, pictures, talk back, white space, “legalese”, confidentiality, ongoing consent		

Webinar Objective	Learning Outcomes	Examples of typical issues or factors to be considered	TCPS2 (2014) & Applicable Regulatory, Policy, Standard and Guideline Alignment[4]	Webinar Participant Assessment Question(s)
(Supplementary) Webinar 3d – Concern for Participant Welfare, Justice and Autonomy (1 hour)				
	By the end of this webinar participants should be able to: Assess the application for ethical issues associated with the principle of "Concern for welfare"		**TCPS2 (2014):** 3.1	
	Differentiate between the concepts of confidentiality, privacy and security		**TCPS2 (2014):** Chapter 5 Introduction, 5.1,	
	Describe the researcher's duty to maintain confidentiality and the limits to this assurance which may arise	• Typical measures for meeting confidentiality requirements • Use of Wigmore criteria • Legal and ethical obligations in conflict • Duty of institutions to support researchers	**TCPS2 (2014):** 5.2	
	Describe the main types of data which may be obtained and why anonymous data is the default for an REB	• Directly identifying • Indirectly identifying • Coded • Anonymized • Anonymous		
	Consider specific privacy obligations which REBs should consider	• Legal responsibilities under PIPEDA PHIPPA, FIPPA compliance, Municipal M:FIPPA • Institutional norms e.g. passwords, encryption, data storage, record retention • Balance privacy concerns and social good • Examples of institutional risk assessments and privacy audits • Assess sufficiency of data security measures (directly identifying, indirectly identifying, coded, anonymized, anonymous data; use of data, risk of breach, consequences of breach, dissemination, retention, disposal, encryption,		

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Webinar Objective	Learning Outcomes	Examples of typical issues or factors to be considered	TCPS2 (2014) & Applicable Regulatory, Policy, Standard and Guideline Alignment[4]	Webinar Participant Assessment Question(s)
(Supplementary) Webinar 3d – Concern for Participant Welfare, Justice and Autonomy (1 hour)				
		data linkage		
	Describe the range of methods which are available to safeguard data	• Responsibilities of researchers • Responsibilities of institutions	**TCPS2 (2014):** 5.3, 5.4	
	Describe the challenges to security and confidentiality, privacy which may arise due to data linkage	• Joining data sets • Data repositories	**TCPS2 (2014):** 5.7	
	Identify the types of practical mitigation mechanisms which REBs might suggest that researchers employ to overcome these typical issues associated with maintaining privacy, confidentiality and data security			
	Identify resources which REBs can use to identify “best practices”			
	Assess the application for ethical issues associated with the principle of “Justice”			
	Ensure no participant group is unfairly burdened/exposed to risks or denied benefits	Review the general considerations associated with the concept of “justice”: • Not arbitrarily excluded • Appropriate consideration of inclusion and exclusion criteria • Exclusion criteria must be related to research • Sex based considerations • Age based considerations • Vulnerability considerations Identify challenges faced when interpreting the above	**TCPS2 (2014):** Article 4.1, 4.2, 4.3, 4.4, 4.5, 4.7	

Webinar Objective	Learning Outcomes	Examples of typical issues or factors to be considered	TCPS2 (2014) & Applicable Regulatory, Policy, Standard and Guideline Alignment[4]	Webinar Participant Assessment Question(s)
(Supplementary) Webinar 3d – Concern for Participant Welfare, Justice and Autonomy (1 hour)				
		Give examples of groups that have been inappropriately excluded from research		
	Assess how treating people fairly does not mean treating them in the same way			
	Describe how the concepts of vulnerability and vulnerable populations can be interpreted differently	Discuss how this will differ depending on the context of the research, depending on the institution reviewing the research, depending on the research question itself Review examples of various research scenarios to ensure that the principle of justice is upheld	**TCPS2 (2014):** 10.1, 10.2, 10.5	

Note: If this webinar is to be used for certification credit, the professional development subcommittee suggests that candidates be given a case study to analyze. The objective would be to have the candidate assess the ethical issues presented by a specific protocol and make recommendations for improvement.

Webinar Topic Title: Reviewing a research study in the bio-medical domain

Target Audience: REB members, REB chairs and administrators who are looking to develop or reinforce their understanding of the most common types of research ethics issues which require consideration when reviewing a biomedical research study. This webinar will also cover relevant strategies and approaches for the review of biomedical research studies.

