SGC230517A



NOTICE OF MEETING

There will be a meeting of the Senate Governance Committee on Wednesday May 17, 2023, at 2:00 pm LOCATION: Room 203 Anthony P Toldo Health and Education Centre or via MS Teams

AGENDA

1	Appr	oval of Agenda	
2	Appr	roval of the minutes of the meeting of April 19, 2023	SGC230419M
3	Busii	ness arising from the minutes	
4	Outs	tanding Business	
5	Repo	orts/New Business Research Ethics Board Report	Martyn -Approval SGC230517-5.1
	5.2	Report on Renewal, Tenure, and Promotion	Weir/Tam-Information SGC230517-5.2
	5.3	Memberships: 5.3.1 Senate Standing Committees	Gordon- Approval SGC230517-5.3.1
		5.3.2 Discipline Appeal Committee, Procedures and Discrimination Committee, SGC Nominating Committee, SGC Special Appointments Committee, SGC Bylaw Review Committee	Gordon -Approval SGC230517-5.3.2
		5.3.3 Senate Membership (2023-2024)	Gordon- Information SGC230517-5.3.3
	5.4	Senate and Senate Standing Committee Diversity Report (2023-2024)	Gordon -Information SGC230517-5.4
	5.5	Strategic Items for Senate Discussion	Gordon -Discussion SGC230517-5.5
	5.6	Senate Meeting Scorecard – Results from Winter 2023 Meetings	Gordon -Discussion (to be distributed)

6 Question Period/Other Business

7 Adjournment

Please carefully review the 'starred' (*) agenda items. As per the June 3, 2004 Senate resolution, 'starred' items will not be discussed during a scheduled meeting unless a member specifically requests that a 'starred' agenda item be 'unstarred', and therefore open for discussion/debate. This can be done any time before (by forwarding the request to the secretary) or during the meeting. By the end of the meeting, agenda items which remain 'starred' (*) will be deemed approved or received.

University of Windsor Senate Governance Committee

5.1:	Research Ethics Board Report
Item for:	Approval
Forwarded by:	Scott Martyn, Chair, Research Ethics Board
MOTION:	That the proposed revisions to the Guidelines for Research Involving Humans (Appendix C) be approved.
Rationale:	

- The Guidelines for Research Involving Humans was last updated since 2019, which aligned the document to the REB Guidelines with the *Tri-Council Policy Statement 2 (2014)*. The proposed revisions to the guidelines to the guidelines are mandated by the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2022)
- The proposed revisions have been approved by the REB Board.
- The annual report is provided for information.

See attached.

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REPORT TO SENATE

January 1, 2022 – December 31, 2022



UNIVERSITY OF WINDSOR RESEARCH ETHICS BOARD

Report to Senate
January 1, 2022 – December 31, 2022

INTRODUCTION

The University of Windsor Research Ethics Board (REB) operates in accordance with the *Tri-Council Policy Statement:* Ethical Conduct for Research Involving Humans – TCPS 2 (2022). The Board is 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 other affiliates regardless of where the research takes place (TCPS2, 6.1). Research requiring REB review includes projects involving human participants or human biological materials derived from living or deceased individuals (TCPS2, 2.1).

Relationship to the University

Per the requirements of the TCPS2, the REB operates independently and at arms-length from the University (TCPS2, 6.2). REB communication with researchers and records are confidential and accessible only to REB members on a need-to-know basis. The REB meets regularly with the Vice President, Research and Innovation and reports to the Senate on its operations.

The Office of Research Ethics

The Office of Research Ethics is directed by the Manager, Office of Research Ethics and the Chair of the Research Ethics Board and staffed by the Manager, Office of Research Ethics, and the Administrative Assistant with the support of the Chair. The Office is responsible for overseeing 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 decisions; documentation and record-keeping; and protocol monitoring. The Office is also responsible for providing education to the University of Windsor community on research ethics, providing consultations, conducting workshops and presentations, providing resources on research ethics, and staying current on local, national, and international issues on research ethics.

Research Ethics Board 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 Full Research Ethics Boards, Socio-Behavioural 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 main Delegated Review Committee meets once per week during the academic year and biweekly over the summer, unless the number of protocol submissions requires additional meetings, and the specialty Delegated Review Committees meet as related applications arise. The additional Delegated Review Committees, and a special advisory committee, were created in 2017-2019—and include the Scholarship of Teaching and Learning (SoTL-E), Administrative Research Committee, and Equity Diversity and Inclusion advisory committee—and are described below.

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. Please see *Appendix A* for a detailed flow chart of how applications are processed and *Appendix B* for an overview of the REB structure and committees.

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 in service. The 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 two additional Delegated Review Committees do not receive compensation and only meet when a relevant protocol is assigned to them for review. The REB Chair facilitates review meetings of the REB including the Full Board, Biomedical Board and regular Delegated Review Committee, and the Manager, Office of Research Ethics fills in as an alternate when needed and chairs the SoTL-E Committee and the Equity, Diversity and Inclusion advisory committee. The latter takes direction from the Full Boards and provides information to them as requested.

REB Members (Socio-Behavioural and Biomedical) and Committees

Dr. Scott Martyn, Chair

Full Board Socio-Behavioural, Biomedical and Delegated Review Committee; Administrative Committee; Kinesiology, Faculty Member

Ms. Harmony Peach, Manager, Office Research Ethics

Full Board Socio-Behavioural, Biomedical, Alternate Delegated Review Committee; Chair SoTL-E; Chair Equity, Diversity, and Inclusion Advisory Committee (non-voting)

Dr. Marc Frey

Full Board Socio-Behavioural, Biomedical; Community Representative

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

Full Board Socio-Behavioural; Community Representative (on maternity leave)

Dr. Laura Chittle

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

Dr. Rosanne Menna

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

Ms. Ashlyne O'Neil

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

Mr. Frank Ely

Full Board Socio-Behavioural; Kinesiology, Student Representative

Dr. Calvin Langton

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

Dr. Saverpierre Maggio

Full Board Socio-Behavioural, Biomedical; Windsor Regional Hospital/Legal Representative

Ms. Sherri Lynne Menard

Full Board Biomedical; Health and Safety Representative

Dr. Siyaram Pandey

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

Mr. Russell Nahdee

Full Board Socio-behavioural; Office of Open Learning; Indigenous Research Representative

Dr. Kathy Pfaff

Full Board Socio-Behavioural; Nursing, Faculty Member (on leave)

Dr. Maureen Sterling

Full Board Socio-behavioural; Business, Faculty Member

Dr. Allyson Skene, CTL

SoTL-E; Centre for Teaching and Learning

Dr. Clayton Smith

SoTL-E; Education, Faculty Member (on leave)

Ms. Loretta Sbrocca

SoTL-E; Science, Research Associate

Dr. Christopher Greig

SoTL-E; Education, Faculty Member

Dr. Katherine Rudzinski

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

Dr. Adrian Guta

Full Board Socio-Behavioural, Biomedical and Delegated Review Committee; Sociology, Faculty Member (non-voting)

Dr. Matthew Krause

Full Board Biomedical; Chair Research Safety Committee; Kinesiology, Faculty Member

Karen Metcalfe

Full Board Biomedical; Vice President Research Innovation, Assistant Director

Dr. Philip Karpowicz

Full Board Biomedical; Biology, Faculty Member (on leave)

Mr. Andrew Ward

Full Board Biomedical; Nursing, Graduate Student

Dr. Glynis George

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

Ms. Nadia Roopnarine

Full Board Socio-behavioural, Biomedical; Nursing; Student Representative

Dr. Phillip Karpowicz

Full Board Biomedical; Biomedical Sciences, Faculty Member (on leave)

Ms. Krista Naccarato

Full Board Biomedical; WRH

Dr. Jennifer Voth

Full Board Biomedical; HDGH; Research Associate

Dr. Wally Liang

Full Board Biomedical; WRH

Mr. Andrew Ward

Full Board Biomedical; Student Representative

Mr. Abrahim Abduelmula

Full Board Biomedical; Schulich; Student Representative

Dr. Stephen Bartol

Full Board Biomedical; Medicine Professional Corporation

Office of Research Ethics Staff

Manager, Office of Research Ethics

Ms. Harmony Peach

Ethics Administrative Assistant

Ms. Mary Jane Nohra

Ethics Training and Review Coordinator

Position is currently de-funded

The Manager, Office of Research Ethics (ORE) provides leadership, direction, and support within ORE to ensure ongoing effective and efficient operation and administration; manages the hiring, training, supervision, mentoring, performance management, and ongoing professional development of ORE staff, conducts consultations providing information to support application development, policy development etc.; develops, and implements policies, procedures, and processes to ensure effective administration of ORE, successful operation of the REB; collaborates with the REB Chair to provide guidance to ORE staff on federal, provincial, and local policies, guidelines, and regulations, manages communication of review decisions, clearance letters, protocol revision requests, progress, and final reports to researchers; manages the ORE budget and related financial administration activities; collaborates with the REB Chair in conducting preliminary reviews and assessments of applications, writing reports, creating forms, identifying content for proportionate review and applications needing additional information to support Board review; serves as Chair of the

Scholarship of Teaching and Learning Committee and Chair of the Equity, Diversity and Inclusion Committee to provide consultation to the Board, and Chair and/or contribute to other committees as deemed necessary; serves as a Delegated Reviewer as requested by the REB Chair; serves as a Member of the two main Research Ethics Boards (Socio-behavioural and Biomedical); formulates review minutes, and edits all Board and Delegated review minutes to prepare for Chair review; serves as a resource to the campus research community and off campus community partners such as Research Data Management Steering Committee and Standing Committee, ITS, Leddy Library, the Centre for Teaching and Learning, the Office of Open Learning, and the Office of Research and Innovation Services, the Research Safety Committee, Windsor Regional Hospital, Hotel Dieu Grace Healthcare, external researchers; oversees new REB member training in consultation with the Chair; prepares and delivers reports.

The Ethics Administrative Assistant provides administrative assistance to the Office of Research Ethics and the REB and is the initial contact for researchers who call, drop-in, or e-mail the REB; conducts preliminary inspection of in-coming ethics applications making assessments for completeness and readiness; prepares REB files for the REB Chair, board and committee reviews and coordinates the review process for Full Board and Committee meetings including scheduling and taking minutes at meetings; sends communications to researchers and committee members; maintains protocol files on the institutional database and on-line records, and maintains the REB website; prepares monthly, quarterly and annual reporting reporting for the Manager, Office of Research Ethics and the Chair; works with ORIS to coordinate testing of updates to the database (eRSO) for research ethics and review of administrative processes.

The Ethics Training and Review Coordinator position is under further negotiation to become an education and compliance position as these are complimentary roles. Limitations have been identified due to resourcing with respect to providing additional education and streamlining education to the research community as well as addressing compliance. A position specific to serving these needs would be appropriate and we will approach the new Vice President Research and Innovation to further discuss funding the position.

SPECIAL ADVISORS TO THE REB

Beginning in 2017, the REB has invited individuals with specific expertise to act as expert advisors to the REB. These expert advisors assist the REB in assessing research ethics issues in specialized topic areas, provide guidance on REB policy and consult with individual researchers referred through the REB.

