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University of Regina

# 2021 REB External Review

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## Preamble

The Vice President Research conducted an external review of the Research Ethics Board (REB). A Review Team was invited to facilitate the review and examine the REB operation and processes. The Associate Vice President of Research, Dr. Chris Yost, shared with the Review Team written comments and input from the University community that was collated and anonymized by his office. The REB Review Team met and listened to REB stakeholders and members of the wider University community April 21-23, 2021. The meetings included current and past REB Chairs, REB support team-Research Office, Associate Deans Research, Department heads of relevant areas, Indigenous Stakeholders, and selected researchers. Participants were invited to identify strengths, weaknesses, and opportunities for improvement in current REB processes and share their experiences with the REB process.

Given the increasing complexity of the nature of research being conducted at the University of Regina, a review of the REB will provide qualitative and quantitative information, and ultimately recommendations to help the REB improve processes that will benefit University researchers.

Overall, the reviewers encountered palpable enthusiasm and a high level of engagement from across the University community. Generally, feedback regarding the Board was positive, especially towards those working in the research ethics office. The level of commentary and general feedback from the written submissions and in-person meetings was largely respectful and productive. This demonstrates genuine commitment among the participants to improve the REB process.

The Review Team was highly impressed with a good number of constructive ideas and suggestions for improvement emanating from the research community. The major areas the REB needs to address include but are not limited:

- *Transparency of the review process:* For REB applicants, the review process seems like a “black box.” Researchers submit applications and even with experience are unsure if their application is received.
- *Overly lengthy time for review process:* Whereas some reviews were received in a timely manner, others took two to three months (or more).
- *Transition to an automated online submission system for applications:* To keep up with many other processes at the University and beyond, it is time for the University to adopt an automated online system for ethics applications.
- *Quality of reviews:* Reviews are lengthy and seemingly exhaustive including both ethical and non-ethical issues.



- *REB qualifications and governance structure:* Some of the comments focused on the appointment process for REB Chair, Vice-Chair, REB membership composition, lack of community representation, training/professional development of REB members, regular meetings, and noncompliance of the board composition.
- *Graduate student REB application:* Graduate students require more training/support and their REB applications need to be prioritized.
- *Indigenous research ethics:* Indigenous researchers felt a great deal of frustration as they struggled to meet the stringent requirements of the REB guidelines that do not account for the specificity of Indigenous-based research and ways of knowing/being.
- *Community-based research:* The REB review process has hampered community-based research and alternative/non-traditional research methodologies.

The underlying themes showed a key erosion of trust between researchers and the REB, a feeling of research being policed, the REB viewed as an “ethics police,” rather than facilitating ethical research processes. The Review Team heard significant concerns regarding disenfranchisement of Indigenous research despite the unrivalled expertise of Indigenous researchers at the University.

The Review Team presents the recommendations below to suggest some ways to restore confidence in the REB and invigorate the Board as a facilitator of research at the University.



## Concerns that Require Immediate Action

The Review Team identifies the following concerns that require immediate action.

### 1. REB membership non-compliance

Currently, according to TCPS2 (2018), the University of Regina is not in compliance with the following REB membership requirements (Article 6.4):

- c. one member is knowledgeable in the relevant law. That member should not be the institution's legal counsel or risk manager. This is mandatory for biomedical research and is advisable, but not mandatory, for other areas of research.
- d. one community member has no affiliation with the institution.

Currently, there does not appear to be a REB member "knowledgeable in relevant law."

Further to this, the TCPS2 (2018) states:

The role of the member knowledgeable in the law (Article 6.4.c.) is to alert REBs to legal issues and their implications (e.g., privacy issues), not to provide formal legal opinions or to serve as legal counsel for the REB...in some instances, the legal issues that may be identified by the REB will necessitate further scrutiny and even formal legal advice by the legal counsel to the institution. Legal liability is a separate issue for the institutions to handle through mechanisms other than the REB.

Currently, there are two designated community members of the REB, both retired University of Regina faculty members.

Further to this, the TCPS2 (2018) states:

The community member shall not be affiliated with the institution (Article 6.4.d). This community member requirement is essential to help broaden the perspective and value base of the REB, and thus advances dialogue with, and accountability to, relevant communities. In addition to a broad-based representation from the community, it is highly desirable that institutions seek to appoint former participants on REBs. Their experience as participants provides the REB with a vital perspective and an important contribution to the research ethics review process. It is advisable that members are not currently engaged in research or legal work as their principal activities. The role of community members on REBs during the ethics review process is unique and at arm's length from the institution. Their primary role is to reflect the perspective of the participant. This is particularly important when participants are vulnerable and/or risks to participants are high.



To maintain effective community representation, the number of community members should be commensurate with the size of a REB and should increase as the size of a REB increases. Given the current size of the University of Regina REB (25 members), it would be expected to have at least three to four community members.

The Review Team recommends the REB (facilitated/supported by Research Office/Office of Associate VP Research Services) immediately develop a plan to recruit at least one member with relevant knowledge of the law and at least three to four community members. Other recommendations related to this are included in this document.

## **2. Overly lengthy time for review process**

As there have been time delays, loss of applications, and issues surrounding reviews, the Review Team has put together several recommendations in this document. To get a handle on the current backlog and allow for more focus on major issues we recommend appointing/hiring someone from the research office staff who has the ethical knowledge and capability to immediately review minimal risk applications. Other recommendations are included in this document.



## General Recommendations

### Review Process

A central theme identified in discussions was the review process, specifically the overly lengthy time for review, the lack of transparency of review timelines, and the extra commentary not focused on ethical considerations included in reviews. And, while the focus of ethical review should be on effectiveness, rather than efficiencies, there is some indication that both are problematic. Both can be addressed by making some adjustments.

In keeping with Article 2.9 and Article 6.12, proportionate review should be explored more fully. Specifically, the TCPS2 (2018) states:

The REB shall adopt a proportionate approach to research ethics review such that, as a preliminary step, the level of review is determined by the level of risk presented by the research: 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). A proportionate approach to assessing the ethical acceptability of the research, at either level of review, involves consideration of the foreseeable risks, the potential benefits and the ethical implications of the research (Article 2.9).

