

**University of Windsor
Senate**

5.3.2: **Report of the Research Ethics Board**
(January 2023 – March 2024)

Item for: **Information**

Forwarded by: **Senate Governance Committee**

See attached.



University
of Windsor

Office of Research Ethics

REPORT TO SENATE

January 1, 2023 – June 30, 2023

and

July 1, 2023 - March 31, 2024



University
of Windsor

Office of Research Ethics

RESEARCH ETHICS BOARD Report to Senate

January 1, 2023 – March 31, 2024

INTRODUCTION

Ethics review and the approval of research involving human participants derives its legitimacy from the *Declaration of Helsinki*, which indicates that protocols must be submitted for consideration, comment, guidance, and approval to a research ethics committee before the study begins (WMA, Guidance 23). Nations who agree to abide by the *Declaration* can establish their own ethics framework; however, they must meet the standards established in the *Declaration*, including ethics review of protocols. As a signatory to the *Declaration*, the Canadian *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2022)* complies with the principles in the *Declaration*, including the establishment of ethics review committees and their responsibilities.

The University of Windsor Research Ethics Boards (REB) and the Office of Research Ethics (ORE) operate in accordance with the *TCPS2* and the *Declaration*. The two Full Boards, and their delegated Committees, are responsible for reviewing the ethical acceptability of all research involving humans conducted within the jurisdiction of the University of Windsor or under its auspices. This includes research conducted by faculty, staff, students, and affiliates regardless of where the research takes place or whether the project is funded (*TCPS2*, 6.1). Research requiring REB review includes all projects involving human participants or human biological materials derived from living or deceased individuals (*TCPS2*, 2.1).

Relationship to the University

As noted in the *TCPS2* Article 6, to ensure the integrity of the research ethics review process and to safeguard public trust in that process, the REB operates independently in its decision making and should be free of inappropriate influence, including situations of real, potential, or perceived conflicts of interest (*TCPS2*, 6.2). REB communications with researchers, review deliberations, and records are confidential and accessible only to REB members on a need-to-know basis. The REB is accountable to the highest body that established them for the process of research ethics review (*TCPS2*, 6.2) and so reports to the University of Windsor Senate on its operations. The REB Chair meets periodically together with the Chair of the ACC, and Chair of the RSC, with the Vice President, Research and Innovation.

Although the REB and ORE operate at arms-length from the University, their work provides an important contribution to the core mission of the University. Through consultation with faculty, students, and affiliated researchers on the ethical conduct of research, the REB contributes to improvements in research protocols which support ethical participant engagement and trustworthiness. Educational presentations, workshops and resources on research ethics scholarship contribute to the quality of research education for students and support the research endeavors of faculty and staff. University community engagement is strengthened through providing ethics review and acting as the Board of Record for community partners, including regional hospitals and the Windsor Essex Community Health Unit as well as responding to requests from local community organizations. The creation of the new Indigenous Review Committee is a first step in the work toward building more trustworthy and respectful relationships with our Indigenous scholars and communities. Finally, the expertise that the ORE, REB Chair and REB members bring to protocol reviews and provide to their colleagues strengthens the research community and promotes impactful research contributing to the improvement of the Windsor-Essex region, nationally, and globally.

THE OFFICE OF RESEARCH ETHICS

The TCPS2 stipulates that institutions provide appropriate administrative resources to their REBs (e.g., research ethics administration staff, a research ethics office, review resources) for the effective and efficient operation of the REB (TCPS2, 6.2). The University of Windsor ORE is staffed by a faculty member acting as Research Ethics Board Chair, a full-time Manager and a full-time Coordinator. The ORE is responsible for supporting all activities of the REB including: developing policies and procedures for operational and committee functions; managing the protocol review process from pre-submission through to file closure; scheduling Full Board and Delegated Review Committee meetings; communicating with researchers on REB requests for revisions, comments and final decisions; documentation and record-keeping; and protocol monitoring. The ORE is also responsible for providing education to the University of Windsor community on research ethics, offering consultation and guidance, conducting workshops and presentations, developing resources on research ethics, and providing expertise on local, national, and international regulations and issues on research ethics.

Office of Research Ethics Staff

Manager, Office of Research Ethics

Ms. Harmony Peach

Coordinator, Office of Research Ethics

Mrs. Mary Jane Nohra

RESEARCH ETHICS BOARDS AND DELEGATED REVIEW COMMITTEES

Protocol reviews are conducted under the TCPS2 guidance of proportionate review (TCPS2, 1C, 2.9, 6.12). The Chair of the REB determines the level of review and assigns protocols to REB Committees. Protocols considered *more than minimal risk* are reviewed by one of two Research Ethics Full Boards—Socio-Behavioral or Biomedical—which meet monthly. Protocols determined to be *minimal risk* are reviewed by the main Delegated Review Committee which is comprised of four Full Board members who are specifically assigned as delegated reviewers or a specialty Delegated Review Committee. The primary Delegated Review Committee meets at least once every week during the academic year and weekly or bi-weekly over the summer, unless the number of protocol submissions requires additional meetings. The specialty Delegated Review Committees include a Biomedical Delegated Review Committee, the Scholarship of Teaching and Learning (SoTL-E) Committee and a recently established Indigenous Research Committee.

Protocols involving secondary use of data, administrative research, protocols cleared by another REB, and other minimal-risk applications, are executively reviewed by the Chair, or the Chair and a second REB member. Determinations of exemptions from REB review under TCPS2 2.2-2.6 are determined by the REB Chair. Please see *Appendix A* for a detailed flow chart of how applications are processed, *Appendix B* for an overview of the REB Board review and responsibilities and *Appendix C* for the ORE and REB Workflow.

REB MEMBERSHIP

The REB depends upon service commitments from faculty, students, and community members to conduct its work. The TCPS2 requires that the REB be comprised of faculty members with expertise in relevant research disciplines, fields, and methodologies representative of the types of research reviewed by the REB (TCPS2, 6.4). Additional members required by the TCPS2 are: one member knowledgeable in ethics; one member knowledgeable in law; student representatives; and members from the community who are not associated with the University (TCPS2, 6.4 a-d). Full Board members serve three-year terms which are renewable. Full Board REB members do not receive any compensation and provide approximately 10-12 hours per month of service. The primary Delegated Review Committee is comprised of the Chair

plus four Full Board members who serve one-year terms, which are renewable. Delegated review members receive compensation in the form of workload relief or research grants and provide 8-15 hours per week in service throughout the year, including the summer. Members of the specialty Delegated Review Committees do not receive compensation and only meet when a relevant protocol is assigned to them for review.