Clinical Research

Dr. Kathy Pfaff, School of Nursing_

Education and Local School Boards

Dr. Geri Salinitri, Faculty of Education

<u>Human Biological Materials</u> **Dr. John Hudson,** Biology

Dr. Phil Karpowicz, Biology

Medical Devices

Dr. Roman Maev, Diagnostic Imaging Centre

Online Research Using social media **Dr. Sarah Woodruff,** Kinesiology

Research Involving the First Nations, Inuit and Métis Peoples of Canada

Dr. Harvey McCue, Treasurer and Secretary, Ontario Heritage Trust

Dr. Brent Angell, Professor Emeritus, School of Social Work

Mr. Russell Nahdee, Aboriginal Education Centre

Research Using Deception **Dr. Josée Jarry,** Psychology

REB PROTOCOL REVIEW ACTIVITY January 1, 2022—December 31, 2022

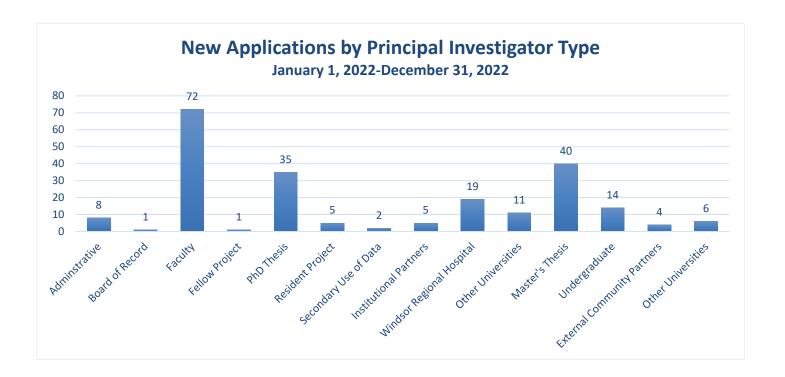
Protocol reviews and monitoring are the activities of the REB which require the most amount of REB labour. Each new file submitted to the REB requires approximately 10-20 hours from point of submission to clearance. This includes: initial processing for file completeness and assessment of readiness for 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 and protocol modifications; 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 *Appendix A* for a detailed flow chart of REB and ORE work and *Appendix B* to see the review structure.

Table 1: New Applications by Level of Review

January 1, 2022-December	er 31, 2022
Full Board	5
Delegated	135
Executive	49
Biomedical	8
SoTL-E	14
Withdrawn/Exempt	12
Total	223

Table 2: New Applications by Principal Investigator Type

January 1, 2022-December 31,	2022
Administrative	8
Board of Record	1
Faculty	72
Fellow Project	1
PhD Thesis	35
Resident Project	5
Secondary Use of Data	2
Institutional Partners	5
Windsor Regional Hospital	19
Other Universities	11
Master's Thesis	40
Undergraduate	14
External Community Partners	4
Other	6
Total	223



Tables 1, 2 and 3, and the graph, identify the activity of the REB by level of review, principal investigator type, and by faculty unit. In keeping with the TCPS2 principle of proportionate review, Table 1 shows that most protocols are reviewed at the delegated level. Executive reviews are conducted 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 and doctoral level thesis projects. Community applications are from organizations in which the REB is contracted for ethical review services, including Hôtel-Dieu Grace and the Windsor-Essex County Health Unit. '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 shows that the most applications come from FAHSS affiliated researchers, with HK researchers having the second highest applications followed closely by the Faculty of Science.

Table 3: New Applications by Faculty Unit

January 1, 2022-December 31, 2022	
Faculty of Education	26
FAHSS	71
Faculty of Engineering	10
Faculty of Human Kinetics	31
Faculty of Law	2
Faculty of Nursing	12
Faculty of Science	30
Human Resources	1
Human Rights, Equity and Accessibility	1
Leddy Library	2
Odette School of Business	6
Office of Enrolment Management	2
Office of the Provost & Vice President Academic	6
Office of Research and Innovation Services	2

Other (Includes Open Learning)	9
External (Non-UWindsor)	26
Total	223

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 request to revise reviews can require one to several hours each of the REB's time depending upon the number and complexity of the requests. Unanticipated and adverse events are rare, but when they do occur, they often require several hours for the REB and researcher communication and meetings, REB communication with participants, and file documentation and clearance. 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, 2022-December 31, 20	22
Files closed	139
Final Reports	119
Progress Reports	97
Requests to revise*	108
Unanticipated/Adverse Events	3
Cleared	184

^{*} 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.

REB INITIATIVES AND ACCOMPLISHMENTS

In addition to protocol reviews, the Office of Research Ethics engages in other activities related to the ethical conduct of research.

Transitioned Chairs

In January 2022 the Research Ethics Board welcomed Dr. Scott Martyn to the position of Chair of the Research Ethics Board for an initial one-and-a-half-year term to bridge the gap created by the departure of Dr. Suzanne McMurphy. Having successfully served as a member of the Delegated Review Committee since 2002, he assumed the position of Vice Chair of the Research Ethics Board in 2014 before his appointment to the position of Chair last year. In addition to keeping the Vice-President, Research and Innovation updated on matters related to the operations of the REB while providing advice as required, the Chair is tasked with ensuring fulfillment of the primary function of the REB in the protection of human participants and their biological materials. The Board would be remiss if it did not thank Dr. McMurphy for her for many contributions as both Vice Chair and Chair of the Research Ethics Board.

Created Position Manager, Office of Research Ethics (ORE)

In 2021, the person holding the position of Training and Review Coordinator, Harmony Peach, was transitioned into the role of Manager, Office of Research Ethics beginning in 2022 to preserve institutional knowledge and to capitalize on her ethics expertise. Due to limitations in Human Resources, the position has not been posted to full time as yet and remains a contract role until the Joint Job Evaluation Committee can meet on the position. It is expected that the position will become full time in 2023. The current incumbent has exceeded all expectations and continues to be an excellent resource for the campus and broader research community and is invaluable to the REB and the ORE.

eRSO Database Cleanup Dating Back to 2012

The ORE hired two Co-op students and was later awarded Ignite funding to rehire the same students to assist the office in performing data cleanup and data migration from paper files to the institutional database (eRSO). In total more than 2500 REB files were reviewed from the years dating from 2022 back to 2012. In addition, files were updated with known metrics tracking information in an effort to establish better reporting data. A date for accurate metrics management was established on June 13, 2022, forward. This means that once the initiative cited in File Management and Quality Assurance under The Looking Forward 2023-2024 section below is implemented, the ORE should be able to offer more granular reporting in future.

Forms Created and Updated

A number of forms have been created and/or updated to help to streamline REB review and services as well as to help guide researchers through the process. The Main Application form has undergone several updates including items that put it in compliance with the TCPS2 2022. The form now also provides education about the review process directly in its preamble contents and has sections specific to human tissue and biologicals which facilitates review by the Biomedical Board without interfering with facilitating review by the Socio-behavioural Board. The ORE has also created a Human Somatic Cell Line Exemption form to help researchers who utilize immortalized cell lines to navigate the Research Safety Committee process more quickly where there is overlap between it and the REB. The form has also been updated to include new regulations for exemption in the TCPS2 2022. The ORE has also created a Letter of No Objection in order to better foster review relationships where our REB will serve as the Board of Record for another institution. This form helps researchers expedite their requests and standardizes our processes to better track these scenarios. The ORE has undertaken a review and update of the Institutional Quality Assurance Process (IQAP) form in order to clarify the document and provide consistency across campus. The form is currently under review by IQAP.

Research Data Management Strategy

The REB continues to support and inform the development of the Institutional Strategy for research data management and the upcoming Tri-Council Policy for Tri-Council funded researchers to create Data Management Plans which include data depositing and preservation as these relate to research ethics. The REB continues to contribute to the development of the University policy on research data management and other university efforts as they relate to research ethics.

Ongoing Collaborations with Windsor Regional Hospital (WRH)/Community Partners

In support of the growing research collaboration between WRH and the University of Windsor, the University of Windsor REB accepts applications on WRH protocol application forms and assists university researchers in preparing their files to submit to WRH REB. To foster this ongoing collaboration, Dr. Saverpierre Maggio represents WRH as a member of the University of Windsor Full Board REB. The REB is currently exploring a Memorandum of Understanding with WRH and Western University to renew the extended agreement and establish a streamlined review process for secondary use of data and human tissue research protocols. Further discussions are also ongoing with the Windsor-Essex County Health Unit, Windsor Essex County District School Board (WECDSB), Windsor-Essex County Health Unit, and Hôtel-Dieu Grace Healthcare (HDGH) to enhance collaboration and streamline the review process.

Research Ethics Education

The Manager, ORE and the Chair of the REB have held a number of consultations with researchers, the campus community and the broader research community. They have held workshops, in-class presentations, and one-on-one education sessions both on request and pre-emptively.

The REB has continued its membership in Network to Networks (N2), a national alliance which supports collaboration across provinces in clinical research. As noted in the previous Senate Report, The Canadian Collaborative Institutional Training Initiative (CITI) courses are available for free to the University of Windsor research community and collaborators. The courses include information on all research guidelines in Canada and the US including Health Canada guidelines, International Conference on Harmonization (ICH) Guidelines for Good Clinical Practice, and modifications to

US 45 CFR 46 Federal Policy for the Protection of Human Subjects (the Common Rule). The REB began promoting these courses more broadly in 2019.

Standard Operating Procedures for Office of Research Ethics and REB Review

As part of the ongoing improvement of the Office of Research Ethics the Manager, Office of Research Ethics and the Chair of the Research Ethics Board have undertaken a review of the previously established standard operating procedures (SOP)—listed below—which reflect the organizational processes of the REB. As a reminder, the SOPs were written using standard templates approved by the Canadian Association of Research Ethics Boards and Clinical Trials Ontario and modified to align with the University of Windsor Guidelines and practice. Each draft SOP must be presented to the Board by the REB Chair, discussed, and approved by the REB Full Board. The updated SOPs were approved by the Board on March 16, 2023. The approved SOPs have been posted to the REB website.

General Administration

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602 Communication—Researcher Participants and Public

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701 Free and Informed Consent

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Updated US IRB Registration and Federal Wide Assurance Certification

The REB has once again 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, or for projects conducted in collaboration with US researchers. The Federal Wide Assurance Certification is necessary for any federally funded project in the US to be conducted in collaboration with researchers at the University of Windsor. These numbers are available to University of Windsor researchers through the REB.

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

Despite the increased number of applications and responsibilities, the Office of Research Ethics/Research Ethics Board with its 2.5 staff remains one of the smallest 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: 2.5 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 StaffWestern: 14 StaffUBC: 19 Staff

LOOKING FORWARD 2023-2024

In addition to conducting protocol reviews and monitoring, the REB and Office of Research Ethics will focus on these four areas of activity.

University of Windsor Guidelines for Research Involving Humans

This global policy document which establishes the authority of the University of Windsor REB, and its guidelines was last updated in 2017-2018 to align with the then newly published TCPS2 (2018). The policy document has been updated again to align REB Guidelines with the newly released TCPS2 (2022) and was approved by the Full Board on May 1, 2023. Once approved by Senate, the updated document will replace the 2017-2018 version.

Complete Clinical Trials Certification through Clinical Trials Ontario

A pre-audit was completed in 2019 with Clinical Trials Ontario. It was determined at that time that the ORE and REB need additional resources (human) to be able to meet the standards for becoming a Clinical Trials Review Board. At this time, the REB does not have sufficient resources to be certified. When the new Vice President Research and Innovation is situated in their role, they will be approached about additional resourcing.

Review of the Research Ethics Committees (RECs)

The pandemic reduced the ability of the REB to conduct necessary auditing of RECs on campus. The REB Chair has begun 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 REB will also look to implement annual training for all REC members on campus as suggested in the last Senate report. The REB 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

The on-line database used by the ORE/REB, ORIS, RSC (and ACC) for research file management continues to underserve the Office of Research Ethics. The Manager, Office of Research Ethics has worked in collaboration with the Research Systems and Metrics Coordinator to address the limitations for systems reporting, and they have been working toward a solution that will offer more nuanced metrics in the Office of Research Ethics which will better assist in benchmarking going forward. There had been some improvements made since the last Senate report that allow for global data to be reported by accessing the reports through the database. However, these global data offer little to evaluate efficiencies and bottle necks. As the database does not allow for this granular level reporting, but does allow for data entry that may be manipulated outside of eRSO to create reports, the two above identified staff members, along with the ORE Administrative Assistant and the REB Chair have collaborated to create data entry tables that should permit better reporting once the data are exported from the database to spreadsheets, and programs such as Excel are used to sort the data. The Research Systems and Metrics Coordinator will have formulas together for fiscal reporting, and the Manager, Office of Research Ethics assisted by the Administrative Assistant will prepare a report using the formulas to achieve a more granular level report.