Length of Session: (As indicated) This is a series of inter-related webinars, each spanning 1 hour in length. This webinar series will cover: General Administration Considerations, Overall Protocol Review Considerations, Participant Protection Considerations, and Special Considerations in the review of biomedical research

Webinar Objective	**Learning Outcomes**	**Examples of Typical Issues or Factors to be considered**	**TCPS2 (2014) & Applicable Regulatory, Policy, Standard and Guideline Alignment[1]**	**Webinar Participant Assessment Question(s)**
General Administrative Considerations - Webinar 4a (1 Hour)				
To provide criteria for the review of the Administrative Components of a bio-medical research including: Sign-offs and Attestations, Conflict of Interest Review and Management, Documentation Required for Appropriate Review, Adequacy of Resources to conduct the research, study type classification and clinical trial registration; and to address the application of appropriate ethical principles and guidelines, and regulatory criteria for the review and approval of the administrative aspects of the research.	By the end of this Webinar participants should be able to: 1. Recognize and determine what signatures and attestations are required for various biomedical research studies, including the difference between REB review requirements and institutional approval and review requirements 2. Recognize and assess situations of actual, potential and/or perceived conflicts of interest; determine when declarations are required; and assess and/or inform appropriate conflict of interest management strategies 3. Identify and describe the documentation required for the review of various biomedical research studies 4. Assess and determine whether adequate resources are in place for the conduct of the study and how these components should form part of the continuing review or audit and the initial approval. 5. Appropriately classify and differentiate between biomedical research studies by study type noting particular characteristics of various biomedical study types	• The application has been signed by the Researcher and, if applicable, by a designated Organizational Official, indicating that the Researcher and study team have the qualifications, training and resources to conduct the research; and for any study specific activities that are considered controlled acts • all of the necessary documentation required for the review of the study have been included in the submission to the REB (e.g. protocol, consent documents, investigators brochures etc.) • Any potential conflicts of interest are declared and are managed appropriately to prevent any compromises to the safety or well-being of the participants or to the integrity of the data; • The investigator has sufficient time to conduct and complete the study within the agreed study period. • The investigator has an adequate number of qualified staff and adequate facilities available for the foreseen duration of the study to conduct the trial properly and safely. • The study is appropriately classified (clinical research vs. clinical trial; etc.). Classification of studies by study type assists in delineating the review criteria that should be utilized during the review of a biomedical study. [note: things to be covered should include: What constitutes biomedical research and what are the different types of biomedical research studies. What are the key features within a study protocol that enables the classification of a study as	TCPS2 2014: Article 7.2-7.4; Article 11.3; Article 11.10 PHIPA: Section 44 subsections 1-4; Regulations Section 16, ICH GCP: Section 4.2; Section 4.4.2; Section 7.1 Health Canada Food and Drug Regulations: C.05.006 (c); C.05.008 (c); C.05.010; C.05.012; Health Canada Natural Health Product Regulations: 66(d); 74(d); 76(g)(h) Natural Health	NOTE: If the webinar qualifies as a certification credit, the professional development subcommittee suggests that candidates are given a case study to analyze and demonstrate the ability to apply each of the administrative review criteria covered in the webinar.

[1] Content developers must cover (make reference to or provide sources/resources) all other relevant provincial requirements which may be different and applicable. Ontario, Quebec, British Columbia and Alberta should be covered as a minimum.

Webinar Objective	Learning Outcomes	Examples of Typical Issues or Factors to be considered	TCPS2 (2014) & Applicable Regulatory, Policy, Standard and Guideline Alignment[1]	Webinar Participant Assessment Question(s)
General Administrative Considerations - Webinar 4a (1 Hour)				
	6. Determine when a biomedical research study should be registered in a public registry, and know how to locate a registered biomedical study within various public registries, and which registries are acceptable to which authorities and entities	biomedical research] • If applicable, the research has been or will be registered with a recognized clinical trial registry and a registration number has been/will be provided	Product Regulations Guideline: 1.1; 1.4; 3.2.3; 11.0; 12.0 Health Canada Clinical Trials for Natural Health Products: 1.1; 12.0; Appendix 4 Part 2 Health Canada Medical Device Regulations: 6.3.3.3	

Webinar Objective	Learning Outcomes	Examples of Typical Issues or Factors to be considered	TCPS2 (2014) & Applicable Regulatory, Policy, Standard and Guideline Alignment[2]	Webinar Participant Assessment Question(s)
Overall Protocol Content Review & Considerations - Webinar 4b (1 Hour)				
To provide criteria for protocol content review of a bio-medical study including: scientific merit, clinical equipoise, risk assessment and mitigation, dissemination of research findings, management of material incidental findings and the return of results, and future access to investigational	By the end of this Webinar participants should be able to: 1. Determine what information is required in order to assess and demonstrate scientific merit, and distinguish between poor design which becomes ethically unacceptable and poor study design which may become an academic issue but bares no risk to study participants 2. Identify the criteria to assess, and determine whether a biomedical research study demonstrates clinical equipoise	• The research addresses an area of importance to the discipline, uses established scientific principles, demonstrates how scientific knowledge will be gained from the study; • The methodology is scientifically sound and capable of answering the research question; • There is a state of clinical equipoise when there is a comparison of two or more treatment arms; • The risks to participants are minimized by: o Using procedures that are consistent with sound research design and that do not unnecessarily expose	TCPS2 2014: Article 3.4; Chapter 11 Section A; Article 11.1; Article 11.2; Article 11.4; Article 11.5; Article 11.12 Title 45 Part 46: 46.111; ICH GCP : Section	NOTE: If the webinar qualifies as a certification credit, the professional development subcommittee suggests that candidates are given a case study to analyze and demonstrate the ability to apply each of the protocol content review considerations covered

[2] Content developers must cover (make reference to or provide sources/resources) all other relevant provincial requirements which may be different and applicable. Ontario, Quebec, British Columbia and Alberta should be covered as a minimum.