The REB Chair facilitates meetings of both Socio-Behavioral and Biomedical Boards, the primary Delegated Review Committee and the Biomedical Delegated Review Committee. The Manager, Office of Research Ethics chairs the SoTL-E Committee and the Indigenous Research Committee. Members of Delegated Review Committees are all assigned to one of the two Full Boards as per the TCPS2 requirement (TCPS2, 6.12). The two Full Boards set policy for the REB, engage with the Chair on research ethics issues, and are the final arbiters on application decisions.

REB Members Full Board and Delegated Committees, January 2023-June 2024

SOCIO-BEHAVIOURAL FULL BOARD

Dr. Scott Martyn, Chair January 1, 2023-June 30, 2023

Dr. Suzanne McMurphy, Chair, July 1, 2023—June 30, 2024

Ms. Harmony Peach, Manager, Office Research Ethics

Ms. Elise Bosson, M.S.W., R.S.W.

Full Board Socio-Behavioural; Community Representative

Dr. Laura Chittle

Full Board Socio-Behavioural, SoTL-E; Centre for Teaching and Learning

Dr. Marc Frey

Full Board Socio-Behavioural, Full Board Biomedical; WECHU representative, community representative

Dr. Glynis George

Full Board Socio-Behavioural; Sociology, Anthropology, and Criminology, Faculty Member

Ms. Kristen Hales

Full Board Socio-Behavioural; Legal Representative

Ms. Megan Kalbfleisch

Full Board Socio-Behavioural; Student Representative

Dr. Calvin Langton

Full Board Socio-Behavioural, Delegated Review Committee; Psychology, Faculty Member

Dr. Rosanne Menna

Full Board Socio-Behavioural, Delegated Review Committee; Psychology, Faculty Member

Dr. Carlin Miller

Full Board Socio-Behavioural; Delegated Review Committee, Psychology, Faculty Member

Ms. Fallon Mitchell

Full Board Socio-Behavioural; Kinesiology, Student Representative

Ms. Samantha Monk

Full Board Socio-Behavioural; Student Representative

Mr. Jesse Myers

Full Board Socio-Behavioural; Student Representative

Mr. Russell Nahdee

Full Board Socio-Behavioural; Indigenous Research Committee; Office of Open Learning

Dr. Kathy Pfaff

Full Board Socio-Behavioural; Nursing, Faculty Member

Dr. Katherine Rudzinski

Full Board Socio-Behavioural, Delegated Review Committee; Social Work, Post Doctoral Fellow

Dr. Francine Schlosser

Full Board Socio-Behavioural; Odette Research Chair

Mr. Mason Sheppard

Full Board Socio-Behavioural; Student Representative

Dr. Allyson Skene, CTL

Full Board Socio-Behavioural, SoTL-E; Centre for Teaching and Learning

Dr. Maureen Sterling

Full Board Socio-Behavioural; Business, Faculty Member

Dr. Vasanthi Venkatesh

Full Board Socio-Behavioural; Law, Faculty Member

BIOMEDICAL FULL BOARD

Dr. Scott Martyn, Chair January 1, 2023-June 30, 2023

Dr. Suzanne McMurphy, Chair, July 1, 2023—June 30, 2024

Ms. Harmony Peach, Manager, Office Research Ethics

Dr. Stephen Bartol

Full Board Biomedical; Community Representative

Mr. Victor Eghujovbo

Full Board Biomedical; Student Representative

Dr. Shelley Evans

Full Board Biomedical; Faculty Member

Dr. Catherine Febria

Full Board Biomedical; GLIER, Faculty Member

Dr. Marc Frey

Full Board Socio-Behavioural, Full Board Biomedical; WECHU representative, community representative

Dr. Adrian Guta

Full Board Biomedical and Delegated Review Committee; Social Work, Faculty Member

Ms. Maja Jelich

Full Board Biomedical; Student Representative

Dr. Philip Karpowicz

Full Board Biomedical; Biology, Faculty Member

Dr. Jessica Kichler

Full Board Biomedical; Psychology, Faculty Member

Dr. Matthew Krause

Full Board Biomedical; Delegated Biomedical Committee, Research Safety Committee Representative; Kinesiology, Faculty Member

Dr. Wallace Liang

Full Board Biomedical; WRH Representative, Medical and Community Representative

Dr. Saverpierre Maggio

Full Board Biomedical; Windsor Regional Hospital/Legal Representative

Ms. Sherri Lynne Menard

Full Board Biomedical; Health and Safety Representative

Ms. Karen Metcalfe

Full Board Biomedical; Associate Director WE-Spark

Ms. Krista Naccarato

Full Board Biomedical; Vice Chair; WRH Representative, Community Representative

Ms. Samira Narimannejad

Full Board Biomedical; Student Representative

Dr. Siyaram Pandey

Full Board Socio-Behavioural; Full Board Biomedical; Chemistry & Biochemistry, Faculty Member

Ms. Elnaz Akhavan Rezaee

Full Board Biomedical; Student Representative

Ms. Nadia Roopnarine

Full Board Biomedical; Student Representative

Dr. Jennifer Voth

Full Board Biomedical; HDGH Representative; Community Representative

Mr. Andrew Ward

Full Board Biomedical; Student Representative

DELEGATED REVIEW COMMITTEE

Dr. Scott Martyn, Chair January 1, 2023-June 30, 2023

Dr. Suzanne McMurphy, Chair, July 1, 2023—June 30, 2024

Dr. Adrian Guta

Full Board Biomedical and Delegated Review Committee; Social Work, Faculty Member

Dr. Calvin Langton

Full Board Socio-Behavioural, Delegated Review Committee; Psychology, Faculty Member

Dr. Rosanne Menna

Full Board Socio-Behavioural, Delegated Review Committee; Psychology, Faculty Member