The combination of insufficient training supplied by the vendor and a database not designed for Research Ethics Administration continues to present challenges. As noted in the previous Senate report, the database was not structured correctly at its inception and so the data being entered were not captured appropriately. Currently, online protocol (application) submissions are not feasible using the existing software as there are limitations to the logic which does not permit nesting; a firewall necessary for confidentiality cannot remain in place if researchers are to submit additional forms (e.g., request for revisions) on previously cleared files; there is no streamlined way that reviews can be undertaken using the system without creating additional burden to reviewers and ORE staff; and the ORE would be put under additional burden to track and maintain file integrity as researchers would have access to either change and/or delete previously submitted items for which the ORE must maintain a record.

Recently, the Research Systems and Metrics Coordinator presented to the REB and indicated that the software vendor is expected to come out with a new module that considers the needs of REBs at some undetermined point in future. The REB has unanimously voted to await the new module before switching to an online submission portal. Researchers continue to submit their applications electronically and they are managed from there by the ORE.

Standard Operating Procedures

As noted in the last Senate report, several additional SOPs will need to be written and approved by the Full Board. SOPs that have been identified as necessary include the Research Ethics Committees, administrative research, research exempt from REB review, course-based research, and multi-jurisdictional research. There are updates in the in the TCPS2 2022 that will be considered as well with respect to research data management and institutional data.

Continue to Explore Areas for Streamlining REB Review

The REB will continue to provide ethics review for research being conducted at Hôtel-Dieu Grace Healthcare and will continue to explore areas of reciprocity with Windsor Regional Hospital. The REB has also initiated an exploration of the review mechanisms for researchers through the Schulich School of Medicine & Dentistry - Windsor Campus, currently under the jurisdiction of Western University's REB. Discussions are also ongoing with both the Greater Essex County District School Board (GECDSB) and the Windsor-Essex Catholic District School Board (WECDSB) to streamline the REB review process for our researcher community.

Expand Educational Resources in Research Ethics Including Exploring Funding Potential

Finally, the Manager, ORE has outlined an education plan going forward which includes creating online resources that address various aspects of the REB application process including "how to" guides on filling out applications, considerations related to the ethical principles outlined in the TCPS2 and ongoing workshops offered in each term that would be recorded and posted as well as attended in real-time. Streamlining and updating/creating forms is also included in the education plan. Also, 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 appears to be eligible to seek out funding for at least one educational conference which it will fully explore and apply for. In addition, the ORE hopes to secure an education and compliance position.

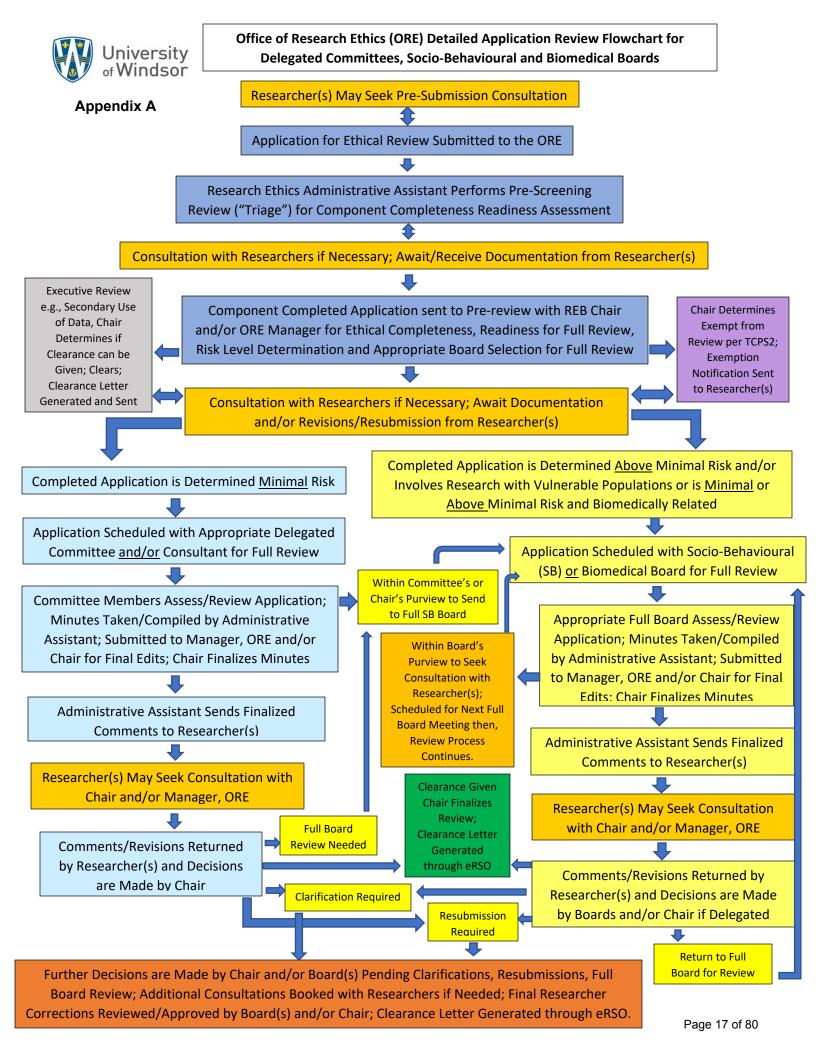
On behalf of the University of Windsor Research Ethics Board, this report is respectfully submitted.

APPENDICES

Appendix A: Detailed Flow Chart

Appendix B: REB Overview of Committees

Appendix C: Guidelines for Research Involving Humans





Appendix B

Research Ethics Board Review Committees, Delegated and Full Boards Prepared by the Office of Research Ethics

Delegated Authority from the Full Board



Chair

(Per Demand)
Executive
Reviews
Protocol

Protocol modifications and final clearance

Executive reviews; Administrative reviews; Secondary use of data; Requests from external researchers Multi-jurisdictional research

Delegated Board

(Weekly) Chair + 2 Board Members

Reviews all minimal risk protocols

Majority of application reviews occur with this



REB for Scholarship of Teaching, Learning and Education

(Per Demand)
Speciality Members

(SoTL-E)

Reviews faculty and student coursebased research, scholarship of teaching and learning research projects



Administrative Research Committee

(Per Demand)
Speciality
Members

Review
administrative
research
protocols and
administrative
survey research
requiring REB
review



Qualitative Methodology Committee

(Per Demand)
Speciality
Members

Review oral history, documentary, case studies and narrative and qualitative methods

Full Review Boards



1

Socio-Behavioral Board-Full Board

(Monthly)
Chair + Full
Board
members
(minimum 5)

Reviews more than minimal risk or speciality protocols

Provides policy direction and planning for REB

Biomedical Board (Monthly)

Chair + Speciality Board members (minimum 5)

Review clinical trials protocols, medical research, and genetic and other human tissue research

Provides policy direction on biomedical research for REB

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

Appendix C



Guidelines for Research Involving Humans

Revised April 2023

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RESEARCH AT THE UNIVERSITY OF WINDSOR

Research is an essential component of the mission of the University of Windsor, and the University is justifiably proud of the contributions to society and to the advancement of knowledge that have resulted from the research of its academic community.

When research involves human participants, their data and/or human biological materials (TCPS 2.1), the University shares with researchers the responsibility that the research is conducted in accordance with the highest ethical standards. In Canada, a common policy of ethical conduct for research has been developed by the Social Sciences and Humanities Research Council of Canada (SSHRC), the Natural Sciences and Engineering Research Council of Canada (NSERC) and what was then the Medical Research Council (MRC). As of 1998, the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)* sets out the interdependent duties to research participants, that are shared by researchers, institutions and Research Ethics Boards (REBs). This policy has been revised four times, and the version at the time of preparation of these revised guidelines is the TCPS2 (2022). "TCPS" refers to this version throughout these guidelines, unless otherwise indicated.

As well as a condition of funding, the *TCPS* sets out, as a minimum, what is expected of researchers and their institutions as ethical standards. It is intended to harmonize the ethics review process involving researchers from different disciplines or institutions. *The University of Windsor Guidelines for Research involving Humans* (2023) are consistent with and reflect the adoption by the University of the *TCPS*, *TCPS2*, and the current *TCPS2* (2022) by the University. Some statements of the University of Windsor *Guidelines* are verbatim adoptions of the *TCPS2* (2022).

CORE PRINCIPLES

Respect for human dignity has been an underlying value of the *TCPS* since its inception. Respect for human dignity requires that research involving humans be conducted in a manner that is sensitive to the inherent worth of all human beings and the respect and consideration that they are due. In this Policy, respect for human dignity is expressed through three core principles – Respect for Persons, Concern for Welfare, and Justice. These core principles transcend disciplinary boundaries and, therefore, are relevant to the full range of research covered by this Policy (*TCPS2*, 2022, Chap. 1B).

The guidelines set out in the *TCPS* and in the *University of Windsor Policy on Research Involving Humans* are based on the following three core principles:

Respect for Persons

The principle 'Respect for Persons' recognizes the intrinsic value of human beings and the respect and consideration that they are due. From this principle flows respect for autonomy; and the need to seek free, informed and ongoing consent.

Concern for Welfare

The principle 'Concern for Welfare' refers to the quality of that person's experience of life in all its aspects. From this principle flows the need to protect the welfare of participants, and in some cases to promote welfare. The welfare of groups of individuals may also be affected by research and must be considered. Generally, risks must be outweighed by benefits in the ethical analysis.

Justice

The principle of 'Justice' is the obligation to treat people fairly and equitably. From this principle flows the need to consider equity in recruitment and inclusion practices; and to manage imbalance of power between members of research teams and research participants.

RESEARCH ETHICS AND LAW

Researchers are responsible for ascertaining and complying with all applicable legal and regulatory requirements with respect to consent and the protection of the privacy of participants. Legal and regulatory requirements may vary depending on the jurisdiction in Canada in which the research is being conducted, and who is funding and/or conducting the research, and they may comprise constitutional, statutory, regulatory, common law, and/or international or legal requirements of jurisdictions outside of Canada. Where research is considered to be a governmental activity, for example, standards for protecting privacy flowing from the *Canadian Charter of Rights and Freedoms*, federal privacy legislation and regulatory requirements would apply (*TCPS2*, 2022, Chap 1C).

The law affects and regulates the standards and conduct of research involving humans in a variety of areas, including, but not limited to privacy, confidentiality, intellectual property and the decision-making capacity of participants. In addition, human rights legislation and most documents on research ethics prohibit discrimination on a variety of grounds and recognize equal treatment as fundamental. REBs and researchers should also respect the spirit of the *Canadian Charter of Rights and Freedoms*, particularly the sections addressing life, liberty and security of the person, as well as those involving equality and

discrimination (*TCPS2*, 2022, Chap 1C).

UNIVERSITY OF WINDSOR RESEARCH ETHICS BOARD

The authority of the University of Windsor REB is established by Senate of the University of Windsor. The REB reports to the Senate annually.

This authority of the REB includes the mandate to SOLELY determine when review is required for any activity that potentially meets the definition of research, and to provide clearance for, reject, propose modifications to, or terminate any proposed or ongoing research involving research participants which is conducted within, or by members of, the institution, using considerations set forth in the most current *TCPS* as a minimum standard.