Webinar Objective	Learning Outcomes	Examples of Typical Issues or Factors to be considered	TCPS2 (2014) & Applicable Regulatory, Policy, Standard and Guideline Alignment[2]	Webinar Participant Assessment Question(s)
Overall Protocol Content Review & Considerations - Webinar 4b (1 Hour)				
agents/devices/procedures. These criteria will be covered with the intent of addressing the application of appropriate ethical principles and regulatory criteria for the review and approval of these aspects of a biomedical research study.	3. Differentiate between and assess both the concepts of probability of harm and magnitude of harm in reviewing a biomedical study; identify favourable and unfavourable risk benefit ratios; and identify risk mitigation strategies for during the initial and ongoing review of biomedical research 4. Identify mechanisms for disseminating research findings and assess whether a biomedical research study has considered and includes an appropriate dissemination strategy 5. Define “material incidental findings” and differentiate between anticipated and unanticipated material incidental findings; Identify biomedical research studies that have the potential to yield material incidental findings; assess the proposed strategy for addressing material incidental findings including justification for any planned disclosures and non-disclosure; and determine whether adequate justification has been provided in order to waive the material incidental finding disclosure requirement 6. Determine which biomedical research studies present with circumstances to necessitate considerations for future access to investigational agents/devices/resources; and assess whether adequate arrangements have been made for future access to investigational agents/devices/resources	participants to risk, and o By using approved procedures already being performed on the participants for diagnostic or treatment purposes whenever appropriate; • The risks to participants are reasonable in relation to the anticipated benefits, and the importance of the knowledge that will be generated; • There will be adequate provisions for the timely and ethical publication and dissemination of the research results [presenter should: provide tools/techniques that can be used by REB reviewers to assess whether best practice reporting guidelines are being followed; address selectibe reporting and lack of transparency as ethical issues to be flagged and addressed in the reiew]; • There is a strategy in place for managing incidental findings and return of clinically significant results; where researchers do not propose a mechanism to share such results and/or findings, justification is provided that demonstrates the impracticability or impossibility of returning such results to participants and/or those impacted by the results and the REB approves of this waiver of reporting obligation • There will be adequate provisions for continued access to the agent or device or adequate replacement of the test agent after the research is complete, when appropriate [presenter should connect this back to the principles of justice and beneficence];	2.2; Section 3.3.8(b); Section 6.2.3; CONSORT	in the webinar.

Webinar Objective	Learning Outcomes	Examples of Typical Issues or Factors to be considered	TCPS2 (2014) & Applicable Regulatory, Policy, Standard and Guideline Alignment[3]	Webinar Participant Assessment Question(s)
Participant Protection Considerations - Webinar 4c (1 Hour)				
To provide criteria for the review of the Participant Protection Components of a bio-medical research study including: Participant Selection; Participant Reimbursement; Informed Consent Procedures; Vulnerable Populations, Data Privacy and Confidentiality; and Data and Safety Monitoring. These criteria will be covered with the intent of addressing the application of appropriate ethical principles and regulatory criteria for the review and approval of these aspects of a biomedical research study.	By the end of this Webinar participants should be able to: 1. Identify and determine whether participant selection criteria are just, fair and equitable in a biomedical research study 2. Distinguish between coercion and undue influence, and appropriately assess and determine whether participant reimbursement amounts are justified and avoid coercion and undue influence 3. Identify the essential components of the informed consent process, and determine whether a proposed informed consent process is appropriate 4. Determine when a population is considered vulnerable in relation to the research study, delineate and appropriately apply the relevant criteria in their review of biomedical research involving such vulnerable populations 5. Delineate the key requirements for ensuring data privacy and confidentiality in biomedical research, and assess the data management plan of a biomedical research study to ascertain whether adequate protections are in place *6.* Identify appropriate data and safety monitoring plans for biomedical research, and determine what should be in them and when additional considerations should be made for alternate safety monitoring in particular biomedical research studies	• The selection of participants is equitable (including elements of distributive justice) and appropriate to address the purpose of the research and the research setting. [note: consider the scientific and ethical reasons for including vulnerable populations, and for ensuring they are included in the research plan] if applicable; • There are sound scientific and ethical reasons for excluding classes of persons who might benefit from the research; • The amount and method of payment/reimbursement to participants is appropriate to ensure that there is no coercion or undue influence and that information regarding payment to participants including method, amounts and schedule is provided to participants when applicable; • Informed consent will be sought from each prospective participant or from the participant's legally authorized representative, in accordance with and to the extent required, by applicable regulations and guidelines and will be ongoing; • The informed consent form will accurately explain the research and contain the required elements of consent; • The informed consent process will be appropriately documented in accordance with the relevant regulations; • Additional criteria for research involving Aboriginal peoples in Canada, or research on materials related to human reproduction, or genetic research, or children, or prisoners, or pregnant women shall be applied when applicable in accordance with governing principles and/or Regulations. • When some or all of the participants, such as children, prisoners, the elderly, pregnant women, those with mental health issues, and those with diminished capacity for self-determination are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the research, and in the REB review process to protect the rights and welfare of these participants; • Studies proposing access to or collection of personal	TCPS2 2014: Chapters 3, 4, 5, 9, 11, 12, 13 PHIPA: Section 16; Regulations Section 44, subsections 1-4 Title 45 Part 46: 46.116; 46.117 46.204; 46.205; 46.206; 46.207; 46.404; 46.405; 46.406; 46.407; 46.408	NOTE: If the webinar qualifies as a certification credit, the professional development subcommittee suggests that candidates are given a case study to analyze and demonstrate the ability to apply each of the participant protection consideration covered in this webinar.