Dr. Katherine Rudzinski

Full Board Socio-Behavioural, Delegated Review Committee; Social Work, Post Doctoral Fellow

SCHOLARSHIP OF TEACHING AND LEARNING AND EDUCATION (SOTL-E) REVIEW COMMITTEE

Ms. Harmony Peach, Manager, Office Research Ethics, Chair

Dr. Allyson Skene, CTL

Full Board Socio-Behavioural, SoTL-E; Centre for Teaching and Learning

Dr. Clayton Smith

Education, Faculty Member

Dr. Christopher Greig

Education, Faculty Member

Ms. Ashlyne O'Neil

Full Board Socio-Behavioural, SoTL-E; Office of Open Learning

Dr. Laura Chittle

Full Board Socio-Behavioural, SoTL-E; Centre for Teaching and Learning

BIOMEDICAL DELEGATED REVIEW COMMITTEE

Dr. Suzanne McMurphy, Chair, July 1, 2023—June 30, 2024

Dr. Christopher Abeare

Psychology, Faculty Member

Dr. Anthony Bain

Full Board Biomedical; Human Kinetics, Faculty Member

Mr. Victor Eghujovbo

Engineering, Student Representative

Dr. Matthew Krause

Full Board Biomedical; Human Kinetics, Faculty Member

Dr. Cheri McGowan

Human Kinetics, Faculty Member

INDIGENOUS REVIEW COMMITTEE

Ms. Harmony Peach, Manager, Office Research Ethics, Chair

Dr. Catherine Febria

Full Board Biomedical; GLIER, Faculty Member

Ms. Jaimie Kehego

Centre for Teaching and Learning Field of Indigenization

Mr. Russell Nahdee

Full Board Socio-Behavioural; Office of Open Learning

Ms. Naomi Williams

Doctoral Student, Social Work

REGIONAL BOARD OF RECORD AND COLLABORATION WITH WINDSOR REGIONAL HOSPITAL

The University of Windsor REB is under contract with several institutional partners as their Board of Record to review, clear, and provide oversight of the ethical acceptability of research being conducted by their staff or taking place under their auspices. The REB operates as the Board of Record for Erie Shores Healthcare, Hôtel-Dieu Grace Healthcare (HDGH) and Windsor-Essex County Health Unit (WECHU). The REB provides research ethics guidance to community organizations on research ethics issues but provides ethical review and clearance only under contract; the REB establishes short-term contracts with community organizations for individual projects.

The University of Windsor REB and Windsor Regional Hospital (WRH) REB collaborate to streamline ethics review for research which falls under both jurisdictions. To foster this ongoing collaboration, Dr. Wally Liang, Dr. Saverpierre Maggio, and Krista Naccarato, are members of the University of Windsor Full Biomedical Board as WRH representatives and Dr. Suzanne McMurphy is a member of the WRH REB. The REB is currently exploring a Memorandum of Understanding with WRH to establish reciprocity for clearing applications for secondary use of WRH patient and medical data and human tissue research protocols.

Single Institutional Review Board with US Universities and International Research

The University of Windsor REB acts as the Single Institutional Board of Record (sIRB) for the University of Michigan and the University of Nebraska for projects being conducted by University of Windsor researchers. Since 2019, the US regulations under US 45 CFR 46 allow for a single IRB to be the Board of Record with multi-jurisdictional studies. As the sIRB, the University of Windsor operates under the US regulatory guidelines to approve and oversee the ethical acceptability of specific research projects conducted by the University of Windsor researchers. This is a significant service to University of Windsor researchers as it means that applications and oversight are under one ethics review committee and researchers do not need to duplicate applications, requests to revise, and reporting across ethics committees in two countries.

To provide this level of support to the University of Windsor researchers, the REB Chair must have a background in reviewing applications under US 45 CFR 46, the Federal Policy on Protection of Human Subjects (Common Rule) and remain familiar with interpretations of these regulations under the Office of Human Research Protection (OHRP). It is also beneficial if the REB Chair is familiar with international research guidelines and their interpretation and application, including World Medical Association guidelines under CIOMS, UK BERA, GDPR requirements and generally within the International Compilation of Human Research Standards (<https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html>) to support University of Windsor researchers conducting international projects.

REB PROTOCOL REVIEW ACTIVITY January 1, 2023—December 31, 2023, and January 1-March 31, 2024

Protocol reviews and monitoring are the activities of the REB which require the most amount of REB labour. Each new file submitted to the REB requires approximately 10-20 hours from point of submission to clearance. This includes: initial processing for file completeness and assessment of readiness for review; assignment to review committee; committee members' individual time to review the protocol; time in committee review; sending comments and communicating with researchers; reviewing researchers' response to comments, protocol modifications, and determining clearance; data entry and file processing. Pre-submission consultations with researchers can vary from several minutes to several hours and over multiple time periods depending upon the complexity of the protocol. Please see *Appendices A, B and C* for visual overviews of application review processes, Boards and committees by type of application, and a detailed flow chart of REB and ORE workflow.

Table 1A: New Applications by Level of Review
January 1, 2023-December 31, 2023

Socio-Behavioural Board	2
Delegated	110
Executive	65
Biomedical	6
SoTL-E	13
Withdrawn	8
Total	204

Table 1B: New Applications by Level of Review
January 1, 2024-March 31, 2024

Socio-Behavioural Board	2
Delegated	32
Executive	16
Biomedical	4
SoTL-E	3
Withdrawn	1
Total	58

Table 2A: New Applications by Principal Investigator Type
January 1, 2023-December 31, 2023

Administrative	7
Faculty	65
Doctoral	34
Master's	39
Undergraduate	17
Institutional Partners	10
sIRB	2
Other Universities and/or Organizations	30
Total	204