Mandate

The mandate of the REB is:

- To keep current on ethical issues related to research involving human participants; to educate the University community on these issues and to formulate policies on these matters;
- b. To act as an intermediary, advocate, and provide resources for research participants;
- To determine the scope of activities that require REB oversight. The REB is the sole body that can determine whether an activity constitutes research, and whether review and oversight is required;
- d. To review, approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human participants conducted at University of Windsor or by members of University of Windsor, including anyone affiliated with the University conducting such research at or under the auspices of University of Windsor;
- e. To assess and limit the risks to participants in research involving humans; and where there is more than minimal risk identified, the REB shall engage in the deliberations necessary to be satisfied that the design of a research project is capable of addressing the questions being asked in the research;
- f. To conduct the continuing review of research projects and to determine guidelines for the review and clearance of ongoing research projects and guidelines for reviewing requests for changes in previously approved research:
- g. To develop policies and procedures for assessing and approving undergraduate student research;
- h. To develop policies and procedures for determining scope of review, assessing and providing clearance for teaching activities that involve the collection of data from or about human participants;

- To act as the Appeal Board for appeals of decisions rendered regarding undergraduate student research;
- j. To proactively educate, communicate, advise and serve as a resource to the research community, on guidelines, procedures and other matters relating to the conduct of research with humans;
- k. To meet regularly to discharge the responsibilities of the REB and to keep and maintain minutes of such meetings; with the documentation being accessible to researchers, as it pertains to their application;
- To inform the institution regarding structure and procedures followed by the REB and to engage in activities to review the processes and procedures of the REB;
- m. To maintain strict confidentiality of applications and deliberations about actions, so as to protect the intellectual rights of researchers; excepting when permission is provided by a researcher to breach confidentiality, or to manage academic misconduct or adverse events;
- n. To implement and monitor the final decision of the Appeal Board on behalf of the Research Ethics Appeal Board;
- o. To establish informal or formal agreements with REBs (or other designated ethical review bodies) at other institutions and organizations regarding shared responsibility for research ethics oversight.

RESPONSIBILITIES FOR PROTECTING RESEARCH PARTICIPANTS

Members of the research team

The Principal Investigator

As the individual responsible for the scientific and ethical oversight of the research and the implementation of the research project, the Principal investigator (PI) bears direct responsibility for ensuring the protection of every research participant. The responsibility starts with project design, which must minimize risks to participants while maximizing research benefits. The Principal Investigator must ensure that all members of the research team comply with the requirements of the *University of Windsor Guidelines* and the *TCPS*. The Principal Investigate will be required to present a certificate of successful completion of the *TCPS On-Line Tutorial*.

University of Windsor Students as Principal Investigators

The University of Windsor REB recognizes undergraduate and graduate students as Principal Investigators, but all student protocols must have a faculty supervisor who serves as the de facto PI with responsibility for the conduct of the research. Final responsibility for the ethical conduct of the research lies with the supervisor.

Co-investigators, Collaborators, Consultants, Research Team

Other individuals affiliated with a research project are responsible for working with the PI to implement the research in accordance with the protocol as cleared by the REB. Such individuals will seek to understand the plan for the ethical conduct of research as appropriate to the role that they hold with the project.

All members of the research team share in the responsibility for the ethical conduct of the research and are expected to communicate any ethical concerns about the research to the PI in a timely manner. Further, all members of the research team who will interact with participants or have access to their data must complete appropriate training regarding the requirements of conducting and overseeing research (TCPS2 CORE-2022 Course on Research Ethics or an equivalent) and should have sufficient expertise in the discipline and methods of the proposed research.

The University Administration

The TCPS2 (2022) states that the highest body within an institution shall: establish the REB or REBs, define an appropriate reporting relationship with the REBs, and ensure the REBs are provided with necessary and sufficient ongoing financial and administrative resources to fulfil their duties (*TCPS2*, 2022, 6.2).

The President of the University of Windsor is responsible for establishing and resourcing the REB. This includes the allocation of resources to support the mandates of the REB listed above, REB coordination, support in policy development and interpretation, record keeping, communication and education functions as well as the provision of research ethics training opportunities to REB members, researchers and students. Research ethics administration staff should also have the necessary qualifications, as well as initial and continuing training, to appropriately perform their roles and responsibilities (*TCSP2*, 2022, 6.2).

The President may delegate their responsibilities to a designate from the senior administrative level who has authority and oversight regarding academic or research matters. At the time of the revision of this policy, the responsibilities are designated to the Vice President Research and Innovation, which satisfies this provision. There shall be no further delegation of responsibility.

THE REB IS independent in its decision making. The Administration recognizes that the REB operates at arms-length to the University of Windsor (TCPS2, 2022, 6.2).

The institution recognizes the mandate of the REB to review the ethical acceptability of research on behalf of the institution, including approving, rejecting, proposing modifications to, or terminating any proposed or ongoing research involving humans. This mandate shall apply to research conducted under the auspices or within the jurisdiction of the institution (*TCPS2*, 2022, 6.3).

The University will establish and maintain policies and procedures related to the responsible conduct of research, for example including: conflict of interest, obtaining and using funds, collaboration with other researchers and other institutions. The University shall include the REB in discussions of activities that involve the collection of information from human participants and any area of activity that fall under the jurisdiction of the REB or which may impact the effective functioning of the REB (*TCPS2*, 2022, 6.2).

Academic administrators, such as Deans, Directors and Department Chairs or Heads, have a responsibility for the ethical conduct of research carried out within their jurisdiction. Additionally, they have a duty to create a climate for ethical practice of such research by promoting awareness of this policy and the requirement for ethics review to researchers. Where students are engaged in research, this responsibility should extend to ensuring that students are adequately instructed in the principles and implementation of research ethics, and that the appropriate review mechanisms are in place at the local level.

The qualifications and expertise that the REB needs shall be considered when appointing and renewing REB chairs and members. The University of Windsor shall provide REB members with support to obtain the necessary training to effectively review the ethical issues raised by research proposals that fall within the mandate of the REB (*TCPS2*, 2022, 6.7).

The University of Windsor Research Ethics Board (REB)

The University of Windsor REB is formally constituted to review and monitor all research involving research participants conducted under the auspices of the University. The Board is an autonomous entity whose primary responsibility is ensuring the safety and well-being of all research participants involved in research programs carried out by the University of Windsor researchers.

The REB is responsible for the overall administration and documentation of the ethics review process.

Membership and Terms

The University of Windsor REB shall consist of at least 5 members, including both men and women, appointed by the President, or designate, and in consultation with the current REB Chair. The members of the REB are appointed for three-year terms; terms should be staggered among the REB members. The appointments are renewable. The REB Chair shall be appointed

by the President and shall serve, normally, a term of three years, which is renewable (*TCPS2*, 2022, 6.6).

REB Composition

The REB will seek to maintain broad representation across the disciplines, faculties, and diverse modes of inquiry.

The membership of the REB shall consist of at minimum (TCPS2, 2022, 6.4):

- a. At least two members have expertise in relevant research disciplines, fields and methodologies covered by the REB;
- b. At least one member is knowledgeable in ethics;
- c. At least one member is knowledgeable in the relevant law (but 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; and
- d. At least one community member who has no affiliation with the institution.
- e. The REB shall endeavor to ensure that each member be appointed to formally fulfil the requirements of only one of the above categories.
- f. To ensure the independence of REB decision making, senior administrators, including but not limited to Board of Governors, Deans, Associate Deans, or any other individuals with a conflict of interest regarding the independence of the REB, shall not serve on the REB.

The REB will seek the consultation of ad hoc advisors in the event that it requires additional expertise or knowledge to review the ethical acceptability of a research proposal competently. The Chair may seek additional members to advise on the particular project, or consult externally, in confidence (*TCPS2*, 2022, 6.5).

Recordkeeping

The REB maintains comprehensive records, including all documentation related to the projects submitted to the REB for review, attendance at all REB meetings, and minutes reflecting REB decisions. Where the REB denies ethics approval for a research proposal, the minutes shall include the reasons for this decision (TCPS2, 2022, 6.13).

Communications with the REB are treated as confidential. The contents of REB files are closed. Only members of the REB and its administrative staff have access to records, and only on a need to know basis. The REB shall maintain a privacy policy to ensure protection of REB records.

The REB Chair has the discretion to breach confidentiality in cases of potential academic misconduct, noncompliance, and for reasons of participant protection. The REB Chair will restrict the information that is released to the scope of the issue that is under consideration.

TYPES OF RESEARCH THAT REQUIRE REVIEW

The following requires ethics review and clearance by the REB before the research commences (*TCPS2*, 2022, 2.1):

- research involving living human participants;
- research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals.

Research is defined by the TCPS as an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation (TCPS2, 2022, 2.1).

Human research participant is defined by the *TCPS* as those individuals whose data, or responses to interventions, stimuli or questions by the researcher, are relevant to answering the research question (*TCPS2*, 2022, 2.1).

Research involving human remains, cadavers, tissues, biological fluids, embryos or fetuses is subject to review by the REB (*TCPS2*, 2022, 2.1).

Research requiring review includes any research that:

- is conducted by University of Windsor faculty, staff or students;
- is performed on the premises of the University of Windsor;
- is performed with or involves the use of resources, facilities or equipment belonging to the University;
- involves University students, staff or faculty;
- satisfies a requirement imposed by the University for a degree program or for completion of a course of study;
- is conducted by or under the direction of any employee or agent of the University of Windsor in connection with his or her institutional responsibilities.

When in doubt about the applicability of this Policy to a particular project, the researcher shall seek the opinion of the REB. The REB makes the final decision on exemption from research ethics review as well as the level of proportionate review.

Relationship between Research Ethics Review and Scholarly Review

To be ethical, research must have potential value (also referred to as scientific merit). Per the guidance in the TCPS, REBs will evaluate the scholarly merit of research (*TCPS2*, 2022, 2.7). The REB will begin this process by considering the argument for merit provided in the application. The REB will seek to understand

the potential value of research within disciplinary scholarly standards. Should the REB determine that additional review beyond the information provided by an applicant is required, the REB will determine when it shall seek ad-hoc independent guidance.

In conducting reviews, the REB must remain impartial and should not reject proposals because they are controversial, challenge mainstream thought, or offend powerful or vocal interest groups.

EXEMPTIONS TO THE REVIEW PROCESS

The following areas are identified by the *TCPS (2022)* as normally being exempt from review and approval by a REB. To obtain an exemption, researchers must consult with the REB, which will issue an exemption letter under the appropriate category. Researchers engaging in activities falling under the descriptions below must consult with the REB to determine if they are exempt from review. If the criteria are met, the REB will issue an exemption letter under the relevant category.

Even though review by the REB is not required, the board encourages researchers to treat those who participate in research projects in a manner consistent with the guidelines set out in the Tri-Council Policy Statement, Second Edition. This includes, for example, seeking consent from individuals to gather information, making clear to individuals how their information will be used, providing confidentiality where appropriate, and using the information gathered in a manner that is respectful to those who contributed.

Publicly available information

Research that relies exclusively on publicly available information does not require REB review when:

- a. The information is legally accessible to the public and appropriately protected by law; or
- b. The information is publicly accessible and there is no reasonable expectation of privacy.

Exemption from REB review is based on the information being accessible in the public domain, and that the individuals to whom the information refers have no reasonable expectation of privacy. Information contained in publicly accessible material may, however, be subject to copyright and/or intellectual property rights protections or dissemination restrictions imposed by the legal entity controlling the information (*TCPS2*, 2022, 2.2).

Observation in public places

REB review is not required for research involving the observation of people in public places where:

- a. It does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups.
- b. Individuals or groups targeted for observation have no reasonable expectation of privacy; and
- c. Any dissemination of research results does not allow identification of specific individuals (*TPS2*, 2022, 2.3).

Secondary use of anonymous information

REB review is not required for research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information (*TCPS2*, 2022, 2.4).

ACTIVITIES NOT REQUIRING REB REVIEW

Researchers engaging in activities falling under the description must consult with the REB to determine if they are exempt from review. If the criteria are met, the REB will issue an exemption letter under the relevant category.

Quality assurance and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do not constitute research for the purposes of this Policy, and do not fall within the scope of REB review. These activities refer to assessments of the performance of an organization or its employees or students, within the mandate of the organization, or according to the terms and conditions of employment or training. Those activities are normally administered in the ordinary course of the operation of an organization where participation is required, for example, as a condition of employment in the case of staff performance reviews, or an evaluation in the course of academic or professional training (*TCPS2*, 2022, 2.5).

Researchers engaging in activities falling under the above description must consult with the REB to determine if they are exempt from review. If the criteria are met, the REB will issue an exemption letter under the relevant category.

Creative Practices

Creative practice activities, in and of themselves, do not require REB review. However, research that employs creative practice to obtain information from

participants to answer a research question is subject to REB review (*TCPS2*, 2022, 2.6).