[3] Content developers must cover (make reference to or provide sources/resources) all other relevant provincial requirements which may be different and applicable. Ontario, Quebec, British Columbia and Alberta should be covered as a minimum.

Webinar Objective	Learning Outcomes	Examples of Typical Issues or Factors to be considered	TCPS2 (2014) & Applicable Regulatory, Policy, Standard and Guideline Alignment[3]	Webinar Participant Assessment Question(s)
Participant Protection Considerations - Webinar 4c (1 Hour)				
		information require consideration of additional items to ensure the protection of the privacy of the personal information and to determine whether the proposed study plans adhere to the appropriate privacy legislation • There will be adequate provisions to protect the privacy of participants and to maintain the confidentiality of data; • There will be provisions for on-going data and safety monitoring that are appropriate to the size, complexity, phase, and level of risk of the research. [note: a Data Safety Monitoring Board (DSMB) may be required; and the REB may recommend the use of a DSMB to enhance participant protection];		

Webinar Objective	Learning Outcomes	Examples of Typical Issues or Factors to be considered	TCPS2 (2014) & Applicable Regulatory, Policy, Standard and Guideline Alignment[4]	Webinar Participant Assessment Question(s)
Special Considerations - Webinar 4d (1 Hour)				
To highlight special considerations in the review of a bio-medical study including: considerations for studies involving new unregulated investigational interventions, studies involving investigational agents accessed through	By the end of this Webinar participants should be able to: 1. Identify an unregulated investigational intervention and apply the appropriate considerations in the review of a biomedical study involving the use of an unregulated investigational intervention 2. Distinguish between special access approval and investigational testing approvals and apply the appropriate considerations in the review of biomedical	• Pre-clinical safety testing • Clinical safety testing • ICH CGP compliance • Considerations when regulatory oversight does not exist • As drugs accessed through the Special Access Program (SAP) do not undergo the scrutiny of a benefit-risk assessment provided within the regulatory framework applied to new drug submissions or clinical trial applications, authorizations through SAP do not constitute an opinion that a drug is safe, efficacious or of high quality. • Extra precautions when reviewing a prospective	TCPS2 2014: Chapter 11	NOTE: If the webinar qualifies as a certification credit, the professional development subcommittee suggests that candidates are given a case study to analyze and demonstrate the ability to apply each of the

[4] Content developers must cover (make reference to or provide sources/resources) all other relevant provincial requirements which may be different and applicable. Ontario, Quebec, British Columbia and Alberta should be covered as a minimum.

Webinar Objective	Learning Outcomes	Examples of Typical Issues or Factors to be considered	TCPS2 (2014) & Applicable Regulatory, Policy, Standard and Guideline Alignment[4]	Webinar Participant Assessment Question(s)
Special Considerations - Webinar 4d (1 Hour)				
Health Canada's Special Access Program as compared to the standard investigational testing regulatory authorization route, and therapeutic misconception from various stakeholder perspectives. These criteria will be covered with the intent of addressing the application of appropriate ethical principles for the review and approval of biomedical research studies impacted by these considerations.	studies that are conducted using investigational agents cleared through the special access program and those cleared through the clinical trial application approach. *3.* Appropriately define therapeutic misconception, identify scenarios of therapeutic misconception for both participants and researchers/research teams, and identify strategies to prevent/eliminate therapeutic misconception through the review of biomedical research studies	observational study of a new/innovative health product used through Health Canada's Special Access Program (SAP) o Safety reporting requirements o REBs scope and jurisdiction over study conduct • Biomedical studies involving participants for whom there are no or limited treatment options often face the risk of therapeutic misconception of both participants and clinician-researchers, and their respective study teams alike • REBs should consider in their review of such studies how information is being presented within study documentation and work to ensure that the investigational nature of the study is accurately articulated. Ensuring "investigational intervention" rather than "treatment" is used when describing the investigational intervention		special considerations covered in this webinar.