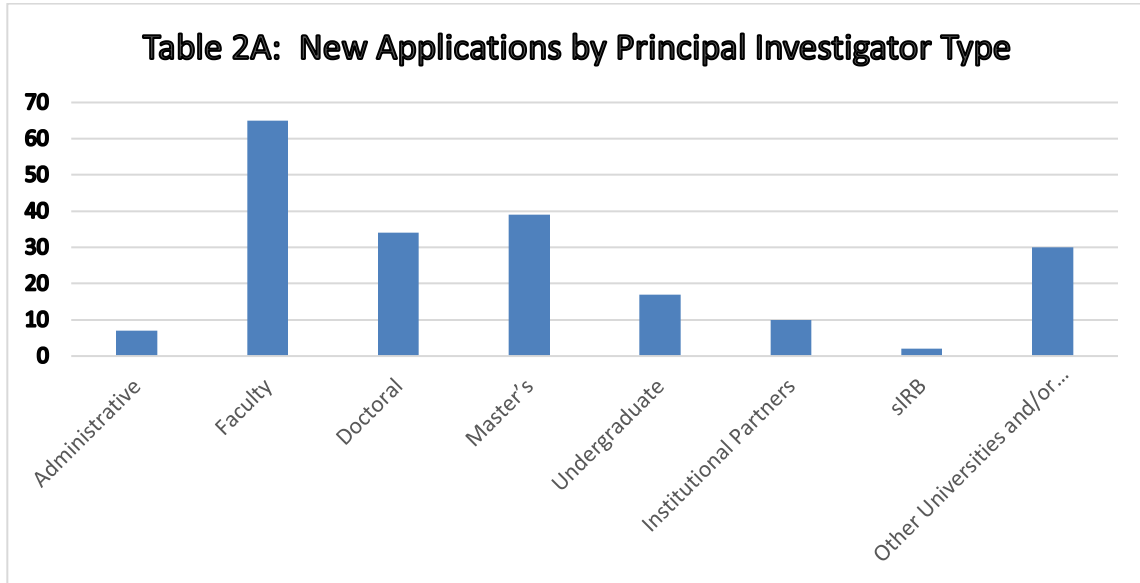


Table 2B: New Applications by Principal Investigator Type
January 1, 2024-March 31, 2024

Administrative	1
Faculty	21
Doctoral	12
Master's	10
Undergraduate	4
Institutional Partners	4
Other Universities and/or Organizations	5
sIRB	1
Total	58

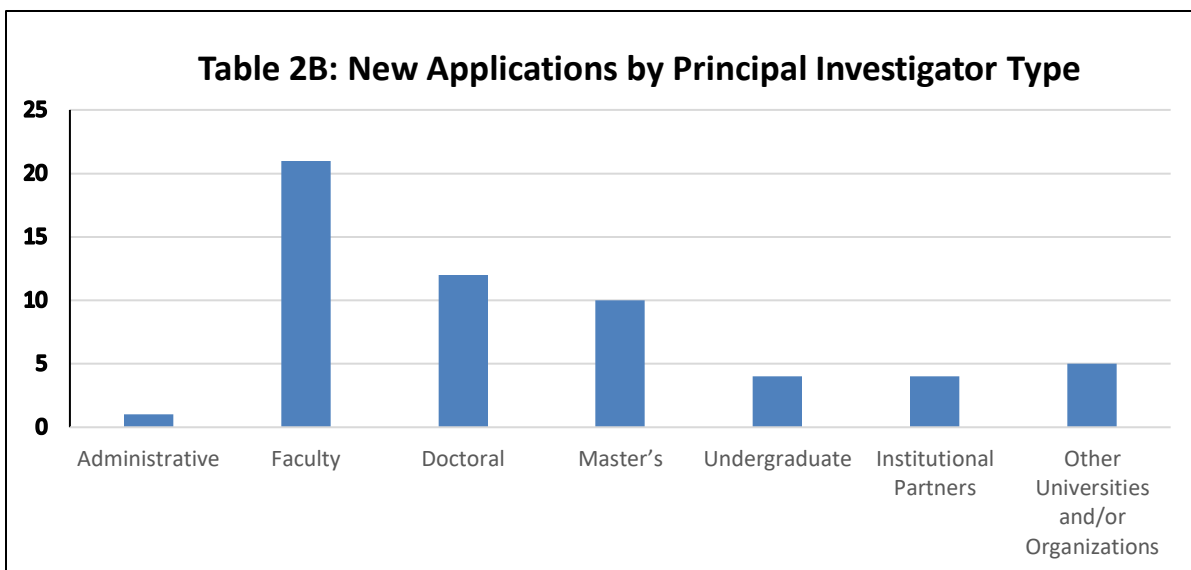


Table 3A: New Applications by Faculty Unit
January 1, 2023-December 31, 2023

Faculty of Education	24
Faculty Of Arts, Humanities, and Social Sciences	65
Faculty of Engineering	9
Faculty of Human Kinetics	23
Faculty of Law	4
Faculty of Nursing	4
Faculty of Science	15
Leddy Library	1
Odette School of Business	7
Office of Enrolment Management	1
Office of the Provost & Vice President Academic	5
Other (Includes Open Learning)	20
External (Non-UWindsor)	26
Total	204