CRITERIA USED BY THE BOARD FOR REVIEW

The following criteria will be considered by the REB when reviewing an application to involve human participants in research:

Risk and risk management

- o the overall level of risk to research participants;
- whether the risks to participants are minimized by using procedures or methods that are consistent with sound research design, but which do not expose participants to unnecessary harm;
- whether the risks are reasonable (balanced) in relation to the anticipated benefits to the participants;
- appropriate provisions are made for the on-going monitoring or continuing review of the participant's welfare;
- whether any potential bystander risks to those who have not been consented to participate in the research have been mitigated;
- o whether the potential benefits outweigh the potential risks;

Consent

- whether the protocol has a consent process which provides for free and informed consent, including providing for withdrawal from the research;
- o whether the purpose of the study is fully outlined;
- if deception is part of the study that it is necessary and justified;
- whether those recruited for the research are competent to provide consent, or if alternative consent will be used;
- o whether rights to withdrawal are provided and are reasonable;

Privacy and confidentiality

 whether there is adequate protection of the privacy of the participants and the confidentiality of the information/data being obtained (prior to, during, and following the completion of the research) and in the data management plan throughout the data life cycle.

Fair inclusion

 whether the selection and recruitment of the participants is inclusive and appropriate in relation to the research participants and to the research;

Conflict of interest, multiple roles, and undue influence

- whether there is any conflict of interest which should be considered, and if so, whether appropriate mechanisms for handling the conflict have been put into place;
- o whether there are any multiple roles between researchers and

- participants, or between individuals involved in the research, and if so if multiple roles are sufficiently acknowledged and managed;
- whether there is a potential for undue influence between any individuals during the conduct of the research.

The REB may consider additional criteria where it is appropriate and in keeping with their mandate.

LEVELS OF REVIEW

The Principle of Proportionate Review

The REB shall adopt a proportionate approach to research ethics review based upon the general principle that the more invasive and risky the research, the greater should be the care in assessing the research (*TCPS2*, 2022, Chap. 1C). 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 (*TCPS2*, 2022, 2.9).

Given that the REB is tasked with assessing risk for a wide range of research activities and must maintain sufficient expertise, specialized review sub-boards may be tasked with reviewing specific classes of research. The REB may designate aspects of a research project to multiple review committees or may seek expert input from a specialized review board at another site for all or a part of a project.

Based upon the principle of proportionate review, the REB reviews applications for research involving research participants at the following four different levels:

- Full REB Review;
- Delegated Review;
- Delegated External Review by a specialized committee formally designated by the REB:
- Executive Review.

Full Board Review

Review by the fully convened University of Windsor REB (Full Board) is the default requirement for all research involving human participants, unless the proposed research meets the criteria for delegated expedited review or review by a formally delegated review committee. Research that requires Full REB review includes:

- All research which involves greater than minimal risk to individuals or a specific community will be reviewed by the Full Board at a regularly constituted meeting;
- Research involving new or unfamiliar methodologies that have greater than minimal risk will be reviewed by the Full Board;
- · Issues specific to biomedical research are discussed below.

The Principal of Minimal Risk

The standard of minimal risk is defined as follows:

"Minimal risk" research is defined as research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research (TCPS2, 2022, Chap. 2).

More-than minimal risk in research projects is assessed through the following methods:

- a. The Chair of the University of Windsor REB or the Chair's designate reviews the projects and assesses whether participants will incur greater-than-minimal risk;
- b. A Delegated internal review board, in the process of reviewing an application, determines that the level of review should be increased in consultation with the Chair of the REB;
- c. A Delegated external board reviews a project or course and the committee identifies factors within the research project which indicate the potential of greater than minimal risk (Delegated boards are expected to consult regularly with the REB regarding this threshold); or
- d. If a researcher requests a Full Board review based on their assessment that the project could incur greater-than-minimal risk.

Delegated Expedited Review

The term "expedited" refers to specific categories of research that may be approved outside a meeting of the Full REB and does not indicate the timing or promptness with which the project is considered and approved.

Research projects meet the criteria for delegated expedited review where:

- The project involves no more than minimal risk;
- The project is a replication of a previously approved protocol with significant revisions, provided it meets the criterion of minimal risk.

Projects which are conducted by expedited review are assessed by the following method: Where the project involves no more than minimal risk or involves significant revisions it will be sent to two REB members and the REB Chair for review and the reviewers will provide a written assessment of the level of risk

and any other ethical issues arising from their review.

Designated external review committees have been established at the University of Windsor. The authority of the external review committee is delegated by the Full REB. The external committee reviews research related to the specific mandate for which the committee is established. All external review committees will operate within written guidelines that have been reviewed and cleared by the Full Board.

Course-Based Research and Research Activities within Courses

Undergraduate and graduate courses which include class projects and activities designed to develop research skills involving research participants require review by the REB. Course activities that involve the collection of information from or about other people require review. A Delegated external specialized committee may include reviewing course-based research skills in their guidelines.

Executive Review

Research projects meet the criteria for executive review, by the Chair of the REB or designate, where:

- a. The project has previously been approved by another Research Ethics Board or other formally constituted ethical review committee;
- b. The project is an application for approval "in principle" to allow for activities not involving human participants, in accordance with the Tri-Council *Memorandum of Understanding*;
- The project is a replication or extension of a previously approved protocol without significant changes to the risks associated with the project;
- d. The project only involves secondary use of existing data;
- e. If the original protocol had notable associated risks, the REB Chair or designate will determine if executive review of the subsequent protocol changes is sufficient.

Decision Making by the REB

Projects for review of research involving research participants may be:

- a. Approved without questions or request for modification;
- b. Approved subject to clarification and/or modifications;
- c. Deferred, pending receipt of additional information or major revisions;
- d. Disapproved

Please note, the reference to "approval" outlines a number of appropriate meanings according to the TCPS 2 and other guiding resources. This language

remains in these Guidelines for compliance. In relationship to the term "clearance", the University of Windsor Research Ethics Board (REB) defines "ethical clearance" as the process set by an institution and presided over by the REB to holistically regulate research projects to ensure their design and execution plan are ethically sound and will render anticipated result with the outcome being approval.

The REB shall function impartially, provide a fair hearing to the researchers involved, and provide reasoned and appropriately documented opinions and decisions. The REB will seek to make decisions on the ethical acceptability of research in an efficient and timely manner, and shall communicate all approvals and refusals in formal correspondence to researchers.

The University of Windsor REB will strive to reach consensus of all members in respect to its decisions concerning applications for review. In the event that consensus cannot be reached, a vote may be taken. The decision of the majority of the REB shall prevail.

The REB shall accommodate reasonable requests from researchers to participate in discussions about their proposals. The REB may also invite researchers to attend an REB meeting to provide further information about their proposal. In either case, the researchers shall not be present when the REB is making its decision. When the REB is considering a negative decision, it shall provide the researcher with all the reasons for doing so and give the researcher an opportunity to reply before making a final decision.

Appeals of REB Decisions

Researchers have the right to request, and REBs have an obligation to provide, prompt reconsideration of decisions affecting a research project (*TCPS2*, 2022, 6.18). Such requests can only be launched for procedural or substantive reasons. The onus is on the researchers to justify the grounds on which they request an appeal and to indicate any breaches to the research ethics review process or any elements of the REB decision that are not supported by the TCPS2 (TCPS2, 2022, 6.20).

The President or designate will, in consultation with the Chair of the REB, designate an Appeal Board Chair and four Appeal Board members. The Appeal Board Chair is a voting member of the Appeal Board. The Chair of REB may not serve on an Appeal Board reviewing an REB decision.

The Appeal Board shall have the authority to review negative decisions made by an REB. In so doing, it may approve, reject or request modifications to the research proposal. Its decision on behalf of the institution shall be final. The Appeal Board will conduct a review of the application and associated documentation, which may include the original ethics application, the original REB decision, all subsequent written communications, documents and records, including REB minutes pertaining to the submission, a copy of a research project for funding of the proposed research, if applicable, relevant references or copies of pertinent guidelines, internal and external policies and legislation.

The Appeal Board will render a final and binding decision by majority vote, which may either

- a. Uphold the original decision;
- b. Modify the original decision; or
- c. Impose specific conditions for approval of the project.

In the event a majority vote is not rendered, the Chair of the Appeal Board shall cast the deciding vote. The Appeal Board will communicate its decision in writing, with reasons, to the researcher, the Chair of the REB and to all members of the Appeal Board. The Appeal Board will provide advice to the REB in the event of the modification of the original decision of the Board, or in the event of the imposition of specific conditions for approval of the project.

Appeals from a decision of a delegated external review committee shall be made to the University of Windsor REB, and the decision of the University of Windsor REB when rendered, shall be final.

MULTI-CENTERED AND INTER-INSTITUTIONAL REVIEW

Research in other jurisdictions or external to the University of Windsor or the University premises

All research conducted by or involving University of Windsor faculty, students or employees or agents, conducted in other jurisdictions or away from the University premises, must comply with the research ethics policy at the University of Windsor, and at the ethics board or through the equivalent board, committee or process at the additional location or institution, provided that there is such a process reasonably available.

Approval by other research boards

Research projects which have been reviewed and approved by research ethics boards other than the University of Windsor REB, will be subject to review, by the Chair of the REB. The REB Chair may seek review by the internal delegated review committee or the Full REB.

Initiating ethical review for multi-jurisdictional research

The ethical review process typically commences with the REB at the institution at which the primary PI is located. In cases where the PI is at another institution, the University of Windsor REB agrees to receive the initial

submission on the other institution's application forms. The REB may request additional information, or ask for the application to be submitted on its form. If the primary PI is from the University of Windsor, the ethics review process should be initiated at the University of Windsor, unless otherwise determined with the Chair of the REB. The University of Windsor REB is the REB of record for its faculty, staff, students, employees or agents.

Multi-Institutional Research

The REB shall be advised as to whether the same project has been reviewed by another REB, including reviews conducted outside of Canada. University of Windsor retains accountability for the research within its institution and by its faculty, staff, students, employees or agents.

Multi-centre research may include:

- A research project conducted at more than one institution or organization either by the same or different researchers;
- A research project conducted jointly by researchers affiliated with different institutions.

Institutional agreements between REBs

The REB may establish formal or informal agreements with other REBs regarding the handling of REB applications between the institutions. Such agreements may be made for individual research projects, or for all research that is jointly conducted between the institutions. Formal agreements must be agreed to by the signatories of both institutions.

CONTINUING REVIEW

The REB shall make the final determination as to the nature and frequency of continuing research ethics review in accordance with a proportionate approach to research ethics review. The proportionate approach means the higher risk, the greater the scrutiny of the continuing review process (*TCPS2*, 2022, 6.14).

Following initial REB review and approval, research ethics review shall continue throughout the life of the project. This includes risks that may remain to participants following the completion of data collection, in the subsequent retention and sharing of data (*TCPS2*, 2022, 2.8).

A progress report will be required at minimum on an annual basis for each project.

Projects that are classified as minimal risk will require an annual status report and a final report upon completion, unless otherwise determined by the REB.

All approved projects may be subject to further review and monitoring by the

REB.

UNANTICIPATED ISSUES AND ADVERSE EVENTS

Researchers, including faculty supervisors and co-investigators, shall report to the REB any unanticipated issue or event that may increase the level of risk to participants, or has other ethical implications that may affect participants' welfare (*TCPS2*, 2022, 6.15). Reports should be directed to the Chair of the REB and submitted according to guidelines on the REB website. Unanticipated issues and adverse events should be reported to the REB no later than 3 days of their occurrence. Serious adverse events should be reported within 24 hours.

Reports of unanticipated issues, adverse and serious adverse events will be investigated by the REB Chair, or their designate, and the results will be communicated to the researcher. Upon report of an unanticipated issue, adverse or serious adverse event; The Chair of the REB may take one or more the following actions until the event is resolved:

- a. Call for a suspension of recruitment for a component or some or all of the research project;
- b. Call for a suspension of activities for some components or all of the research project;
- c. Request additional documentation, REB review or other reports from the research team;
- d. Other action as relevant to addressing the event.