Webinar Topic Title: Assessing and addressing the ethical implications of the use of, and access to, new emerging internet-based study tools and interventions[1] throughout and following study conduct.

Target Audience: REB Members, REB Chairs, REB Administrators, Researchers/Research Teams, Learners.

Length of Session: One hour

Webinar Objective	**Learning Outcomes**	**Assessment Criteria**	**TCPS2 (2014) & Applicable Regulatory Alignment[2]**	**Webinar Participation Assessment Question(s)**
To analyze and understand, complex ethical issues[3] related to the use and access to newly emerging internet-based study tools and interventions throughout a study's life-cycle and apply ethical principles in the review and consideration of their use in research.	**By the end of this Webinar Researchers/Research Teams/Learners should be able to:** 1. Effectively identify and apply appropriate data security parameters in research studies involving the internet-based tools and interventions discussed during this Webinar. 2. Utilize established ethical principles in the development of appropriate consent practices in studies involving use of internet-based tools and interventions discussed during this Webinar ensuring the highest ethical standards are applied. 3. Demonstrate an appreciation for relevant ethical considerations in the establishment of appropriate parameters for access to internet-based study tools and interventions discussed during this Webinar, throughout and following study activity. 4. Effectively differentiate public space from private space in the design of	*Present a Case Study or current issue highlighted in the media/social networks* The participant shall demonstrate the ability to: 1. Correctly identify the ethical issues arising 2. Describe the applicable ethical principles that will help resolve any ethical tensions 3. Explain how researchers, REB chairs/members should seek out institutional resources to deal with one or more of these issues	**TCPS2**: Ch. 3 (A, B, D), Ch. 5 (A-E) **ICH GCP:** 4.8 **21 CFR Part 50**: (Subpart B, 50.51) **21 CFR Part 56**: (56.103-105) **45 CFR Part 46**: (46.116-117)	*Base questions on the case study or current issues highlighted in the media/social network* 1. What are the emergent ethical issues in this case study or current issue? 2. What ethical principles apply and why? What institutional resources should investigators/REB members or Chairs seek out to deal with one or more of these emergent ethical issues?

[1] *Proposed internet-based tools and interventions include: mobile device applications, mobile devices (e.g. smartphones, wearable technologies, eHealth devices), online questionnaires, interviews and research on online communities,, and online focus groups*

[2] Content developers must cover (make reference to or provide sources/resources) all other relevant provincial requirements which may be different and applicable. Ontario, Quebec, British Columbia and Alberta should be covered as a minimum.

[3] *See Appendix A for potential ethical issues/considerations to be covered*

Webinar Objective	Learning Outcomes	Assessment Criteria	TCPS2 (2014) & Applicable Regulatory Alignment[2]	Webinar Participation Assessment Question(s)
	research studies involving internet-based study tools and interventions discussed during this Webinar. **By the end of this Webinar REB Chairs/Members/Administrators should be able to:** 1. Effectively identify appropriate data security parameters in research studies involving the internet-based tools and interventions discussed during this Webinar. 2. Utilize established ethical principles in the review and assessment of appropriate consent practices in studies involving use of internet-based tools and interventions discussed during this Webinar ensuring the highest ethical standards are applied. 3. Employ relevant ethical principles and considerations in the review and assessment of appropriate parameters for access to internet-based study tools and interventions discussed during this Webinar, throughout and following study activity. 4. Effectively differentiate public space from private space in the review and approval of research studies involving internet-based study tools and interventions discussed during this Webinar.			

APPENDIX A

Technology	Ethical Issues/Considerations
Mobile Device Applications	Is it approved for use? Is it easy to use? Is the data collected held securely? Who owns the data collected through the app? Will some participants be placed at risk as they may trust and rely solely on health information provided by the app rather than seeking medical advice from a health professional?
Mobile Devices (e.g. smartphones, wearable technologies, eHealth devices	How is participant eligibility determined? Are vulnerable participants placed at higher risk of psychological or other harm? What technical support will be available for participants during the study? How will participants' expectations about the benefits and use of the device be addressed? How will access to the device after study completion be determined?
Online questionnaires, interviews and research on online communities	When and how should a researcher obtain permission to observe and gather data about an online community? (i.e. is the researcher lurking?) How does the researcher represent this data in study findings? What type of psychological risks are involved, and how will they be addressed? How will the researcher deal with a crisis? How will privacy be assured? How will online consent be obtained?
Online focus groups	How is confidentiality ensured amongst and between members? How will the data collected be represented? What type of psychological risks are involved? How will the researcher deal with a crisis with one of its members?
Internet infrastructure and data storage models	Where will the data be stored and for how long? What happens if the data is held on a server outside Canada? Who owns the data? What measures are in place to ensure the data is collected and/or held securely?