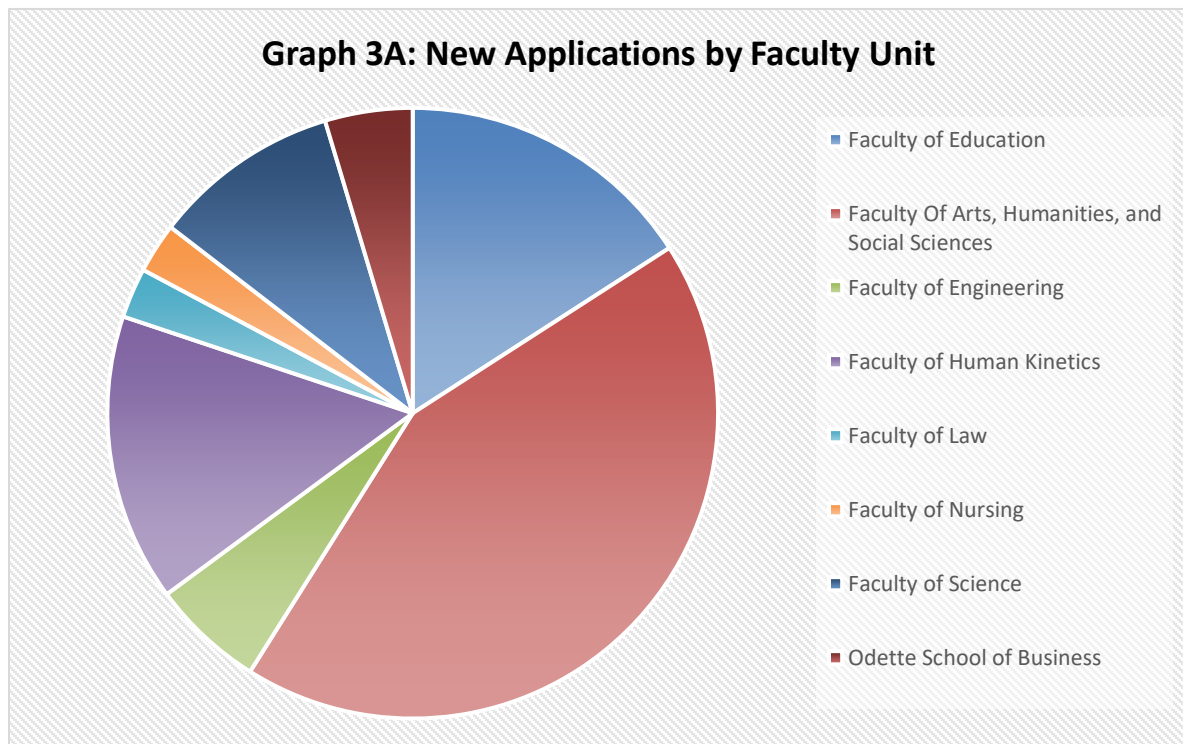
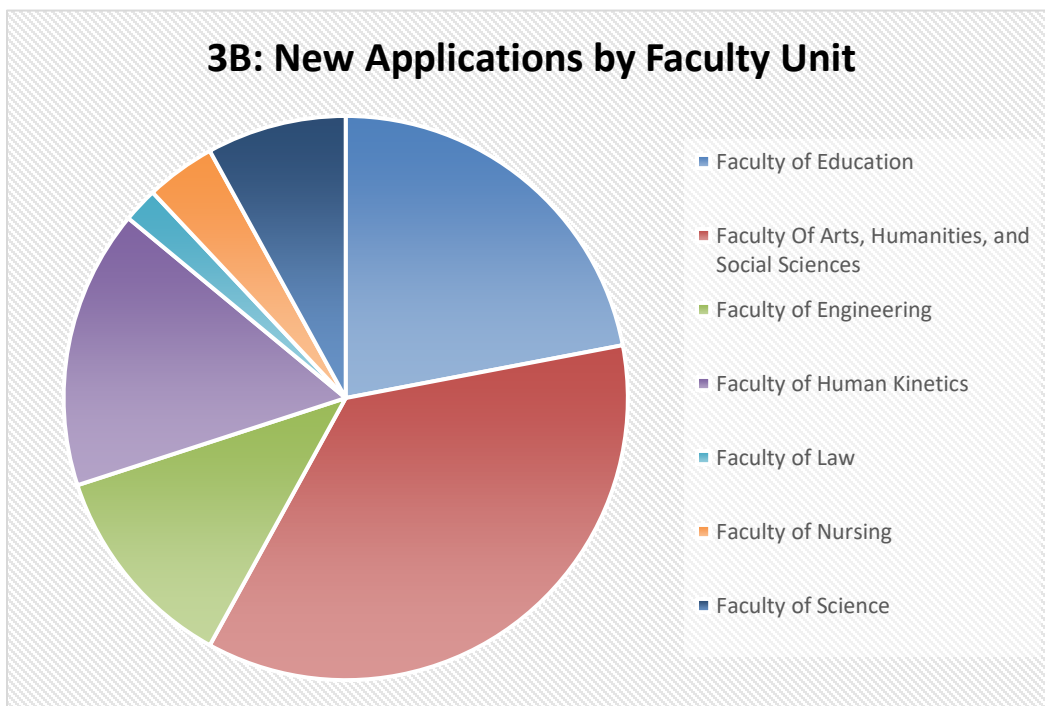


Table 3B: New Applications by Faculty Unit
January 1, 2024-March 31, 2024

Faculty of Education	11
Faculty Of Arts, Humanities, and Social Sciences	18
Faculty of Engineering	6
Faculty of Human Kinetics	8
Faculty of Law	1
Faculty of Nursing	2
Faculty of Science	4
Office of the Provost & Vice President Academic	1
External (Non-UWindsor)	7
Total	58



Tables 1, 2 and 3, and the corresponding graphs, illustrate the activity of the REB by level of review, principal investigator type, and by academic Faculty. In keeping with the TCPS2 principle of proportionate review (TCPS2, Chapter 1C, Article 2.9, Article 6.12), Table 1 shows that most protocols are reviewed by a Delegated Review Committee or as an executive review by the Chair alone or together with another REB member. Table 2 and the corresponding graph illustrate that the majority of protocols over the academic year are faculty-based research projects, followed by student applications, primarily master’s theses and doctoral dissertation projects. Institutional partner applications are from organizations in which the REB is considered the Board of Record and is contracted for ethical review and protocol oversight services as well as consultation and guidance on research ethics issues, including Erie Shores Healthcare, Hôtel-Dieu Grace Hospital, the Windsor-Essex County Health Unit and community organizations as requested. ‘Other’ applications refer to external researchers who are seeking to conduct research at the University of Windsor and are typically cleared at another REB and executively reviewed by the REB Chair. Table 3 illustrates that most applications come from FAHSS affiliated researchers, with Faculty of Education and HK researchers having the second highest applications followed closely by the Faculty of Science and Faculty of Engineering.

Post Clearance Review Activity

After protocols are cleared, four additional areas of protocol activity are monitored by the REB. These include: requests to revise an existing protocol; unanticipated or adverse events; annual progress reports, and final reports. Post clearance requests to revise reviews can require one to several hours each of the ORE and REB Chair's time depending upon the number and complexity of the requests. Unanticipated and adverse events range in severity and occur infrequently, but when they do occur, they often require several hours for the REB Chair to review, communicate and/or meet with the researcher, sometimes communication with participants, file documentation, clearance, and follow-up. Progress reports and final reports require less time as these tend to be straightforward descriptions of project process or conclusion.