And when determining the Level of Research Ethics Review, the TCPS2 (2018) states:

In keeping with a 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) (Article 6.2).

Based on the TCPS2 (2018) and conversations with stakeholders there were several suggestions to overcome the lengthy review process. One recommendation is to vet the applications by levels of risk and delegate the reviews, such as the following. This is based on standard practice in larger REBs.

1. No/low risk - REB staff (such as Compliance officer) review and discuss with REB Chair.
2. Medium risk - Two board members, Chair and staff member.
3. High risk (full board meeting) -- Chair is primary reviewer with a second reviewer from the board. The results of the review are presented at a board meeting. Other REB members are encouraged to read, express their thoughts and weigh in at the meeting. The recommendations are tabulated and shared with the researcher in the Notice of Ethical Review.

Additionally, to alleviate the burden that exists, there is a recommendation to hire/reallocate a dedicated person (such as a compliance officer) with TCPS2 knowledge and reviewer experience, who is able to support the needs of the REB by reviewing **all** minimal risk





applications, with priorities being given to undergraduate and graduate projects. This person(s) could consult weekly with the REB Chair to review the applications and compile draft notices. This would allow the REB to focus on above minimal risk applications, reduce the bottleneck that currently exists, and offer consistency in reviews. This shift seems necessary as an immediate action item so as to alleviate the burden of piling up applications and move to address other issues.

This person(s) could also work with the REB Chair to evaluate risk. They could also evaluate risk for expedited reviews (reviews from other institutes). There could also be a process to assess the nature of the application so as to be proportionate and timely. Specifically, course-based approval, undergraduate honours projects, and graduate projects should be at the forefront of this effort so as not to hamper timely degree completion.

The TCPS2 (2018) supports the investment by the institute of research administrative staff, specifically:

It is critical that institutions provide appropriate administrative resources to REBs (e.g., research ethics administration staff, a research ethics office) for the effective and efficient operation of the REB. The means by which this support may be provided will vary by institution, but may include REB coordination, support in policy development and interpretation, record keeping, and provision of research ethics training opportunities to REB members, researchers and students. The research ethics administration staff may provide important ethics expertise in support of the REB's ethical analysis and discussion. Research ethics administration staff should also have the necessary qualifications, as well as initial and continuing training, to appropriately perform their roles and responsibilities. Institutions should recognize the integral role of research ethics administration staff and research ethics office(s), as applicable, in supporting the REB in fulfilling its mandate (Article 6.2. application).

## Flow Chart and Transparency

The Review Team heard concerns regarding REB transparency on several levels. Within the board, members mentioned that REB should show more transparency in the selection of reviewers, and better communication on the expectations of reviewers - how many review requests to expect in a given time block. From applicant experiences, the need for more transparency/better communication with applicants on status updates and clearer sense of time in review, since lengthy reviews can impede research. The Review Team recommends:

- More transparency in decision-making, review assignments, and workload expectations. Transparency of the REB includes: "Files, minutes and other relevant documentation shall be accessible to authorized representatives of the institution, researchers, sponsors and funders when necessary, to assist internal and external audits, or research monitoring, and to facilitate reconsideration or appeals" (Article 6.17, application)



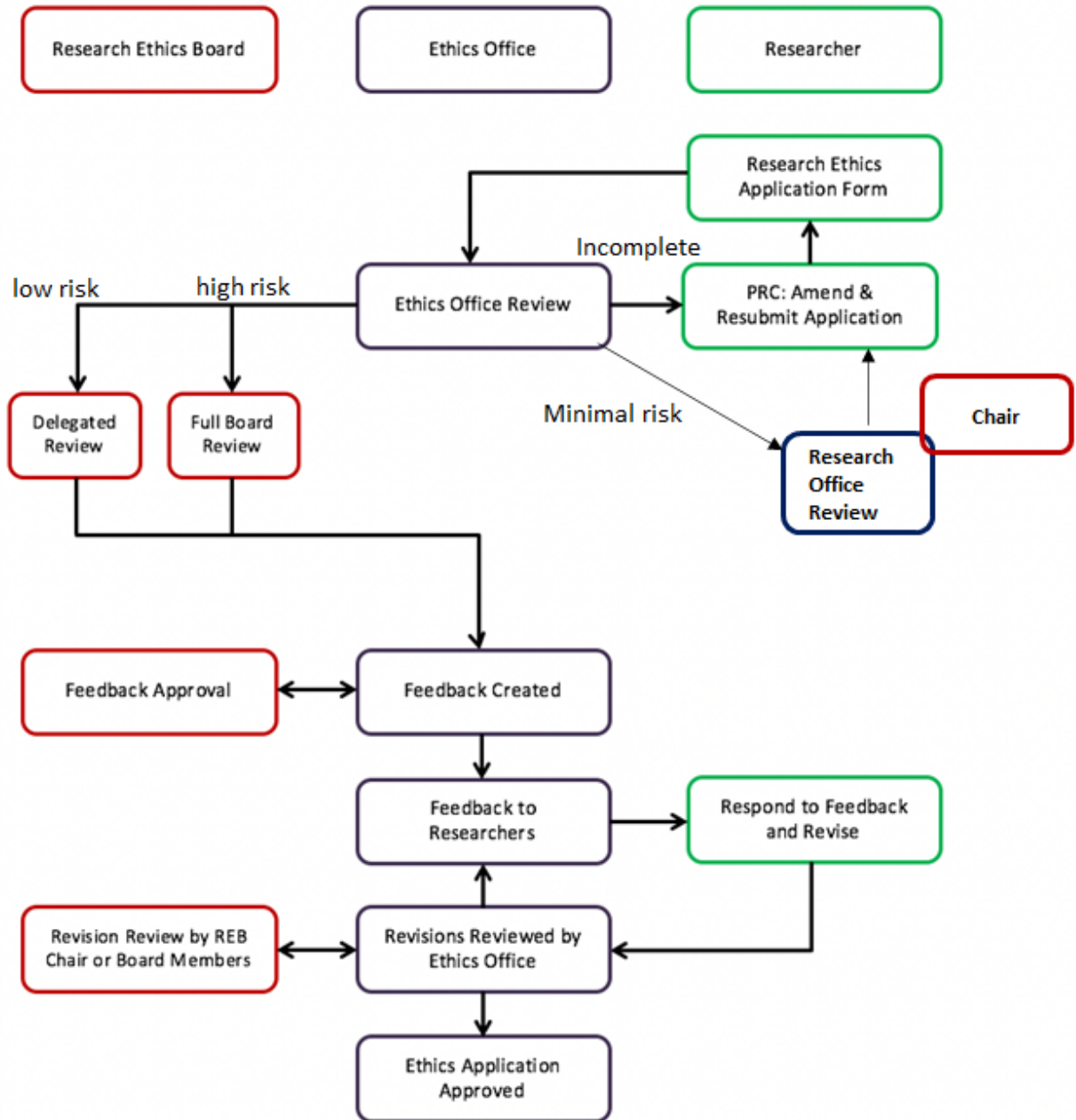
- The REB should publish and disseminate annual reports about the REB review statistics submitted directly to the Associate Vice President Research and the university community.
- The REB should come up with mechanisms to solicit feedback on REB application and review processes to improve the review process and provide better/consistent support for researchers.
- Standardized communication such as automatic email response functions to inform researchers of timelines and triage processes. A proposed email template:

"Thank you for contacting the REB. Your application has been received. Within [x time] we will let you know if there are technical problems with your submitted documents or if documents are missing from your application. Our current processing times are [x time for a simple/minimal-risk project, y time for a project with moderate risk, z time for a complex/high-risk project]. We are not able to expedite applications or confirm the status of applications prior to [x time] after submission, but other questions can be directed to [contact]."

- Develop and publish on the REB website a flow chart showing the different steps involved in reviewing REB applications so that researchers are better informed of the REB review process. The REB at the University of Guelph has designed the chart below which could be used as an example:



## Research Ethics Board Review Process



Modified from Source:

<https://www.uoguelph.ca/research/services-divisions/ethics/approval-process/flow>



As you can see from the example, changing the review process into three lanes would facilitate reduction in the backlog, consistency in reviews for minimal risk, and allow for more focus on higher risk categories by the REB. We heard that there are few full board reviews. We also suggest this modification to minimal risk review may go a long way to repairing the relationship between the REB and researchers.

### **Automated Workflow: Design Considerations**

As mentioned, there is a need to address transparency in the REB review process. Automating this process would allow for assignment of reviews, automation of communications, transparent workflow (both by researcher and reviewers), and clear delineation for connection to funding. This was echoed by members of the board, past chairs, and the AVP.

There was some concern expressed by researchers about being listed on ethics applications without their knowledge. There were also some concerns with the pdf form and its barriers to sharing and ease of use. There were indications of lost applications. There was also commentary about a lack of transparency in the workflow. All of these concerns could be removed by an automated system. However, just automating the system alone, may exacerbate issues if the previous recommendations are not considered.

There are several systems available including linking with the existing grant management system, Iriss, RAExperts, and many more custom and off the shelf systems. At NAIT, students created a home-grown system to meet the REB needs. The University of Victoria also has a custom-built system. Features to look for

1. Being able to track the review process
2. Allowing sharing of documents with researchers
3. Allowing for printouts of the pdf documents may ease transitions
4. Automated reminders for reviewers with specific timelines, such as two weeks for the review
5. Automating reminders for annual renewals
6. Include ways for REB members to declare COI, holidays, availability
7. Specific ways to ensure TCPS2 issues are flagged, ensure the ethical and collegial comments are split for example
8. Notify all applicants for verification. There was some issue with applicants not knowing their names were linked with REB submissions
9. Ensure that forms are easy to use
10. Removing the requirement for hand written signatures
11. Aligning with the process flow for reviews

Of course, an automated solution only works when the other processes are also cleaned up. This system should go hand in hand with supports, suggestions, and ideas presented in this document and suggestions from the REB and Research Office.



## Overstepping the REB Purview

There were commentaries in all sessions regarding the overstepping of the REB in their mandate, specifically including review of research design and methodology not part of research ethics. Training, consistency, ranking risk, minimal risk reviews by one person and other solutions presented in this document may provide ways to alleviate this overstepping.

Additionally, the REB should keep in mind that sometimes usurping an ethics application by making comments on research design by a student mentored by the supervisor may undermine the student-supervisor relationship. As well, there seemed to be a lack of understanding of community-based and Indigenous research practices and how they fit into the REB expectations.

Dividing the Notice of Ethical Review into three columns: Ethical Concerns, TCPS2 Guidance, Solutions might work well as an immediate strategy to reduce the tendency to include comments not associated with research ethics. For the ethical concerns, in the first column, the reviewer highlights the section of the application and writes commentary on the issue, in a second column specifically points to article/chapter/section of the TCPS2 or other guiding documents (such as information privacy), and in a third column, details the verbiage or solution from the reviewer. This allows for better communication, clears up the uncertainty of how to answer issues, and highlights important ethical concerns.

Further to this, the TCPS2 (2018) states

As part of research ethics review, the REB shall review the **ethical** implications of the methods and design of the research.

..... Research in the humanities and the social sciences that poses, at most, minimal risk shall not normally be required by the REB to be peer reviewed... if scholarly review as indicated by the relevant disciplinary tradition has not yet been done, and there is nobody available to do it, the REB should consider the following mechanisms in satisfying itself that scholarly review of the research is completed:

- establish an ad hoc independent peer review committee;
- if the REB has the necessary scholarly expertise, assume complete responsibility for the scholarly review. In assuming this responsibility, the REB should not be driven by factors such as personal biases or preferences, and should not reject proposals because they are controversial, challenge mainstream thought, or offend powerful or vocal interest groups (Article 2.7).



There are several institutes that are looking for ways to assess quality control (QC) processes in the reviews at this time. For example, McGill University has some interesting plans for QC assessments of the review process assessments and might be able to shed some light on this process.

This again, could be approached as a policing of REB reviews, and we would caution against this approach. Rather, quality control measures should be used as a learning tool to enhance the overall quality of REB reviews.

### Consistency of Review

There were many comments about lack of consistency in the reviews and even re-review of amended applications. Some of this can be dealt with using recommendations above. Other ways to improve consistency include providing templates or information sheets for frequently included information. Similar to a menu listing, clear verbiage around each tool should be consistent with informed consent information. This list could be made by researchers and the REB and a comprehensive FAQ sheet/templates could be developed. Various examples from other REBs abound and could be compiled by a summer student. There are some on the University of Regina website but are not easy to navigate.