As technology is advancing rapidly, the ethical issues arising cannot be anticipated. The content of the webinar should evolve accordingly.

Webinar Topic Title: Ethical Issues Related to Research involving individuals engaged in defined Criminal Activities[1]

Target Audience: REB Members, REB Chairs, REB Administrators, Researchers/Research Teams, Learners, Institutional Administrators, Legal/Lawyers, Risk Managers

Length of Session: One hour

Webinar Objective	Learning Outcomes	Assessment Criteria	TCPS2 (2014) & Applicable Regulatory Alignment[2]	Webinar Participant Assessment Questions
To assess the ethical implications of research involving participants who are engaged in 'illegal'/criminal activities including identified terrorist organizations, and to address the application of appropriate ethical principles for the review, approval and conduct of the research – including the protections required for the research participants who are defined as 'vulnerable.	**By the end of this Webinar Researchers/Research Teams and Learners should be able to:** 1. Identify and explore appropriate alternative models of consent for research conducted within this context, including ensuring the voluntary and truly informed consent of participants. 2. Identify, explore, minimize and mitigate potential risks to participants 3. Determine, evaluate and describe appropriate protections that should be incorporated into their data management practices, including the collection, use , disclosure, retention and destruction of collected data for research conducted within this context to ensure the confidentiality and privacy of participant data and associated personal data 4. Recognize the potential legal implications that may arise in research conducted within this context 5. Appreciate and adequately plan to address issues relevant to the return of results and the publication of research data where risk of disclosure may	*Presenter shall present a Case Study or current issue highlighted in the media/social networks.* *The participant shall demonstrate the ability to:* 1. Correctly identify the ethical issues that may present in research conducted within this context 2. Describe the applicable ethical principles that will help resolve the issues 3. Explain how researchers, REB chairs/members, and participants should seek out institutional resources (local and external) to deal with one or more of these issues	**TCPS2 (2014)**: Article 5.1; Interagency Advisory Panel and Secretariat on Research Ethics Notification of Public Interpretation of Article 5.1 of the revised 2nd edition of the TCPS2(2014)	*Base questions on the case study or current issues highlighted in the media/social network.* *Require Participant responses to the following questions:* 1. What are the emergent ethical issues as presented in this session? 2. Which ethical principles apply and why? 3. What local institutional resources and/or external institutional resources should investigators/REB members or Chairs use as resources to address these ethical issues? 4. What is the nature and extent of institutions' responsibilities under Article 5.1 to "support their researchers in maintaining promises of confidentiality" where complying with legal obligations would conflict with those promises? (April 2014) 5. What are the responsibilities of

[1] (i.e., an act committed in violation of relevant laws: e.g., illegal drug use, acts committed by Terrorist Organizations [Canadian government identified/ listed terrorist entities: http://www.publicsafety.gc.ca/cnt/ntnl-scrt/cntr-trrrsm/lstd-ntts/crrnt-lstd-ntts-eng.aspx])

[2] Content developers must cover (make reference to or provide sources/resources) all other relevant provincial requirements which may be different and applicable. Ontario, Quebec, British Columbia and Alberta should be covered as a minimum.

Webinar Objective	Learning Outcomes	Assessment Criteria	TCPS2 (2014) & Applicable Regulatory Alignment[2]	Webinar Participant Assessment Questions
	engender complications for the organization, the researcher and/or participants. 6. Appreciate and describe the application of the required resources (e.g. policies and procedures, staff), within institutions and external to institutions that may assist in dealing with legal obligations to disclose vs ethical requirements to support researchers and protect their interests **By the end of this Webinar REB Members/Chairs/Administrators should be able to:** 7. Identify the ethical issues presented by research conducted within this context through the review and approval process 8. Identify and explore appropriate alternative models of consent for research conducted within this context, including ensuring the voluntary and truly informed consent of participants. 9. Identify, explore, minimize and mitigate potential risks to participants 10. Determine, evaluate and describe appropriate protections that should be incorporated into data management practices, including the collection, use , disclosure, retention and destruction of collected data for research conducted within this context to ensure the confidentiality and privacy of participant data and associated personal data 11. Appreciate and adequately plan to address issues relevant to the return of results and the publication of research			researchers, REBs and institutions with respect to privacy and confidentiality? 6. What are the institution's responsibilities when there is a conflict between ethics and legal obligations?