Table 4: Protocols requiring modifications, adverse events, and other monitoring
January 1, 2023-December 31, 2023

Files closed	130
Final Reports	136
Progress Reports	156
Requests to revise*	149
Unanticipated/Adverse Events	10
Cleared	195

* Number of protocol files in which revisions were requested. The total number of revisions reviewed and cleared is much higher as researchers can submit multiple revisions.

Table 4: Protocols requiring modifications, adverse events, and other monitoring
January 1, 2024-March 31, 2024

Files closed	8
Final Reports	8
Progress Reports	14
Requests to revise*	39
Unanticipated/Adverse Events	6
Cleared	48

* Number of protocol files in which revisions were requested. The total number of revisions reviewed and cleared is much higher as researchers can submit multiple revisions.

RESEARCH ETHICS EDUCATION, PRESENTATIONS, AND CONSULTATION

In addition to assessing the ethical acceptability of research through application reviews and post-review oversight, the REB and Office of Research Ethics is instructed under the TCPS2 and *Declaration of Helsinki* to provide research ethics education, guidance and consultation services to faculty, staff, students, community partners and others as requested (TCPS2, 6.2 and *Declaration* Guideline 23).

Consultation

The REB Chair and ORE Manager provide on-going consultations to the campus community, researchers, and Windsor-Essex community about various aspects of the REB application process, application content, requests for guidance on research ethics issues and other research ethics questions. Consultations requests are made through the ethics mailbox, some are sent directly to the REB Chair's or ORE Manager's personal email, and Teams chat requests. A Bookings site is available on the REB website where meetings can be scheduled with the REB Chair during the day, evenings, and weekends. Since July 1, 2023, the REB Chair has had over 52 meetings scheduled through the Bookings site and 50 additional consultation meetings and the ORE Manager has had 62 consultation requests since July 1, 2023. Jointly, the REB Chair and the ORE Manager have responded to 173 consultation communications in the Ethics mailbox over the same time period.

Application content support at the pre-review stage is primarily available from the ORE Manager. These consultations can be requested by researchers prior to submission or if an application has been determined to require revisions prior to being allocated to Board or Committee review. The ORE Manager has provided 36 pre-review meetings since July 1, 2023.

Post-review consultations on Board/Committee review comments, project revisions, guidance on research ethics issues during project implementation, research integrity questions, adverse event consultations and other questions are handled by the REB Chair. The REB Chair has provided approximately 67 post-review meetings and guidance requests since July 1, 2023.

EXPANDED EDUCATIONAL RESOURCES IN RESEARCH ETHICS – EDUCATION WORKSHOPS AND PRESENTATIONS

Indigenous Research Review Committee

The REB, under the guidance of the Chair, has advanced its efforts towards Indigenization and decolonization of the review process by establishing an Indigenous Research Review Committee. The Committee is made of members who bring Indigenous voices and Indigenous-specific knowledges and leadership which is moving the REB towards appropriate sensitivity to cultural and community rights, roles and responsibilities across all research projects. The Committee provides research review of Indigenous research projects and provides guidance to the Socio-Behavioural and Biomedical Boards with Committee representation on each Board. The ORE Manager chairs this new Committee and together with the members, will be developing resources for the research community.

REB AND ORE EFFORTS FOR IMPROVEMENT

Environmental Scan of Canadian University REBs as Part of Needs Assessment for the ORE

Despite the increased number of applications and responsibilities under the TCPS2, the Office of Research Ethics/Research Ethics Board with its 2 full-time staff and 1 part-time REB Chair who is also a full-time faculty member, remains one of the smallest ORE/REBs in the country. A scan of Canadian university REBs highlights the need for additional support as other comprehensive institutions, such as Brock University, University of Guelph, and Concordia University have 4 staff, while larger institutions such as Western University and the University of British Columbia have 14 and 19 staff respectively. Based on available data, the known staffing levels of the Canadian University REBs are as follows:

- Windsor: 2 Staff
- Brock, Guelph, Concordia: 4 Staff
- Manitoba, Victoria: 5 Staff
- McGill, Alberta: 6 Staff
- McMaster, York: 7 Staff
- Toronto, New Brunswick, Dalhousie: 8 Staff
- Waterloo: 9 Staff
- Calgary, Regina: 10 Staff
- Ottawa: 11 Staff
- Western: 14 Staff
- UBC: 19 Staff

Identifying Bottlenecks and Areas for Streamlining the Application and Review process

The REB Chair and ORE have identified several areas for streamlining and bottlenecks which cause delays in the application and review process. These bottlenecks include: review time for managing poorly written applications; applications with insufficient content for review; time for editing comments on lengthy and complex reviews—often related to the quality and content of the application; and managing the review process and research oversight while also providing consultation, education and support to the research community. The amount of work required to manage all the activities involved in the administration of the ethics review process, education and consultation, and post review monitoring by the ORE and by the REB Chair, requires that the Chair work weekends, during all vacations and holidays, and, depending upon the volume of work, necessitates ORE staff work evenings and weekends as well.

To portion the workload, the REB and ORE have modified the consultation process so that the ORE Manager provides consultation and support at the pre-review stage and the Chair provides support at the post review stage. To address the bottlenecks related to quality of applications and impact on review time, the REB Chair has increased their availability for consultation to include evenings and weekends. These consultations provide support for the improvement of application content, and to lesson reviewer time, but require the REB Chair and ORE staff to work more and longer hours. The introduction of the workshop series by the REB Chair is another initiative to address bottlenecks related to application quality and content as well as providing additional time for consultation.

The application forms were another area identified as needing improvement to address bottlenecks. The Main Application form has undergone several updates including additional items required to ensure compliance with the most recent version of the TCPS2. A Tissue and Fluids Form has been created for researchers who conduct research using these biological materials, which streamlines services to researchers who require approval from several institutions and/or require Research Safety Committee approval. The Human Somatic Cell Line Exemption form continues to help researchers who utilize immortalized cell lines to navigate the Research Safety Committee process more quickly when there is overlap between RSC and the REB. Updates to the Institutional Quality Assurance Process (IQAP) form which provide consistency across campus are under currently under review.