For example, what does the REB expect when a researcher is using Zoom for an interview? Qualtrics for a survey? Is there some standardized verbiage?

“Qualtrics is **cloud based software**. All data collected under the University of Regina's enterprise license are stored on servers in Ireland. The University of Regina has an institutional license for Qualtrics, and consequently all employees and students of the University of Regina have unlimited use of Qualtrics for teaching, learning and research.”  
([Qualtrics Software Information | Information Services, University of Regina \(uregina.ca\)](#))

Based on this, informed consent documents would not need to cite the U.S. Freedom Act. However, searching the University of Regina website there was no clear guidance on what an informed consent on a survey using Qualtrics would look like. Taken from Waterloo, below is some standardized verbiage:

You will be completing the study by an online survey operated by Qualtrics. Qualtrics has implemented technical, administrative, and physical safeguards to protect the information provided via the Services from loss, misuse, and unauthorized access, disclosure, alteration, or destruction. However, no Internet transmission is ever fully secure or error free.



[If IP tracking is turned off]: “Please Note: We do not collect or use internet protocol (IP) addresses or other information which could link your participation to your computer or electronic device.”

[If IP tracking is not turned off]: “Qualtrics temporarily collects your computer IP address to avoid duplicate responses in the dataset but will not collect information that could identify you personally.” (Taken from [Information-consent letters and forms | Research | University of Waterloo \(uwaterloo.ca\)](#))

We recommend that the REB, REB Chair, Compliance Officer and Director compile a list of “frequently used verbiage” as they encounter repeated issues in submissions. Once compiled, this list could be made available to researchers and reviewers. As well, a summer student or REB sub-committee could look for verbiage or examples from other institutes.

We also suggest that the compliance officer in charge of the reviews set up weekly debrief sessions with the Chair so as to maintain consistency and include a second set of eyes examining the recommendations.

## Supports for Researchers

Our review summarized a number of issues plaguing the REB application process, including but not limited to lack of clarity about the application process and delays in processing/reviewing REB applications. A number of key participants expressed that they lack confidence in the REB’s assessment and reviews because they encountered instances of contradictory instructions. To address these issues, the Review Team **strongly recommends** that the REB develop more supports and resources for researchers:

### 1. FAQ Sheet

The Research Ethics Office needs to develop an FAQ sheet providing answers to a set of most Frequently Asked Questions (FAQs). Some FAQs, for example, may include guidelines from the Tri- Agency Framework: The Responsible Conduct of Research, a brief explanation of “risk” and “harm” to participants that the REB approval seeks to mitigate and prevent, the type of research deemed above “minimal risk” and thus requires a full REB review. This type of resource may help reduce the email inquiries the REB staff handles on a regular basis.

### Some examples of REB FAQs sheets are below:

- The University of Waterloo’s Ethics review process frequently asked questions (FAQs): <https://uwaterloo.ca/research-experiences-group/ethics-review-process-frequently-asked-questions-faqs>





- Western's FAQ - Ethics Review/Approval for studies with human participants posted on their linguistics department is also helpful:  
<https://www.uwo.ca/linguistics/research/perl/faq.html>
- University of Victoria's - Human Research Ethics Office -FAQ for a variety of frequently asked questions  
<https://www.uvic.ca/research/conduct/home/regapproval/humanethics/index.php>
- University of Victoria's - Human Research Ethics Office -FAQ conducting research virtually  
[Conducting Research Virtually with Participants: Platforms, Programs and Security](#)

## 2. Exemplary applications

To provide mentorship and education to the research community, including graduate students and postdocs, the REB has to make a reasonable effort to post/share templates and examples of exemplary REB applications that involve community-based research, Indigenous community research, surveys, interviews or other non-traditional research methods.

## 3. Checklists

Some of the frustration the Review Team heard from key participants was regarding the guidance and checklists available to REB applicants. We recommend the REB should:

- Conduct a needs assessment on where new “checklists/”support documents” are needed e.g., Is there an information document on “if you are doing research using social media...”
- Develop new guidelines to assist researchers in dual roles (e.g., University of Victoria's dual role guidelines  
<https://www.uvic.ca/research/assets/docs/Ethics/geidrr.pdf>)
- A web-based and a PDF checklist must be made available to researchers to consult prior to submitting an REB application to ensure an application is complete.

## 4. Form accessibility

Some participants have indicated that the application document has not been updated for more than a decade. The REB needs to update application forms and post them in different formats on the website.

## 5. Website

The Review Team has heard a number of complaints about the difficulties with navigating the REB website and locating relevant information. It is acknowledged that some website issues may be out of the REB Office control, but more efforts could be made to ensure the REB





website page is more user-friendly and less text heavy. Some of the changes to implement on the REB website may include:

- Update all current forms/support documents.
- Prominently post application information and guidelines so that applicants can easily locate resources.
- Publish regularly scheduled REB meetings online.
- Publish review timelines online to set clear expectations about the turnaround time for reviews.
- Update the list of the REB members and Chair's contact information.

## **6. Appeal of REB Decisions**

The Review Team heard concerns from researchers about the REB appeal process and the difficulties of navigating that process when a REB application is denied.

We recommend that a prominent link on the website and the FAQ address this concern. Additionally, researchers have to be adequately informed about the options available to them whenever the REB renders a negative decision to help demystify and facilitate the appeal process.



## Education of Researchers

The Review Team heard complaints and experiences questioning the competence of the REB members and the obstacles researchers and graduate students face when they submit REB applications. We characterize as urgent the need to make training materials and educational resources available for board members and researchers on a regular basis in the following categories:

### 1. REB Members Training

The Director of Research Services or REB compliance officer should work with the REB Chair to set clear expectations for the educational and training requirements for REB members. We recommend that an orientation package be prepared for each new REB member. Continuous educational and training opportunities focused on research ethics should be scheduled as part of regularly scheduled meetings. New policy and guidance documents should be shared with REB members to keep them engaged. In addition, the REB Office may want to support and encourage REB members to attend CAREB and workshops on research ethics.