REQUESTS FOR CHANGES TO APPROVED RESEARCH

Researchers shall submit to their REBs in a timely manner requests for substantive changes to their originally approved research. REBs shall decide on the ethical acceptability of those changes to the research in accordance with a proportionate approach to research ethics review.

Researchers are advised to consult with the REB if uncertain whether a change is sufficiently minor to not require reporting.

In general, it is not the scope of the change that dictates the ethics review process, but rather the ethical implications and risk associated with the proposed change.

Changes that substantially alter the nature of the approved research may be assessed as a new research project and require a new REB review (*TCPS2*, 2022, 6.16).

NON-COMPLIANCE

All research involving human research participants must be submitted for

review and receive clearance from the REB before being initiated. The Office of Research Ethics (ethics@uwindsor.ca) and the website www.uwindsor.ca/reb/make these *Guidelines* and the *TCPS* available to researchers.

Researchers should be aware that failure to comply with these *Guidelines* constitute misconduct in research. Allegations of non-compliance can have disciplinary implications. Please refer to the Collective Agreement (Article 60 - Ethical Conduct of Research) *Investigation of Allegation(s) of Fraud and/or Misconduct in Academic Research* and the *Policy on Research Integrity and the Responsible Conduct of Research* (2013) found on the Office of Research Services website.

THE PRINCIPLES OF REVIEW

Risks and Benefits

The REB will determine whether the risks of the research are reasonable in relation to the anticipated benefits (if any) to the research participants and the importance of the knowledge that may reasonably be expected to result. Foreseeable harms should not outweigh anticipated benefits (TCPS2, 2022, Section C).

Risks

Research participants must not be subject to unnecessary risks of harm, and their participation in research must be essential to achieving scientific and societal important aims.

The REB is concerned about risks of:

- Physical harm;
- Psychological and social harm;
- · Injury to reputation or privacy; and
- Breach of any relevant law.

The REB is concerned about risks to:

- The participants involved;
- Bystanders to the research;
- Clearly identifiable third parties;
- · The researcher personally and any staff involved; and
- Broader cultural, ethnic and national interests.

Benefits

In all research involving research participants, there is a duty not only to benefit others, but to maximize the net benefits of the research. Potential benefits include:

- Specific advantages to participants or to third parties or to society;
- Any general increase in human knowledge;
- Increased knowledge of the researcher, especially for student researchers.

Risk Assessment

The REB must determine that risks to participants in all research are minimized by the use of procedures that are consistent with sound research design and which will not expose the participants to unnecessary risks. In keeping with this principle, the REB will examine the research plan, including the research design, debriefing where appropriate, methodology and the data management plan. Research that is poorly designed or is lacking in statistical power such that meaningful results cannot be obtained is ethically problematic because it may erode the public trust in the research process by subjecting research participants to unnecessary risk or by wasting their time.

The REB will also consider the professional qualifications and resources of the research team in its assessment of risk.

Participant Recruitment

Research benefits and burdens should be distributed fairly. Researchers must justify any exclusions based on sex or gender, race, or ethnicity, and exceptions should be made only when there is adequate scientific justification for exclusion.

Recruitment of students, employees, colleagues and subordinates

Researchers should avoid using their own students or employees, colleagues or subordinates as research participants, as both explicit and subtle undue influence or coercion can occur in these cases.

If there is good scientific reason for including students, researchers should provide a rationale addressing the following issues:

- a. Ensure that students are confident that their participation will not influence class standing, grades, or other benefits under the control of the researcher;
- b. Limit the use of extra credit points as a reward for participating;
- c. Keep financial rewards commensurate with the risks of participation;
- d. Inform students who might participate about the review process, the rationale for the study, the process of data collection and the researcher's interest;
- e. Seek to recruit from a broad base of students.

Fairness and Equity in Research Participation

Appropriate Inclusion. Taking into account the scope and objectives of their research, researchers should be inclusive in selecting participants. Researchers shall not exclude individuals from the opportunity to participate in research on the

basis of attributes such as culture, language, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, gender or age, unless there is a valid reason for the exclusion (*TCPS2*, 2022, 4.1).

Inappropriate Exclusion

Research Involving Women

Women shall not be inappropriately excluded from research solely on the basis of gender or sex. Women shall not be inappropriately excluded from research solely on the basis of their reproductive capacity, or because they are pregnant or breastfeeding (*TCPS2*, 2022, 4.2, 4.3).

Research Involving Children

Children shall not be inappropriately excluded from research solely on the basis of their age or developmental stage (*TCPS2*, 2022, 4.4).

Research Involving the Elderly

Elderly people shall not be inappropriately excluded from research solely on the basis of their age (*TCPS2*, 2022, 4.5).

Research Involving First Nations, Métis, Inuit

Chapter 9 of the TCPS2 (2022) provides detailed guidance regarding working with individuals and communities.

Research Involving Participants Lacking Decision-Making Capacity

Subject to applicable legal requirements, individuals who lack capacity to decide whether or not to participate in research shall not be inappropriately excluded from research (TCPS2, 2022, 4.6). Where a researcher seeks to involve individuals in research who do not have decision-making capacity, the researcher shall, in addition to fulfilling the conditions in Articles 3.9 and 3.10, satisfy the REB that:

- a. The research question can be addressed only with participants within the identified group;
- b. The research does not expose the participants to more than minimal risk without the prospect of direct benefits for them; or
- c. Where the research entails only minimal risk, it should at least have the prospect of providing benefits to participants or to a group that is the focus of the research and to which the participants belong.

Participants' Vulnerability and Research

Individuals or groups whose circumstances may make them vulnerable in the context of research should not be inappropriately included or automatically excluded from participation in research on the basis of their circumstances (*TCPS2*, 2022, 4.7).

Research with Specific Populations

Research involving Children and Young People

Research involving children and young people should only be conducted where:

- a. The research question posed is important to the health and well-being of the children;
- b. The participation of children is indispensable to the purpose of the research;
- c. The study method is appropriate for children and young people;
- d. The circumstances in which the research is conducted provide for the physical, emotional and psychological safety of the child or young person; and
- e. An authorized legal representative cannot consent to research that is not in the best interests of the person they represent.

Age of Consent

There are no clear legal requirements about children's abilities to consent to, or to refuse participation in a research project. A young person's consent or a child's consent can be given whenever that person or child has sufficient competence to make a decision about participating in the research. Similarly, a young person or child can withdraw consent or refuse to participate.

Researchers must consider the competence of children relative to the tasks that they will be asked to undertake. In cases that children are thought to be not competent to consent, children will be asked for their assent. Guidelines AND OR POLICIES regarding consent and assent of children may vary depending on the location where the research will take place (e.g., recruiting or administering research within a school board or health care setting).

Research involving Persons who are mentally incompetent

Researchers should consider that those who are not competent to consent for themselves should not be automatically excluded from research which could potentially benefit them as individuals or the group that they represent.

An incompetent participant's withdrawal of consent must be respected, whether or not the participant was competent at the time of the withdrawal.

Research involving First Nations, Métis, Inuit Peoples

The REB will review all research with these groups using the guidance provided in Chapter 9 of the TCPS2 (2022) and subsequent versions of the guidance.

Informed Consent

Overview of the elements of Informed Consent

Informed consent is a process whereby a choice is made:

- by a competent person;
- on the basis of adequate information concerning the nature of the research to be conducted and foreseeable consequences;
- without undue influence or coercion (TCPS2, 2022, 3.1).

The informed consent process is different from getting a research participant to sign the consent form. Researchers should strive to convey information to participants, not merely disclose it to them. In the case of translations, the researcher must satisfy the REB that the translation is accurate and appropriate.

Consent Shall Be Given Voluntarily

- Consent shall be given voluntarily.
- Consent can be withdrawn at any time.
- If a participant withdraws consent, the participant can also request the withdrawal of their data or human biological materials.

Consent Shall Be Informed

Researchers shall provide to prospective participants, or authorized third parties, full disclosure of all information necessary for making an informed decision to participate in a research project (*TCPS2*, 2022, 3.2).

The information generally required for free and informed consent includes:

- Contact information and identification of the researchers;
- Information that the individual is being invited to participate in a research project;
- A statement of the research purpose in plain language, the identity of the researcher, the identity of the funder or sponsor, the expected duration and nature of participation, a description of research procedures, and an explanation of the responsibilities of the participant;
- A plain language and accessible description of all reasonably foreseeable benefits;
- A plain language and accessible description of foreseeable risks both to the participants and in general, that may arise from research participation;
- An assurance that prospective participants:
 - are under no obligation to participate; are free to withdraw at any time without prejudice to pre-existing entitlements;
 - will be given, in a timely manner throughout the course of the research project, information that is relevant to their decision to continue or withdraw from participation; and

- will be given information on the participant's right to request the withdrawal of data or human biological materials, including any limitations on the feasibility of that withdrawal;
- Information concerning the possibility of commercialization of research findings, and the presence of any real, potential or perceived conflicts of interest on the part of the researchers, their institutions or the research sponsors;
- The measures to be undertaken for dissemination of research results and whether participants will be identified directly or indirectly;
- The identity and contact information of a qualified designated representative who can explain scientific or scholarly aspects of the research to participants;
- The identity and contact information of the appropriate individual(s) outside the research team whom participants may contact regarding possible ethical issues in the research;
- An indication of what information will be collected about participants and for what purposes;
- An indication of who will have access to information collected about the identity of participants, a description of how confidentiality will be protected (see <u>Article 5.2</u>);
- A description of the anticipated uses of data; and information indicating who
 may have a duty to disclose information collected, and to whom such
 disclosures could be made:
- Information about any payments, including incentives for participants, reimbursement for participation-related expenses and compensation for injury;
- A statement to the effect that, by consenting, participants have not waived any rights to legal recourse in the event of research-related harm; and
- A statement informing participants of their rights as research participants and the contact information for the Research Ethics Board Office;
- In clinical trials, information on stopping rules and when researchers may remove participants from trial.

Consent Shall Be an Ongoing Process

Consent shall be maintained throughout the research project. Researchers have an ongoing duty to provide participants with all information relevant to their ongoing consent to participate in the research. Consent encompasses a process that begins with the initial contact (e.g., recruitment) and carries through to the end of participants' involvement in the project (TCPS2, 2022, 3.3).

Change in participant capacity is an important element of ongoing consent. Rather than an age-based approach to consent, this Policy advocates an approach based on decision-making capacity as long as it does not conflict with any laws governing research participation. This includes those whose decision-making capacity is in the process of development, those whose decision-making capacity is diminishing or fluctuating, and those whose decision-making capacity

remains only partially developed (Application of <u>Article 3.10</u>) (TCPS2, 2022, 3.3).

Incidental Findings

Researchers have an obligation to disclose to the participant any material incidental findings discovered in the course of research (*TCPS2*, 2022, 3.4).

Consent Shall Precede Collection of, or Access to, Research Data

Research shall begin only after the participants, or their authorized third parties, have provided their consent (*TCPS2*, 2022, 3.5).

Consent and Critical Inquiry

Research in the form of critical inquiry, that is, the analysis of social structures or activities, public policies, or other social phenomena, requires an adjustment in the assessment of consent. In critical inquiry, permission is not required from an institution, organization or other group in order to conduct research on them. If a researcher 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. Specific requirements pertain to aboriginal and indigenous organizations.

Departures from General Principles of Consent

The REB may approve research that involves an alteration to the requirements for consent set out above if the REB is satisfied, and documents, that all of the following apply (*TCPS2*, 2022, 3.7A/B):

- a. The research involves no more than minimal risk to the participants;
- b. The alteration to consent requirements is unlikely to adversely affect the welfare of participants;
- c. It is impossible or impracticable to carry out the research and to address the research question properly, given the research design, if the prior consent of participants is required;
- d. In the case of a proposed alteration, the precise nature and extent of any proposed alteration is defined; and
- e. The plan to provide a debriefing (if any) which may also offer participants the possibility of refusing consent and/or withdrawing data and/or human biological materials.