Webinar Objective	Learning Outcomes	Assessment Criteria	TCPS2 (2014) & Applicable Regulatory Alignment[2]	Webinar Participant Assessment Questions
	data where risk of disclosure may engender complications for the organization, the researcher and/or participants through the review and approval process. **By the end of this Webinar Institutional Administrators/Legal/Risk Managers should be able to:** 1. Recognize, manage and mitigate potential legal implications that may arise in research conducted within this context 2. Appreciate and adequately plan to address issues relevant to the return of results and the publication of research data where risk of disclosure may engender complications for the organization, the researcher and/or participants. 3. Determine, evaluate and describe appropriate protections that should be incorporated into data management practices, including the collection, use , disclosure, retention and destruction of collected data for research conducted within this context to ensure the confidentiality and privacy of participant data and associated personal data 4. Appreciate and describe the application of the required resources (e.g. policies and procedures, staff), within institutions and external to institutions that may assist in dealing with legal obligations to disclose vs ethical requirements to support researchers and protect their interests			

Webinar Topic Title: Legislative compliance issues presented in the review, consideration, approval and conduct of clinical studies – determining the difference between clinical care activities and research related activities and understanding when research specific regulations, rules and guidelines apply

Target Audience: REB Members, REB Chairs, REB Administrators, Researchers/Research Teams, Learners, Institutional Administrators, Legal/Lawyers, Risk Managers

Length of Session: One hour

Webinar Objective	**Learning Outcomes**	**Assessment Criteria**	**TCPS2 (2014) & Applicable Regulatory Alignment[1]**	**Webinar Participant Assessment Questions**
To distinguish clinical care activities from research related activity within the context of clinical studies to: assess and address the ethical implications of any failure to appropriately distinguish between these activities, to describe appropriate methods/tools to support making these determinations and demonstrate how to appropriately apply the existing regulations, rules and guidelines in the review, consideration, approval and	**By the end of this Webinar Researchers/Research Teams/Learners should be able to:** 1. Effectively distinguish clinical care(e.g. standard of care) procedures from study specific procedures 2. Assess and determine when applicable regulations, policies, rules and guidelines apply in the governance of their study(in particular as it relates to study activities) 3. Establish decision-making tools/criteria to assist in distinguishing standard of care procedures/activities from study specific activities 4. Design studies incorporating appropriate logistical considerations to appropriately manage overlapping (hybrid) standard of care and study specific activities, in particular when study specific activity is layered on top of and/or incorporated into standard of care activities/procedures to facilitate mitigating the risk of therapeutic misconception, and understanding their legal and liability risk exposure **By the end of this Webinar REB Members/Chairs/Administrators should be able to:**	A series of scenarios should be presented to participants that are representative of various study designs, including the design of a study that is being conducted appropriately in terms of the delineation between standard of care and study specific activity and appropriately managing these activities. Each scenario should incorporate one of the following elements: 1. Straightforward clinical trial with all activity being study specific 2. Hybrid/layered clinical study with both standard of care and study specific activities occurring within the study protocol 3. Clinical study evaluating multiple approved clinical interventions. 4. An investigative procedure being billed to OHIP The participants shall demonstrate the ability to : 1. appropriately distinguish standard of care procedures/activities from study specific activities 2. identify study designs/methods	**TCPS2(2014):** Chapter 11, 11.1; 11.5; 11.6; 11.10; and 11.11 **Health Canada Good Clinical Practice: Consolidated Guideline ICH Topic E6** 4.2.3; 4.2.4; 4.3.1; 4.5.1; 4.6.5; 4.6.6; 4.8.10; 4.9.6; 5.9; 6.4.4; 6.4.5; 6.14; 8.2.4; 8.2.6 **Health Canada General Considerations for Clinical Trials ICH Topic E8:** 2.2; 3.1.3; 3.2.1; 3.2.2; 3.2.3; **Health Canada Food and Drug Consolidated Regulations:** C.05.010 (f)(g) **Health Insurance Act, R.R.O. 1990, Regulation 552** S.24(16); S.28.0.2(2)a; S.28.5(2)	Base questions on the scenarios presented and the content of the webinar. Require Participant responses to the following questions: 1. How do you distinguish clinical care activities from research activities? 2. Why is it important to distinguish clinical care activities from research activities? 3. What ethical issues may present if you fail to appropriately distinguish clinical care activities from research activities? 4. What institutional resources can be leveraged in resolving: a. ethical issues regarding this subject matter b. legal and liability issues regarding this subject matter; and c. institutional business

[1] Content developers must cover (make reference to or provide sources/resources) all other relevant provincial requirements which may be different and applicable. Ontario, Quebec, British Columbia and Alberta should be covered as a minimum.