### 2. New Faculty Training Platform (onboarding)

The REB Office and the Chair should engage with faculty members, especially new faculty, to ensure they are up to speed regarding REB application processes.

### 3. Graduate Student Training Supports

The Review Team learned that the REB Office has coordinated with the Faculty of Graduate Studies and Research to deliver presentations on research ethics and the REB application process. This is laudable and the two units need to collaborate more so that graduate students are educated on the application process and their applications should be prioritized.



## Indigenous Research Ethics

It was clear to the Review Team that there is a very strong representation of accomplished and committed Indigenous scholars and other Indigenous leaders, both within the University of Regina and the First Nations University of Canada, and the wider Indigenous community. However, despite this expertise and proven leadership, it was evident to the Review Team that the concerns of this group regarding ethical issues and processes associated with research with Indigenous peoples are numerous, serious, and longstanding. From the chronic low representation of Indigenous members on the REB to a lack of understanding of and respect for cultural traditions and values and how this impacts the interpretation of the core principles of Respect for Persons, Concern for Welfare, and Justice in ethical reviews, present serious concerns. We think it is important to highlight the following excerpt from TCPS 2 (2018):

*Chapter 9 of TCPS 2 is designed to serve as a framework for the ethical conduct of research involving Indigenous peoples. It is offered in a spirit of respect. It is not intended to override or replace ethical guidance offered by Indigenous peoples themselves. Its purpose is to ensure, to the extent possible, that research involving Indigenous peoples is premised on respectful relationships. It also encourages collaboration and engagement between researchers and participants. This chapter acknowledges the unique status of the Indigenous peoples of Canada. It interprets how the value of respect for human dignity and the core principles of Respect for Persons, Concern for Welfare, and Justice apply to research involving Indigenous peoples. It accords respect to Indigenous peoples' knowledge systems by ensuring that the various and distinct worldviews of First Nations, Inuit and Métis peoples are represented in planning and decision making, from the earliest stages of conception and design of projects through to the analysis and dissemination of results. It affirms respect for community customs and codes of research practice to better ensure balance in the relationship between researchers and participants, and mutual benefit in researcher community relations.*

In addition, whereas the University of Regina has started some initial actions in response to the *Truth and Reconciliation Commission of Canada: Calls to Action* as evidenced in *Peyak aski kikawinaw - Together we are stronger* (2018), these have not begun to address any of the issues of research ethics identified by Indigenous scholars, in fact, research involving Indigenous peoples is not mentioned in the *Call to Action* document. As the Review Team, we have grounded the following recommendations in the spirit and stated intent of *TCPS2 Chapter 9* and University of Regina's *Call to Action* document.

### 1. Indigenous Research Protocols and Expectations

The Associate Vice President of Research and Chair of REB initiate a consultation process with U of R Indigenous scholars/leaders, and other Indigenous leaders within the wider Indigenous community with the goal to establish research ethics protocols and expectations grounded in the stated purpose of *TCPS2 Chapter 9* and University of Regina's own *Call to Action* document.



## 2. REB Training and Professional Development

Completion of unconscious bias training workshop (insert name of U of R course) as a requirement for REB membership.

Completion of Indigenous Peoples' Health Research Centre (IPHRC) training module Building Research Relationships with Indigenous Communities (BRRIC) within the first year of REB membership.

Explore the possibility of Ownership, Control, Access, Possession (OCAP) training offered by the First Nations Information Governance Centre as part of REB membership professional development. There are key Indigenous stakeholders that can advise on the best path as you have this knowledge within the University of Regina.

## 3. Researcher Training and Professional Development

Explore the possibility of requiring completion of the BRRIC training module for researchers engaging in research involving Indigenous communities.



## Community-Based Research

The Review Team acknowledges the wide range of approaches to research by University of Regina researchers, from more traditional approaches to those approaches self-described by researchers as “non-traditional and/or emergent.” As approaches to research continue to grow and evolve, it is necessary to ensure that REB ethical review processes remain current and are able to adjust to and interpret these approaches.

Of particular note in this section, are concerns expressed by researchers engaged in approaches to research that are participatory and community-based. These researchers identified numerous contextual issues associated with community-based participatory research that require REB reviewers to understand and appreciate different views/and understanding(s) of ways to interpret the concepts of the core principles of Respect for Persons, Concern for Welfare, and Justice in ethical reviews. Researchers expressed serious concerns that in some instances, comments in ethics reviews were requiring changes that are contrary to accepted, and in some cases, longstanding best practices in conducting ethical research in the community-based context.

As the Review Team, we provide the following recommendations to support REB reviewers and researchers:

- 1. REB Reviewer Expertise**

Recruit REB members with community-based participatory research expertise.

- 2. REB Professional Development**

As part of ongoing professional development of REB members, invite researchers engaged in community-based participatory research to present their approaches (including identifying how they resolve ethical issues) at a Board meeting. This provides an opportunity for researchers and reviewers to have collegial discussions on best practices associated with resolving ethical issues.

- 3. Best Practices Support Document**

Compile a support document that summarizes best practices (focused on ethical issues) used by researchers engaged in community-based participatory research. Such a document will support both researchers and reviewers.



## Critical Inquiry

The Review Team heard serious concerns from some researchers, that in some instances, the REB appears to be discouraging and even prohibiting research that takes a critical inquiry approach (TCPS2, 2018, Article 3.6). According to Article 3.6, critical inquiry is “the analysis of social structures or activities, public policies or other social phenomena...where the goal of the research is to adopt a critical perspective with respect to an institution, organization or other group...”

Further to this, the TCPS2 (2018) states:

In critical inquiry, permission is not required from an institution, organization or other group in order to conduct research on them. If a research engages the participation of members of any such group without the group’s permission, the researcher shall inform participants of any foreseeable risk that may be posed by their participation. (Article 3.6)

The Review Team would like to emphasize that the application section of Article 3.6 provides important guidance that helps researchers conduct critical inquiry and REBs review of ethical matters often associated with such research. In particular, the researcher’s primary responsibilities include a “commitment to protect the anonymity and confidentiality of participants to ensure that their human rights...are not compromised” and fully inform participants of the “possible consequences of participation.” The REBs responsibility is to “concern themselves with the welfare of the participants and the security of research materials in such circumstances.” We recommend that researchers and REB members alike, familiarize themselves with Article 3.6 in order to address relevant ethical concepts associated with critical inquiry.