Debriefing must be a part of all research involving an alteration to consent requirements whenever it is possible, practicable and appropriate.

Participants in such research must have the opportunity to refuse consent and request the withdrawal of their data and/or human biological materials whenever possible, practicable and appropriate.

There may be circumstances in which debriefing is impossible, impracticable or inappropriate in research involving alterations to consent requirements. Note that "impracticable" refers to undue hardship or onerousness that jeopardizes the conduct of the research. It does not refer to mere inconvenience. The onus is on researchers to satisfy the REB that their research involves circumstances that make it impossible, impracticable or inappropriate to offer a debriefing.

All research involving intentional deception will be evaluated by the REB Chair using guidelines established by the Full Board to determine the level of review required. The nature, extent, associated risks, and degree to which the deception can be corrected must be considered. The default for research involving deception absent such review is review by the Full Board.

Consent for Research in Individual Medical Emergencies

Subject to all applicable legal and regulatory requirements, research involving medical emergencies shall be conducted only if it addresses the emergency needs of the individuals involved, and then only in accordance with criteria established in advance of such research by the REB. The REB may allow research that involves medical emergencies to be carried out without the consent of participants, or of their authorized third party, if all of the following apply:

- a. A serious threat to the prospective participant requires immediate intervention;
- Either no standard efficacious care exists or the research offers a realistic possibility of direct benefit to the participant in comparison with standard care;
- c. Either the risk is not greater than that involved in standard efficacious care, or it is clearly justified by the prospect for direct benefits to the participant;
- d. The prospective participant is unconscious or lacks capacity to understand the risks, methods and purposes of the research project;
- e. Third party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so; and
- f. No relevant prior directive by the participant is known to exist.

When a previously incapacitated participant regains decision-making capacity, or when an authorized third party is found, consent shall be sought promptly for continuation in the project, and for subsequent examinations or tests related to the research project.

It is the responsibility of researchers to justify to the REB the need for this exception.

Consent and Decision-Making Capacity

Competence means that a person is capable of making a morally and legally

valid choice to participate in research. In the context of research, it means the capacity to understand the nature and consequences of one's acts. Competence is determined by both the situation and the person's understanding of it. A prospective research participant may be incompetent in certain situations but competent in others (*TCPS2*, 2022, Chap. 3C).

To be considered competent to make a valid choice, prospective research participants should be able to understand and appreciate:

- the nature and purpose of the research in question;
- why they, as opposed to others, are being selected and asked to participate;
- the fact that the suggested intervention is for research purposes;
- the relevant elements of uncertainty about the project;
- what participation in the particular research protocol means for the participant;
- whether or not the intervention may provide any direct personal benefit to them:
- how the consequences of a decision to participate or not to participate will affect their own current and future circumstances;
- that they will be free to withdraw from participation at any time during the course of the protocol;
- that a decision not to participate or to withdraw from participation will not adversely affect their care;
- any conflict of interest on the part of the person recruiting the participants or conducting the study;
- the confidentiality of any records that identify the participant;
- research that involves physical contact or physical activity and, whether compensation or social and psychological support will be available if the participant is harmed and where to get further information about this;
- who can answer questions about the research, including the principal investigator and a neutral third party who can explain the rights of research participants.

Decision-making capacity refers to the ability of prospective or actual participants to understand relevant information presented about a research project, and to appreciate the potential consequences of their decision to participate or not participate.

Assessing decision-making capacity is a question of determining, at a particular point in time, whether a participant (or prospective participant) sufficiently understands the nature of a particular research project, and the risks, consequences and potential benefits associated with it.

One may therefore have diminished capacity in some respects but still be able to decide whether to participate in certain types of research. Researchers should be aware of all applicable legal and regulatory requirements with respect to

decision-making capacity and/or consent. These may vary among jurisdictions. Authorized third parties who are asked to make a consent decision on behalf of a prospective participant should also be aware of their legal responsibilities.

Those who lack the capacity to decide on their own behalf must neither be unfairly excluded from the potential benefits of research participation, nor may their lack of decision-making capacity be used to inappropriately include them in research.

For research involving individuals who lack the capacity, either permanently or temporarily, to decide for themselves whether to participate, the REB shall ensure that, as a minimum, the following conditions are met: (*TCPS2*, 2022, 3.9).

- a. The researcher involves participants who lack the capacity to decide on their own behalf to the greatest extent possible in the decision-making process;
- b. The researcher seeks and maintains consent from authorized third parties in accordance with the best interests of the persons concerned;
- c. The authorized third party is not the researcher or any other member of the research team;
- d. The researcher demonstrates that the research is being carried out for the participant's direct benefit, or for the benefit of other persons in the same category. If the research does not have the potential for direct benefit to the participant but only for the benefit of the other persons in the same category, the researcher shall demonstrate that the research will expose the participant to only a minimal risk and minimal burden, and demonstrate how the participant's welfare will be protected throughout the participation in research; and
- e. When authorization for participation was granted by an authorized third party, and a participant acquires or regains decision-making capacity during the course of the research, the researcher shall promptly seek the participant's consent as a condition of continuing participation.

Broad Consent for the Storage of Data and Human Biological Materials for Future Unspecified Research

Broad consent is defined as consent for future unspecified research (subject to applicable law). Unlike blanket consent, which is typically unrestricted, broad consent always includes specific restrictions (e.g., consent may be restricted to a particular field of study, to a specific disease, or may prevent use by private industry). Broad consent applies to the storage and secondary use of participants' data and human biological materials collected for research purposes. The use of broad consent is in the context of future research using data and human biological materials with no direct contact or intervention with participants at that time. While blanket consent is not permitted under the TCPS, broad consent is permitted (TCPS2, 2022, 3.13).

When seeking consent for a specific research project at the same time as seeking

consent for storage of data and human biological materials for future unspecified research, prospective participants must be provided with an option to consent to each separately.

To seek broad consent for the storage and future unspecified use of data and human biological materials, researchers shall provide prospective participants, or authorized third parties, with applicable information as set out in Articles 3.2 and 12.2 in the TCPS as well as the following details, as appropriate to the particular research project:

- a. the type, identifiability, and amount of data and human biological materials being collected and stored for re-use, and for what potential purpose;
- b. the voluntariness of the participant's consent, including any limitations on the feasibility of withdrawal;
- a general description of the nature and types of future research that may be conducted, including whether the research might be conducted outside of Canada (if known);
- d. the risks and potential benefits of storage of data and human biological materials, and of their use in future unspecified research, including areas of uncertainty where risks cannot be estimated;
- e. access to a general description of the repository and its governance;
- f. a statement regarding participants' preference to being re-contacted for additional future research;
- g. whether the data or human biological materials could be shared with researchers who are not subject to the TCPS;
- h. whether the research will (if known) or might include whole genome sequencing or similar technologies that may pose a substantial risk of reidentification of the participant or identification of material incidental findings (when appropriate);
- i. whether linkage of data gathered in the research or derived from human biological materials with other data about participants either contained in public or personal records is anticipated (Article 5.3); and
- j. separate options for consenting to participate in a specific research project and for consenting to the storage of data and human biological materials for future unspecified research.

Principle of Assent

Where an authorized third party has consented on behalf of an individual who lacks legal capacity, but that person has some ability to understand the significance of the research, the researcher shall ascertain the wishes of that individual with respect to participation. Prospective participants' dissent will preclude their participation (*TCPS2*, 2014, 3.10).

Many individuals who lack legal capacity to make decisions may still be able to express their wishes in a meaningful way, even if such expression may not fulfil

all of the requirements for consent. Prospective participants may be capable of verbally or physically assenting to, or dissenting from, participation in research.

Those who may be capable of assent or dissent include:

- those whose decision-making capacity is in the process of development,
 such as children whose capacity for judgment and self-direction is maturing;
- those who once were capable of making an autonomous decision regarding consent but whose decision-making capacity is diminishing or fluctuating; and
- those whose decision-making capacity remains only partially developed, such as those living with permanent cognitive impairment.

While the assent of individuals who lack legal capacity to make decisions would not be sufficient to permit them to participate in the absence of consent by an authorized third party, their expression of dissent or signs suggesting they do not wish to participate must be respected.

Research directives

Where individuals have signed a research directive indicating their preferences about future participation in research in the event that they lose capacity or upon death, researchers and authorized third parties should be guided by these directives during the consent process (TCPS2, 2014, 3.11).

Consent shall be documented

Evidence of consent shall be contained either in a signed consent form or by the researcher utilizing another appropriate means of consent, which shall be documented (TCPS2, 2014, 3.12). The researcher shall bear the onus to comply with the REB guidelines and standards for free and informed consent and must satisfy the REB that all elements of consent have been addressed.

Written consent in a signed statement from the participant is a common means of demonstrating consent, and in some instances, is mandatory. However, written documentation of consent is not required. Where consent is not documented in a signed consent form, researchers may use a range of consent procedures, including oral consent, field notes and other strategies, for documenting the consent process. Consent may also be demonstrated solely by the actions of the participant (e.g., through the return of a completed questionnaire).

Where individual written consent is inappropriate, either because of the nature of the research or the characteristics or culture of the proposed research participants, an alternative process for consent should be developed by the researcher and details of the alternative process should be submitted to the REB for review and approval.

Whether or not a consent form is signed, it may be advisable to leave a written

statement of the information conveyed in the consent process with the participant. For participants, it is evidence that they have agreed to participate in a particular research project. It may serve as a reminder to participants of the terms of the research project. It may also facilitate the ability of participants to consider and reconsider their involvement as the research proceeds. However, researchers should not leave any documentation with participants if it may compromise their safety or confidentiality. Additionally, in some cases it may not be appropriate to leave a written statement, such as in cultural settings where such written documentation is contrary to prevailing norms.

Consent and Disclosure of Information

Informed consent means a choice based upon all relevant information concerning the proposed research. The researcher must provide information concerning the purpose and nature of the research, the potential harms and benefits, and the process of research participation as outlined above in *Consent Shall Be Informed*.

Information must be provided to the participant in a way that meets the following requirements:

- in the prospective research participant's preferred language;
- in lay terms that avoid the overuse of technical terms;
- preferably in the first or second person (e.g., "you" or "your child");
- at an appropriate level for the person's age and educational level; and
- with descriptive accounts of relevant information.

Voluntariness of consent

For consent to be voluntary, free and genuine, an individual must have the opportunity to choose between consent and refusal, without undue interference, fear, constraint, compulsion or undue inducement. Undue influence includes physical duress; fraudulent misrepresentation, or promises of companionship, or affection; economic incentives; emphasis on benefits over risks or burdens; or appeals to emotional weaknesses, loyalty to professional care givers, or family solidarity.

Particular care must be taken in cases where the prospective research participants are students, or employees, or are dependent upon family or other care-givers, or where the prospective participants are in long-term care facilities and other institutional settings.

Payments or incentives to participate must be reasonable and must not place undue pressure on research participants either to join or remain within a research project.

Potential research participants should not feel rushed or coerced and they should have the time to consult with others.

Exceptions and alterations to normal consent requirements

The REB may approve a consent procedure which does not include, or which alters some or all of the elements of the normal requirements for informed consent, or waive the requirement to obtain informed consent, provided that the REB can be offered a rationale that:

- a. The research involves no more than minimal risk to the participants;
- b. The waiver or alteration is unlikely to adversely affect the rights and welfare of the participants;
- c. The research could not be practicably carried out without the waiver alteration;
- d. Whenever possible and appropriate, the participants will be provided with additional pertinent information after participation; and
- e. The waiver or altered consent does not involve a therapeutic intervention.

When in doubt about an issue involving free and informed consent, researchers should consult the REB.

Deception

Prospective participants normally must be fully informed about the purpose of the study before being asked to agree to participate. There may be legitimate reasons, however, for needing to withhold specific details about a study. In this situation, it is the researcher's responsibility to provide sufficient detail on the application form about the nature of the deception as well as a rationale for why it is necessary.