Webinar Objective	Learning Outcomes	Assessment Criteria	TCPS2 (2014) & Applicable Regulatory Alignment[1]	Webinar Participant Assessment Questions
conduct of a clinical research study.	1. Effectively distinguish clinical care(e.g standard of care) procedures from study specific procedures when evaluating studies 2. Assess and determine when applicable regulations, policies, rules and ethical guidelines apply in the governance and conduct of research studies(in particular as it relates to study activities) 3. Effectively evaluate and consider logistical implications of studies involving hybrid models of activity (standard of care and study specific) to facilitate mitigating the risk of therapeutic misconception **By the end of this Webinar Institutional Administrators/Legal/Risk Managers should be able to:** 1. Effectively distinguish clinical care(e.g. standard of care) procedures from study specific procedures when authorizing clinical research studies 2. Assess and determine when applicable regulations, policies, rules and guidelines apply in the governance of research studies(in particular as it relates to study activities) 3. Interpret the applicable law, policies, rules and guidelines to facilitate institutional legislative and procedural compliance of research engagement activities to ensure appropriate delineation of legal and liability risk and prevent inappropriate billing (OHIP and institutional operating dollars) as applicable	that make use of a hybrid/layered model incorporating both standard of care and study specific procedures/activities 3. identify solutions in study design to appropriately manage hybrid/layered model activity in clinical studies to mitigate the risk of therapeutic misconception, facilitate an appropriate informed consent process, and understand the associated legal and liability risks and delineation of the risks associated with such activities 4. determine which of the existing regulations, rules and guidelines apply to a given research study 5. identify institutional resources/departments/personnel with expertise in resolving (1) ethical issues regarding this subject matter (2) legal and liability issues regarding this subject matter; and (3) institutional business decisions required regarding this subject matter		decisions required regarding this subject matter 5. What are the existing regulations, rules and guidelines govern clinical research studies? 6. How do you determine which of the existing regulations, rules and guidelines govern a given clinical research study?

Webinar Topic Title: Risk Management Plans for Sensitive Research Topics & Researcher Safety

Target Audience: REB Members, REB Chairs, REB Administrators, Researchers/Research Teams/Research Team Members, Learners, Institutional Administrators, Legal/Lawyers, Risk Managers

Length of Session: One hour

Webinar Objective	**Learning Outcomes**	**Assessment Criteria**	**TCPS2 (2014) & Applicable Regulatory Alignment[1]**	**Webinar Participant Assessment Questions**
To assess the ethical implications of research aimed at addressing sensitive topics that threaten the safety of the researcher and demonstrate how to appropriately determine which of the existing regulations, rules and guidelines apply to risk management plans for sensitive research topics (e.g. illegal drug use, prostitution, research involving participants living in active war zones)	**By the end of this Webinar Researchers/Research Teams/Learners should be able to:** 1. Effectively identify when they should consider drafting a detailed risk management plan 2. Assess and determine when applicable regulations, policies, rules and guidelines apply in the governance of their study (in particular as it relates to study activities) 3. Establish decision-making tools/criteria to assist in distinguishing the types of research activities that raise additional concern for the safety of researchers and their teams **By the end of this Webinar REB Members/Chairs/Administrators should be able to:** 1. Effectively identify when a detailed risk management plan should be developed by researchers/research teams 2. Assess and determine when applicable regulations, policies, rules and guidelines apply in the governance of research that covers sensitive topics (in particular as it relates to researcher	*Presenter shall present a Case Study or current issue including the recent Notification of Public Interpretation of the TCPS2 regarding the nature and extent of institution's responsibilities to support researchers mainlining promises of confidentiality* *The participant shall demonstrate the ability to:* 1. Correctly identify the ethical issues 2. Describe the applicable ethical principles that will help resolve the issues 3. Explain how researchers, REB chairs/members, and participants should seek out institutional resources (local and external) to deal with one or more of these issues	**TCPS2 (2014):** Article 5.1	*Base questions on the case study or current issues highlighted in the media/social network.* *Require Participant responses to the following questions:* 1. What are the emergent ethical issues presented in this session? 2. Which ethical principles apply and why? 3. What local institutional resources and/or external institutional resources should investigators/REB members or Chairs use as resources to address these ethical issues? 4. How do you determine which of the existing regulations, rules and guidelines govern a potentially "high risk" research study? 5. What is the nature and extent of institutions' responsibilities under Article 5.1 to "support their researchers in maintaining promises of confidentiality" where complying with legal obligations would conflict with those promises?

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Webinar Objective	Learning Outcomes	Assessment Criteria	TCPS2 (2014) & Applicable Regulatory Alignment[1]	Webinar Participant Assessment Questions
	safety in the conduct of research study activities) 3. Establish decision-making tools/criteria to assist in distinguishing the types of research activities that raise additional concern for the safety of researchers and their teams **By the end of this Webinar Institutional Administrators/Legal/Risk Managers should be able to:** 1. Effectively identify when they should consider drafting a detailed risk management plan 2. Assess and determine when applicable regulations, policies, rules and guidelines apply in the governance of research studies that cover sensitive topics (in particular as it relates to researcher safety in the conduct of research study activities) 3. Interpret the applicable law, policies, rules and guidelines to facilitate institutional legislative and procedural compliance with the institutions obligation to support the ethical conduct of research while protecting the researchers against potential legal challenges, and risk exposure that might arise while meeting this obligation 4. Establish institutional standards and practices to facilitate minimizing and mitigating the potential risk researchers are exposed to in conducting research that covers sensitive topics.			6. Why are institutions required to support researchers? 7. Why is it important for the researcher to obtain independent legal advice? 8. How can the institution fulfill its responsibilities as outlined in Article 5.1 of the TCPS2(2014)?