## Research Ethics Board Operations

Whereas the significant service commitment expected of REB members is highly commendable, there was considerable discussion about how the board learns about issues, updates, and educational efforts. It was unclear how board members stay current on Canadian research ethics. The Review Team had several recommendations including: having regular board meetings, planning ongoing REB education, and engaging in REB outreach.

### 1. Regular Meetings

Regularly scheduled board meetings allow people to build this into their schedules. And while not all reviewers may be able to make a specific time, efforts should be made to find some common time that fits most REB members. In the future, these meetings should be part of the expectation of REB members with regularly scheduled meetings set well in advance to adjust teaching and meeting dates. The TCPS2 (2018) supports this:

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.

#### Application

Face-to-face meetings are essential for adequate discussion of, and effective REB decision making on, research proposals, and for the collective education of the REB (Article 6.10).

Having a set agenda for each meeting is also a good practice. For example, including a time to review applications and any issues or learnings that arose, an educational component (such as looking at cases, or guest speakers, or specific training). This can be followed by application support as listed above (including but not limited to FAQ sheets, application form, checklists, processes, and/or policy) updates.

In terms of education, there are numerous opportunities that can be explored. For example, CAREB-ACCER has training modules, webinars and virtual ethics board case studies. And, as was seen by the stakeholders that attended the sessions, there is a wealth of knowledge within the University of Regina and First Nations University that could be tapped into. There are also University of Regina sessions such as BRRIC that abound.

### 2. Set Educational Goals

In line with regular board meetings that seek to have an educational component, additional training is recommended. This recommendation was based on concerns highlighted by researchers that REB were not familiar with aspects of the TCPS2, not clear on emergent research issues, and not clear on Indigenous research approaches. There should be concerted effort to plan specific professional development activities to enhance the REB's knowledge. A list of target areas could be made at a board meeting with specific timelines for each area. Some educational aspects could become part of the regular REB meeting, while others could be



separate endeavours that could be shared at meetings. During the consultation session, specific educational opportunities were identified such as the BRRIC training, OCAP© training, TCPS2 training, CAREB-ACCER conference and webinar training, and others.

### **3. Set Outreach Goals**

There were some indications that researchers feel the REB is acting in a policing role rather than supporting ethical compliance at the institute. There may be historical reasons for this, however, reparations need to be made to rebuild the connections between the REB and the researchers.

Outreach is one way to do this. Hosting educational sessions, which, it sounds like the Research Ethics Office is already doing, is a great endeavour and should be encouraged to continue. As well, hosting “lunch and learn” type sessions where researchers can bring their applications and concerns could be useful to strengthen the perceptions of the REB.

### **4. Celebrate the REB**

The significant service commitment expected of REB members is acknowledged and commendable. However, as was evident by the conversations, the REB is not necessarily celebrated. The time, energy, and efforts of the REB was continuously reiterated. Several stakeholders commented on the positive impact of the REB suggestions on their research study. This needs to be acknowledged and celebrated.

One recommendation is to send a letter of appreciation each year from upper administration, possibly the AVPR, to the REB member’s Department Chair, to highlight REB members’ contributions. This letter should celebrate the significant contributions (including time and effort) that is required to be on the REB.





## Research Ethic Board Membership and Leadership

### 1. Composition

As highlighted in the immediate action items, the board is currently not compliant with the TCPS2. Non-compliance could put tri-agency funding at risk across the institute if not addressed. Proportional representation and compliance with Article 6.4., specifically persons knowledgeable in the law and community representation must be addressed. Ideally, community representation could also help to address the “serious gap” identified between the REB and the Indigenous community. Community engagement, such as reported by the Indigenous Peoples' Health Research Centre, might be a good model to explore in terms of community membership and involvement.

The University of Regina has a large REB considering the number of applications reviewed each year. As a comparison, for example, the University of Victoria has 20 members and reviews three to four times as many applications. Having more people on a REB does spread around the workload but it also means there are more issues such as obtaining quorum, obtaining consensus and collaboratively reviewing.

### 2. REB Membership and Selection, including the Chair and Members

#### a. REB Chair

Throughout the consultation process, there were several mentions concerning the appointment and qualifications of the REB Chair. That is not to say the current chair is not qualified nor adequately appointed, as these concerns may also stem from historical issues.

The Chair role is critical. To reiterate its importance, according to the TCPS2 (2018):

The REB Chair is responsible for ensuring that the REB review process conforms to the requirements of this Policy.

#### Application

The role of the REB Chair is to provide overall leadership for the REB and to facilitate the REB review process, based on institutional policies and procedures and this Policy. The Chair should monitor the REB's decisions for consistency and ensure that these decisions are recorded accurately and communicated clearly to researchers in writing as soon as possible by the Chair or his or her designate. Institutions shall provide the necessary resources and adequate administrative support to enable the REB Chair to fulfill his or her responsibilities (Article 6.8).



There was also some discussion regarding the chair appointment. Having the REB decide who sits as Chair is in alignment with TCPS2 (2018), specifically “REBs are independent in their decision making and are accountable to the highest body that established them for the process of research ethics review” (Article 6.2). In keeping with this role, there should be clear terms of reference, expectations, and obligations (see Appendix A - Sample terms of reference for Chair and Vice Chair University of Victoria). The Chair should be qualified or at least supported in obtaining professional development to support their role at the institute.

**a. REB Vice Chair**

In addition to clarity in the REB chair role, the Review Team recommends exploration of the possibility of establishing a Vice Chair position (see Appendix A University of Victoria terms of reference for Chair and Vice Chair). This role could support the Chair by reviewing a smaller proportion of applications. For example, the chair/vice chair could be responsible for 75%/25% of reviews. This time commitment could also be supported by a smaller course release.

**c. REB Members Expectations**

There should also be clear expectations and terms for REB members. This can be included in an orientation package (See Appendix B: University of Victoria Information Package for New HREB Members). This package should include at minimum, a letter of engagement that details expectations, code of conduct and terms of service. The package could also contain a confidentiality agreement (what happens at REB meetings stays at REB meetings), a list of REB members, their terms and contacts (to allow for connections or advice to be sought), clear details regarding terms of removal from the REB. Each board member should submit a resume, a CORE tutorial certificate, and a clear indication of which role they fulfill under Article 6.4.