Collaboration with WE-SPARK on Educational Resources and Training through CITI

The REB has effectively transitioned its membership in Network to Networks (N2), a national alliance which supports collaboration across provinces in clinical research, to WE-SPARK. As noted in the previous Senate Report, The Canadian Collaborative Institutional Training Initiative (CITI) courses are still available for free to the University of Windsor research community and institutional partners; the move to provide these trainings under WE-SPARK expands these offerings to their members and the broader research community including biomedical sciences. The CITI courses include not only research ethics with human participants, but also information on all research guidelines in Canada and the US including Health Canada guidelines for clinical trials, drug and device trials, Food and Drug Administration in the US and International Conference on Harmonization (ICH) Guidelines for Good Clinical Practice. The REB and WE-SPARK collaboration and transitioning the CITI training oversight improves the process of access, increases the opportunity to develop CITI certificates across biomedical and clinical research, as well as fosters additional collaboration between institutional partners and the University of Windsor through WE-SPARK.

Updated US IRB Registration and Federal Wide Assurance Certification

The REB has updated its registration as a recognized Institutional Review Board (IRB) with the US Office of Human Research Protection. This allows the University of Windsor REB to act as an IRB for research conducted in the US, projects conducted in collaboration with US researchers, and as a single IRB of Record. The Federal Wide Assurance Certification is necessary for any federally funded project in the US and supports collaboration with funded research in the US and researchers at the University of Windsor. The University of Windsor REB is currently the Single Board of Record for several research projects being conducted by University of Windsor affiliated researchers in the US as noted above.

LOOKING FORWARD 2024-2025

Funding for educational support

The Secretariat on Responsible Conduct of Research (SRCR), in conjunction with the Panel on Research Ethics (PRE) and the Panel on Responsible Conduct of Research (PRCR), administer a grant program to support events that complement their mandate to promote research ethics and the responsible conduct of research. The ORE is eligible to seek funding for at least one educational conference.

Decolonization and Indigenization

The ORE and REB, under the guidance of the Chair, will continue to seek out additional means of decolonizing and Indigenizing research ethics review through ongoing consultation and communication with Indigenous leaders, Elders and Knowledge Keepers. The REB will seek out additional support to be able to expand its efforts toward an independent Indigenous ethics review process.

Review of the Research Ethics Committees (RECs)

TCPS2, 2022 included strengthened guidelines for the type of reviews that can be conducted at the department level RECs limiting oversight to research activities related specifically to pedagogical purposes (TCPS2 6.12). The REB Chair has initiated communications with the REC Chairs on campus to discuss the development of common forms, shared operating procedures, and standard reporting practices to the University REB. The ORE will also explore annual training for all REC members on campus as suggested in the last Senate report. The ORE will also explore mechanisms for communicating with the RECs on changes in ethics guidelines, updates in review practices as well as other support as needed.

File Management and Quality Assurance (New Database?)

The on-line platform used by the ORE/REB, ORIS, RSC (and ACC) for research file management (eRSO) continues to underserve the Office of Research Ethics and does not provide the file management or reporting capabilities necessary for the ORE. The eRSO platform is not designed for research ethics administration and this limitation, combined with insufficient training supplied by the vendor, continues to present challenges. Last year, the ORE Manager worked in collaboration with the Research Systems and Metrics Coordinator to address the limitations for systems reporting. Their solutions have improved internal benchmarking capabilities, but substantial limitations still exist. As noted in previous Senate reports, the database was not structured correctly at its inception and so the data being entered were not captured appropriately. Further, the current eRSO platform does not provide the capacity for producing aggregate or detailed reports and only allows for data entry that may be manipulated outside of the database, meaning that the ORE staff must duplicate the information entered in the database in two, sometimes three different systems in order to oversee systems flow and management, provide monitoring reports and track protocol progress, revisions and communications. The limitations of the eRSO system and need for duplication of information significantly increases ORE staff burden. Finally, the eRSO platform does not provide the ability to communicate with researchers regarding compliance, so the ORE is not able to send requests or reminders to researchers when progress and final reports are due, increasing the rate of non-compliance.

Recently, a committee was formed to explore other database options; the ORE Manager is a member of the committee representing the ORE and REB. We are hopeful that a new platform and database system will be identified that will be applicable to research ethics administration, responsive to ORE management and reporting needs, and allow for researchers to submit their applications through an online portal. This will reduce the administrative burden including duplication of work and create greater transparency and more effective communications between the ORE, REB and the research community.

On behalf of the University of Windsor Research Ethics Board, this report is respectfully submitted.