**3. Communication between Chair and the Research Office Staff**

There seems to be a disconnect between REB reviews, the REB Chair and the Research Office staff. To alleviate this, it is recommended the Chair meet regularly (i.e., weekly/biweekly) with the ethics administrative staff to discuss applications and issues as they arise. This communication allows for both to effectively address issues as they arise, problem solve any risk mitigation strategies, prioritize applications and have open communication regarding any concerns. A clear agenda and formal meetings biweekly, along with weekly informal conversations may go a long way to bridge this gap.



## **Conclusion**

The University of Regina has amazing potential and could easily be a leader in Canadian Research Ethics given the skills observed in the stakeholder consultations. Small changes can lead to big impacts, but the biggest change is often the desire to improve. We are happy that the institute has taken steps to hold stakeholder consultation and is sharing this desire. The number of constructive suggestions, the expertise, and the level of engagement at the stakeholder's meetings and comprehensive written submissions was to be commended.



## Appendix A: Chair and Vice Chair Terms of Reference (University of Victoria)

### ROLES AND RESPONSIBILITIES of Human Research Ethics Board Chair and Vice-Chair April 2019

#### **HREB CHAIR**

The Human Research Ethics Board (HREB) Chair is appointed by and reports to the Vice-President Research. The HREB Chair provides leadership and guidance regarding the monitoring and conduct of all research involving humans in accordance with the most current version of the Tri-Council Policy Statement.

The HREB Chair provides oversight of the HREB and the integrity of the human research ethics review and approval process at the University of Victoria, according to University of Victoria Human Research Ethics policies and procedures. The Associate Vice-President Research Operations (AVPRO) provides guidance and support to the Chair when appropriate.

#### **Responsibilities**

- Chairs HREB meetings and prepares meeting agendas in consultation with REB staff; reviews minutes
- Advises regarding board development, recruitment, structure
- Reviews all types of applications: full-board/above minimal, board review, expedited review, course-based, anonymized data, and anonymized biological materials, and harmonized studies.
  - o If the Chair has a conflict of interest on an application, the application is assigned to the Vice-Chair. The assignment of applications between the Chair and the Vice-Chair may be facilitated by HRE staff and takes into account adequate HREB workflow coverage in the event of vacations and absences.
- Works closely with HRE Coordinator, HRE Facilitator and HRE Liaison in scheduling the review of applications to facilitate timely reviews; consults with student and faculty researchers when needed
- Finalizes notices of ethical review prepared by HRE staff
- Creates notices of ethical review for applications where the Chair is the only reviewer and where the study has not been assigned to HRE staff
- Monitors the HREB's decisions at board meetings, ad hoc review meetings, and board member reviews for consistency and proportionate review; ensures that these decisions



are recorded properly and that researchers are given written communication of the HREB's decisions (with reasons for negative decisions) as soon as possible

- Acts on behalf of the HREB in approving ethics applications for new research that are above minimal risk and minimal risk research (unless delegated to the HRE Coordinator or Facilitator, in the case of modifications and annual renewals)
- Acts on behalf of the HREB in reviewing modifications of approved studies that may require a higher level of proportionate review
- Assists with investigations and advises regarding incidents, complaints, and concerns such as breach of ethical requirements; liaises with students, supervisors, department chairs and other UVic entities when applicable (e.g., Faculty of Graduate Studies)
- In consultation with HRE staff, determines when a project is exempt from HRE review
- Represents the UVic HREB at meetings and conferences when applicable
- Member of Human Research Ethics Advisory Committee (HREAC)
- Assists with recruitment of Vice-Chair
- Sends out call for new graduate student members, and in consultation with the Research Ethics Facilitator, interviews candidates
- Assists with the educational mandate of HREB
- Contributes to HRE policy development and revises, where/when appropriate and in consultation with HRE staff, HRE application forms, documents and policies (internal and external)
- Nominates appropriate ad hoc members for the duration of the review when expertise is not available on the existing board
- Works with the HREB Vice-Chair to support the HREB

## **HREB VICE-CHAIR**

The Human Research Ethics Board (HREB) Vice-Chair is appointed by and reports to the Vice-President Research. The HREB Vice-Chair supports the HREB Chair in providing leadership and guidance regarding the monitoring of conduct of all research involving humans in accordance with the most current version of the Tri-Council Policy Statement.

The HREB Vice-Chair provides back-up to the Chair's responsibilities in the event the Chair is absent, on vacation, or is unable to carry out their responsibilities. The Associate Vice-President Research Operations (AVPRO) provides guidance and support to the Vice-Chair when appropriate.



## **Responsibilities**

- In consultation with the Chair and/or HRE staff on the assignment of applications, reviews the following types of applications: full-board/above minimal, board review, expedited review, harmonized review. The assignment may also include course-based, anonymized data, and anonymized biological materials; this is usually determined in consultation with the Chair, but in the event the Chair has a conflict or is unable to carry out a review, the Vice-Chair assumes responsibility for these latter types of applications, as required.
  - o If the Vice-Chair has a conflict of interest on an application, the application is assigned to the Chair. The assignment of applications between the Chair and Vice-Chair may be facilitated by HRE staff and takes into account adequate HREB workflow coverage in the event of vacations and absences by the Chair.
  