APPENDICES

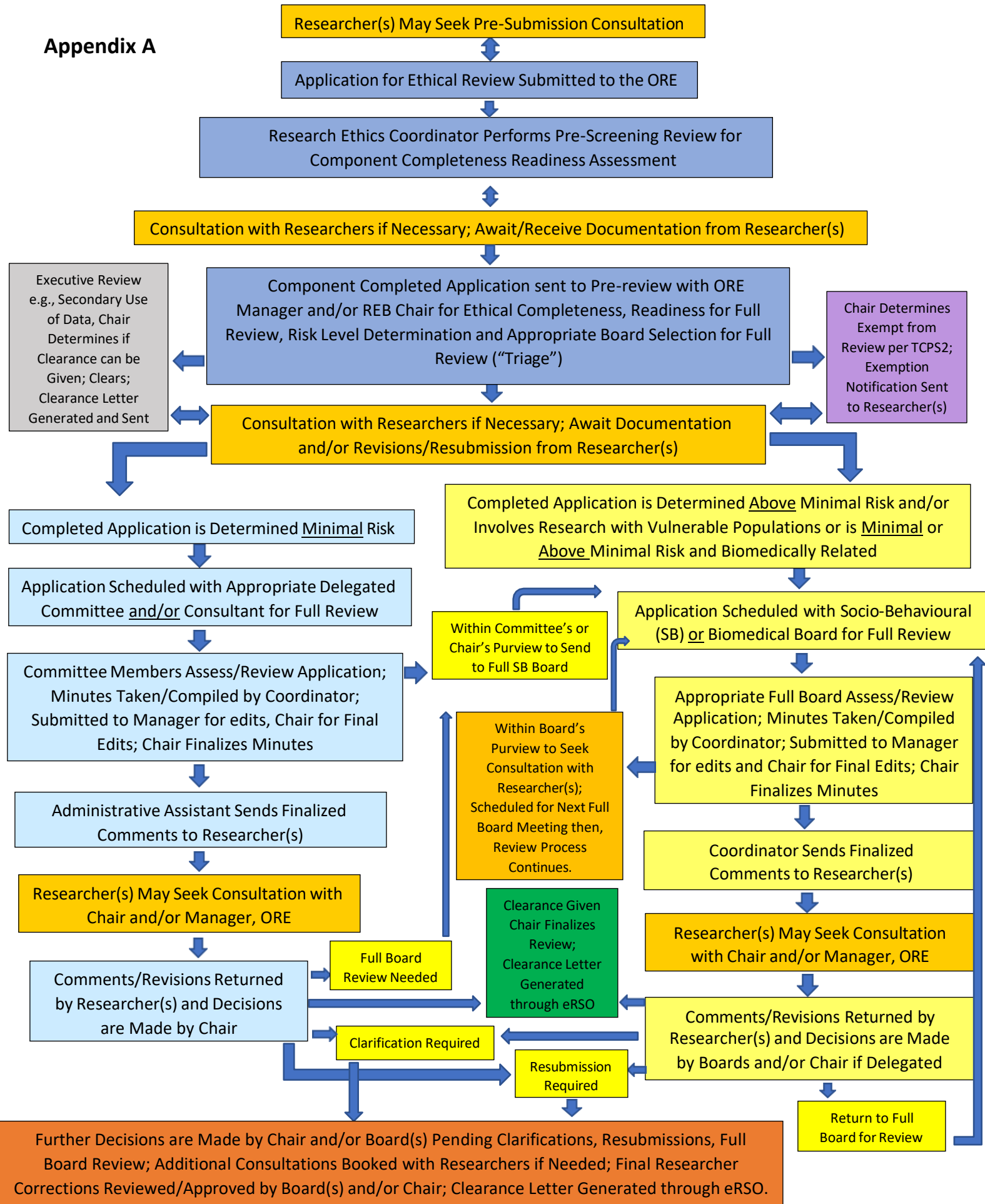
Appendix A: Office of Research Ethics Detailed Application Review Flow Chart

Appendix B: Research Ethics Board Review by Application Type and Responsibility

Appendix C: Overview of ORE and REB Structure and Workflow

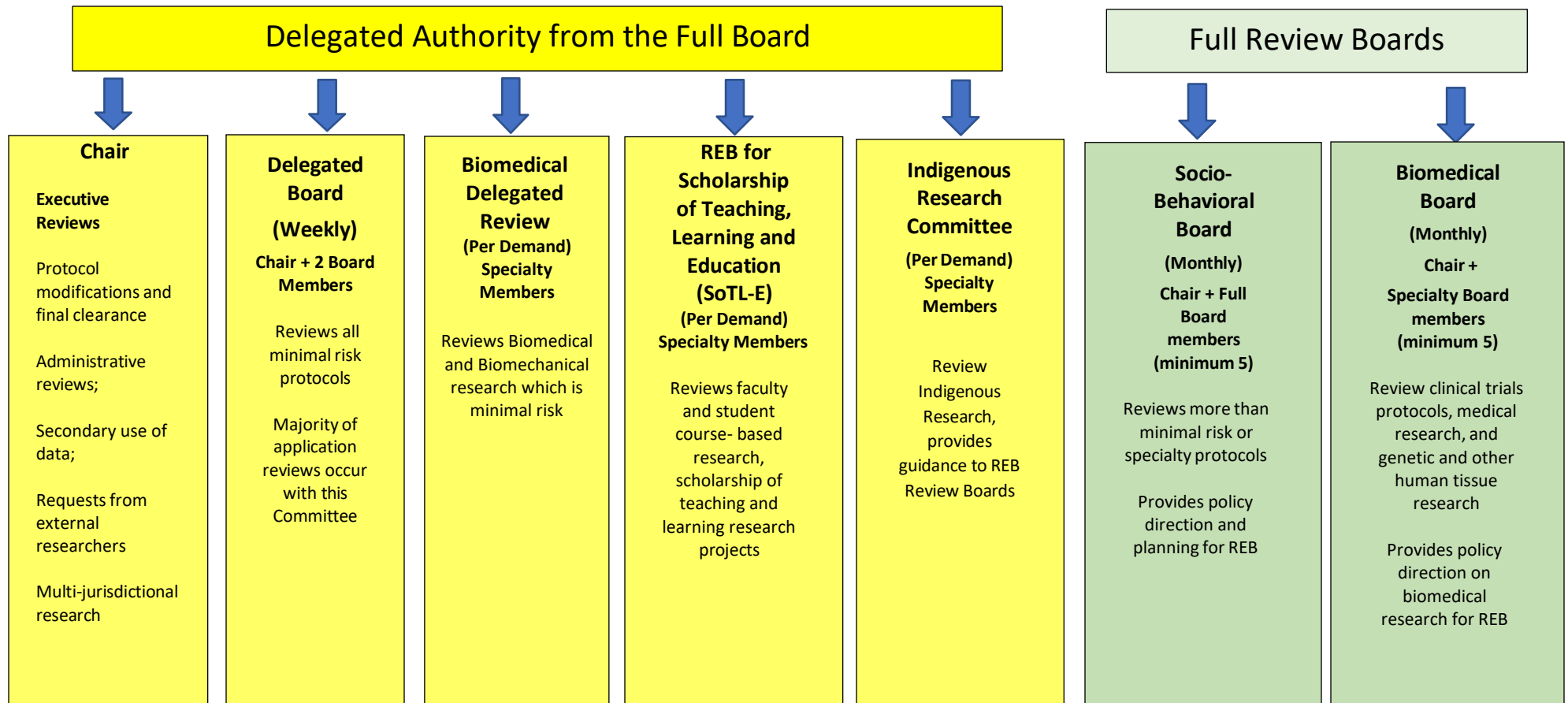
Office of Research Ethics (ORE) Detailed Application Review Flowchart

Appendix A



Research Ethics Board and Committee Review by Application Type and Responsibility

Appendix B



*Note: The Full Board can ask for specialty expert consultations and form ad hoc advisory committees as required.

Overview of ORE and REB Structure and Workflow

APPENDIX C