- On those applications that are assigned to the Vice-Chair:
  - o Works closely with HRE Coordinator, HRE Facilitator and HRE Liaison in scheduling the review of applications to facilitate timely reviews; consults with student and faculty researchers when needed
  - o Finalizes notices of ethical review prepared by HRE staff
  - o Assists in the monitoring of the HREB's decisions at board meetings, ad hoc review meetings and board member reviews for consistency and proportionate review; ensures that these decisions are compiled properly in notices of ethical review
  - o Acts on behalf of the HREB in approving ethics applications for new research that are above minimal risk and minimal risk research (unless delegated to the HRE Coordinator or Facilitator, in the case of modifications and annual renewals)
  - o Acts on behalf of the HREB in reviewing modifications of approved studies that may require a higher level of proportionate review
  - o In consultation with HRE staff, determines when a project is exempt from HRE review
  - o Member of Human Research Ethics Advisory Committee (HREAC)
  - o Assists with the educational mandate of HREB
  - o Contributes to HRE policy development
  - o Represents the UVic HREB at meetings and conferences when applicable



## Appendix B: Information Package for New REB Members (University of Victoria)

### The University of Victoria Human Research Ethics Board

#### *Information for Prospective Board Members*

##### Preamble

The Human Research Ethics Board (HREB) provides an important service to the University's research and teaching missions in departments and disciplines where research involving humans and human biological materials is conducted. The work of the Board is critical in ensuring that faculty researchers meet regulatory requirements, are cleared to access research funds (if applicable), and are ready to begin their projects in a timely manner. Likewise, the Board's work interacts with and supports graduate student research across campus by providing constructive ethical assessments of a study, and having an impact on the start date of research for theses and dissertations.

##### Mandate

The Human Research Ethics Board is a regulatory board whose mandate is to certify that all research involving human participants and human biological materials conducted by University of Victoria researchers (faculty, students and staff) conforms to agreed-upon ethical guidelines ([University Policy RH8105](#)) and federal requirements.

All board members are volunteers. They do not receive monetary compensation for their service.

As a condition of receiving federal research funds, the university has signed an Agreement with the Tri-Council — the major federal funders comprised of the *Social Sciences and Humanities Research Council (SSHRC)*, *Natural Sciences and Engineering Research Council (NSERC)*, and the *Canadian Institutes of Health Research (CIHR)* to abide by the research ethics guidelines as described in the second edition of the *Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans (TCPS2)*.

<http://www.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/>



## **Structure and Composition**

The Board is part of the Vice President Research portfolio under the Associate Vice-President Research Operations (AVPRO).

The Board is comprised of 20-22 members at any one time, the majority of whom are faculty from various departments covering a range of research expertise. The Board is led by a Chair and a Vice-Chair (faculty members). Members are appointed by the Associate Vice-President Research Operations.

In addition, the Board includes two or three people from the local community and two or three UVic graduate students at any one time. Community members are provided with UVic parking tickets when attending meetings.

The Human Research Ethics unit within the Office of Research Services provides administrative support to the Board. Staff of the Office of Research Services (Coordinator, Facilitator, Liaison and Assistant) work closely with the Board, Chair and Vice-Chair but are non-voting members.

## **Why Join?**

*“[I]t was far and away the best committee I have ever been on, in the sense that it was always raising interesting and important issues that have deep professional and personal relevance to me, and I very much enjoyed seeing and assessing the proposals, which I always found a highly engaging and creative and critical process. I don’t normally think of committee work as fostering these sorts of processes, but for me, the HREB [Human Research Ethics Board] certainly did.” - Former Board Member*

*“I thoroughly enjoyed my time on the board and the many learning opportunities it provided. The experience allowed me to develop a level of comfort and capacity with ethics applications and reviews that will benefit me for the duration of my academic career!” – Former Board Member*

## **Terms of Service**

Board members are appointed for a term of three years by Associate Vice-President Research Operations with the option of re-appointment for a second three-year term.

Graduate student members are normally appointed for a one-year term with the option of re-appointment for an additional one-year term depending on anticipated program completion.





**All board members agree to:**

- Attend all scheduled board meetings (see schedule)
- Come to board meetings prepared to provide comments when an application is assigned for review at a board meeting. Primary and secondary reviewers will be identified for each application
- Review **two to three** assigned applications each month (*over 12 months*) and file their review comments within 10 days of receiving the application
- Attend an ad hoc meeting to review an above minimal application when required/called upon (see ad hoc review meetings)
- Provide the ethics office with prior notification of sabbaticals and holidays and consider reviewing a few additional applications before anticipated leaves or holidays in order to avoid build-up of applications upon their return.
- Attend a new board member training and orientation session (normally in September)
- Complete the TCPS2 Course on Research Ethics ([TCPS2 CORE](#) online ethics tutorial) within two to three months of their appointment start date. New board members will not be assigned applications for review until they have completed the tutorial.

**Board Meeting Schedule**

The Board meets on the **third Tuesday** of the following months in the morning or afternoon to support teaching and work schedules etc. and maximize attendance for quorum. One above minimal risk or ethically interesting application is normally reviewed at each board meeting provided that such a study is identified.

September 22, 2:00-3:30pm  
November 17, 9:00-10:30am

January 19, 2:00-3:30pm  
March 16, 2:00-3:30pm



May 18, 9-10:30am

\* Note that schedule may change

Board meetings are usually held in the Michael Williams Building (MWB). Special presentations and events may also be planned.

### Ad Hoc Review Meetings

During summer months (June through August) and months without a scheduled board meeting, a small number of board members may be contacted to review an above minimal risk application together at a specially scheduled meeting.

### Conduct 2-3 Reviews of an Assigned “Medium Risk” Application Per Month, Over 12 months

The office receives approximately 600 applications for new research each academic year. A portion of these applications (about 30%) are assigned for review to board members due to the medium level of risk associated with the research.

Two board members are assigned to review one application. Each board member can expect 2-3 assigned applications for medium level of risk per month. Staff members assign applications to board members as evenly as possible to allow ample time between applications.

Board members are expected to be available during the summer months (June through August) and other times of the year to review these medium risk applications (via email). In the event they are unavailable to review for a period of time, they should notify the ethics office in advance.

Board members file their comments to the office via email usually within 10 days of receiving the application. Each review takes **about 30-45 minutes** depending on application length and complexity.

The ethics assistant will contact board members to confirm that he/she is available to review an application and that there is no conflict of interest with the researcher/study before the application is assigned.



### **Orientation and Training**

The research ethics staff provides an orientation and training to new Board members. The orientation is normally scheduled for late August or early September.

All members are required to complete TCPS 2 Course on Research Ethics ([TCPS2 CORE](#)) on their own time before they can commence reviewing applications.

<http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/>

Scheduled board meetings include guest speakers and topics of interest as identified by the Board, Chair, Vice-Chair and staff.

Ongoing professional development opportunities are scheduled during board meetings with guest speakers, the review of above minimal risk or ethically complex applications, and special topics throughout the year.