Research participants involving deception must be involved in a debriefing session at the end of their participation. This debriefing session serves as an opportunity to provide participants with an explanation for why deception was required to answer any questions in regard to the use of deception. In cases where the research may have impacted upon the psychological health or well-being of the participant, it may be appropriate to provide additional follow-up or to offer counseling or other types of assistance.

The REB requests that researchers seek written consent from participants to use the data obtained in the research that employed the deception. Once the deception is revealed, participants should be given a contact on the REB if they have any concerns about the conduct of the research.

Privacy and Confidentiality

Privacy. Privacy refers to an individual's right to be free from intrusion or

interference by others. It is a fundamental right in a free and democratic society. Individuals have privacy interests in relation to their bodies, personal information, expressed thoughts and opinions, personal communications with others, and spaces they occupy. An important aspect of privacy is the right to control information about oneself (*TCPS2*, 2022, Chap. 5A).

The concept of consent is related to the right to privacy. Privacy is respected if an individual has an opportunity to exercise control over personal information by consenting to, or withholding consent for, the collection, use and/or disclosure of information.

Confidentiality. The ethical duty of confidentiality refers to the obligation of an individual or organization to safeguard entrusted information. The ethical duty of confidentiality includes obligations to protect information from unauthorized access, use, disclosure, modification, loss or theft (*TCPS2*, 2022, Chap. 5A).

Security. Security refers to measures used to protect information. It includes physical, administrative and technical safeguards.

Identifiable Information. Where researchers seek to collect, use, share and access different types of information or data about participants, they are expected to determine whether the information or data proposed in research may reasonably be expected to identify an individual. Information is identifiable if it may reasonably be expected to identify an individual, when used alone or combined with other available information. Information is non-identifiable if it does not identify an individual, for all practical purposes, when used alone or combined with other available information. The assessment of whether information is identifiable is made in the context of a specific research project. Researchers and REBs shall consider whether information proposed for use in research is identifiable. The following categories provide guidance for assessing the extent to which information could be used to identify an individual:

- Directly identifying information the information identifies a specific individual through direct identifiers (e.g., name, social insurance number, personal health number).
- Indirectly identifying information the information can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g., date of birth, place of residence or unique personal characteristic).
- Coded information direct identifiers are removed from the information and replaced with a code. Depending on access to the code, it may be possible to re-identify specific participants (e.g., the principal investigator retains a list that links the participants' code names with their actual name so data can be re-linked if necessary).
- Anonymized information the information is irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-

- identification of individuals from remaining indirect identifiers is low or very low.
- Anonymous information the information never had identifiers associated with it (e.g., anonymous surveys) and risk of identification of individuals is low or very low.

Ethical duty of confidentiality

Researchers shall safeguard information entrusted to them and not misuse or wrongfully disclose it. Institutions shall support their researchers in maintaining promises of confidentiality (*TCPS2*, 2022, 5.1).

Researchers shall describe measures for meeting confidentiality obligations and explain any reasonably foreseeable disclosure requirements in application materials they submit to the REB; and during the consent process with prospective participants (*TCPS2*, 2022, 5.2).

Researchers shall provide details to the REB regarding their proposed measures and data management plan throughout the data life cycle for safeguarding information, for the full life cycle of information: its collection, use, dissemination, retention and/or disposal (*TCPS2*, 2022, 5.3).

Institutions or organizations where research data are held have a responsibility to establish appropriate institutional security safeguards.

Research participants have a right to privacy and researchers have a corresponding duty to treat private information in a respectful and confidential manner. When reviewing applications for approval, the REB must balance the need for research against infringements of privacy; invasions of privacy must be minimized as much as possible. The value of privacy of research participants is not absolute, some public interests such as protection of health, life and safety may require infringement of the right to privacy, as may the type of research being conducted; without access to personal information, it would be difficult if not impossible to conduct important societal research in such fields as epidemiology, history, genetics and politics.

Different cultures will value privacy in different ways and these values must be respected. The issue of privacy must be looked at from the cultural perspective of the participant, not the researcher. As a general guide, the best protection of the confidentiality of personal information and records will be achieved through anonymity. Researchers are responsible for ensuring the confidentiality of data on research participants by maintaining such data in secure storage and by limiting access to data to authorized individuals.

The REB is required to review research projects in adherence to both provincial and federal privacy laws.

Group Research Events and the Limits of Confidentiality

When information is gathered in a group setting (including focus groups) for research, the following statement or a statement of a similar nature needs to be included in the confidentiality section of the Letter of Information and the Consent Form:

"The focus group is a group event. This means that while confidentiality of all the information given by the participants will be protected by the researchers themselves, this information will be heard by all the participants and therefore will not be strictly confidential."

Researchers must discuss how they plan to manage the inherent risks to confidentiality that are present in group research events.

Disclosure of Results

In all cases, where data have been obtained, research participants have the right to request and receive the results and interpretation of grouped data within a reasonable period of time. The investigator has the responsibility to present individual data, accurately, sensitively, and in a language comprehensible by the participant. Researchers may also articulate an intention to select information that will be reviewed and then communicated to participants under certain circumstances as part of the research plan.

Immediate full disclosure of results may not be feasible in all cases, for example where data has been collected over an extended period of time. Disclosure of results may have to be deferred until the end of the project. In some cases, it may be more appropriate to disclose the results to the parents, guardians or authorized third parties, or the entire family or community.

Equitable Distribution of Research Benefits

Researchers should consider ways to ensure the equitable distribution of any benefits of participation in research.

Researchers should also be sensitive to the expectations and opinions of participants regarding potential benefits of the research. Prior to the commencement of the research, researchers should formally or informally discuss these expectations with individuals and/or groups, and outline the scope and nature of potential benefits that may accrue to participants during and after the research. REBs should be vigilant to ensure that the proposed distribution of benefits is fair, without imposing undue burdens on the researcher that would make it too difficult or costly to complete research (TCPS2, 2022, Chap. 4).

Researchers should normally provide copies of publications, or other research reports or products, arising from the research to the institution or organization – normally the host institution – that is best suited to act as a repository and disseminator of the results within the participating communities. In general, researchers should ensure that participating individuals, groups and communities are informed of how to access the results of the research. Results of the research should be made available to them in a culturally appropriate and meaningful format, such as reports in plain language in addition to technical reports.

Conflict of Interest

Researchers and REB members must disclose actual, perceived or potential conflicts of interest.

Conflicts of interest involving researchers

Conflicts of interest most often arise out of the structural features of relationships or practices. In many situations it is impossible to eliminate conflicts of interest, however, they must be identified so that steps can be taken to disclose them openly and to control their impact. Conflicts of interest may or may not involve financial or monetary interests. The central issue is that individuals may be drawn in two directions at once in such a manner that their judgment may be affected, or their motives may be open to question (*TCPS2*, 2022, 7.4).

To identify and address conflicts properly, researchers must advise the REB on budgets, commercial interests, consultative relationships and any other relevant information, if requested. When a significant real or apparent conflict of interest is apparent, the REB may require the researcher to disclose this conflict to the prospective participants during the informed consent process.

The REB should seek to ensure that financial considerations do not serve to diminish respect for the principles of this Policy or the scientific validity and transparency of research procedures (TCPS2, 2022, Chap. 7).

To assess the likelihood of a real or an apparent conflict of interest which must be disclosed, researchers should consider:

- Whether an outside observer would question the ability of the individual to make a proper decision despite possible considerations of private or personal interests;
- Whether the public would believe that the trust relationship between the relevant parties are a conflict of interest.

Management of multiple roles

Multiple roles of researchers and their associated obligations (e.g., acting as both a researcher and a therapist, health care provider, caregiver, teacher, advisor, consultant, supervisor, student or employer) may create conflicts, undue

influences, power imbalances or coercion that could affect relationships with others and affect decision-making procedures (e.g., consent of participants). To preserve and not abuse the trust on which many professional relationships rest, researchers should be fully cognizant of conflicts of interest that may arise from their dual or multiple roles, their rights and responsibilities, and how they can manage the conflict. When acting in dual or multiple roles, the researcher shall disclose the nature of the conflict to the participant in the consent process (TCPS2, 2022, Chap. 7).

Conflicts of interest by REB members

If the REB is reviewing research in which a member of the Board has a personal interest (e.g. as a researcher or as an entrepreneur), conflict of interest principles require that the member not be present when the REB is discussing or making its decision.

No member of an REB should review research in which he or she has any conflict of interest, including any personal involvement or participation in the research, financial interest in the outcome, involvement in competing research, or an interest as a supervisor of a student researcher, for the purpose of carrying out the research project.

Institutional conflict of interest

The REB maintains an arms-length relationship with the University and is an autonomous board with a mandate to ensure that all research involving human participants are in compliance with the current version of the *TCPS*, including avoiding and managing real and apparent conflicts of interest between the institution and human research participants (*TCPS2*, 2022, 7.1).

Conflicts of interest will be managed per the guidance in the TCPS2 (2022), subsequent guidance, and the University of Windsor Conflict of Interest Policy.

SPECIFIC RESEARCH METHODOLOGIES AND DOMAINS

Qualitative research

Issues regarding the ethical conduct of research using qualitative methods are discussed in detail in Chapter 10 of the TCPS2 (2022).

Qualitative research may pose special ethical issues around gaining access, building rapport, using data and publishing results. Researchers and REBs should consider issues of consent, confidentiality and privacy, and relationships between researchers and participants in the design, review and conduct of the research. Some of these may be identified in the design phase. Others will arise during the research itself, which will require the exercise of discretion, sound judgment and

flexibility commensurate with the level of risk and potential benefit arising from the research, and considering the welfare of the participants, individually or collectively.

Clinical trials

Detailed information about ethical considerations when conducting clinical trials is provided in Chapter 11 of the TCPS2 (2022).

Human biological materials and genetic research

Detailed information about ethical considerations when conducting research with human biological materials and genetic research is provided in Chapters 12 and 13 of the TCPS2 (2022).

Naturalistic observation

Ethics review is normally required for research involving naturalistic observation. Naturalistic observation which does not allow for the identification of the participants and that is not staged should normally be regarded as of minimal risk and eligible for expedited review.

REB review is not required for research involving the observation of people in public places where (*TCPS2*, 2022, 2.3):

- a. It does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups;
- Individuals or groups targeted for observation have no reasonable expectation of privacy; and
- c. Any dissemination of research results does not allow identification of specific individuals.

Projects involving the use of naturalistic observation where it is clear that the participants are seeking public visibility (for example at political rallies, demonstrations or public meetings) and where participant confidentiality and anonymity are ensured do not require ethics review.

Secondary use of data

Secondary use refers to the use in research of information originally collected for a purpose other than the current research purpose.

Secondary use of data is the use in research of data contained in records collected for a purpose other than the research itself, such as patient or school records, or records from previously conducted research.

Reasons to conduct secondary analyses of data include: avoidance of duplication in primary collection and the associated reduction of burdens on

participants; corroboration or criticism of the conclusions of the original project; comparison of change in a research sample over time; application of new tests of hypotheses that were not available at the time of original data collection; and confirmation that the data are authentic.

REB review is not required for research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information (*TCPS2*, 2022, 2.4).

If the participants were anonymous or the information collected was completely anonymized under a prior REB clearance, then REB review is not required for subsequent use.

Privacy concerns and questions about the need to seek consent arise when information provided for secondary use in research can be linked to individuals, and when the possibility exists that individuals can be identified in published reports, or through data linkage. Privacy legislation recognizes these concerns and permits secondary use of identifiable information under certain circumstances (TCPS2, 2022, Chap. 5D).

Researchers who have not obtained consent from participants for secondary use of identifiable information shall only use such information for these purposes if they have satisfied the REB that (*TCPS2*, 2022, 5.5A):

- a) identifiable information is essential to the research;
- b) the use of identifiable information without the participants' consent is unlikely to adversely affect the welfare of individuals to whom the information relates;
- c) the researchers will take appropriate measures to protect the privacy of individuals, and to safeguard the identifiable information;
- d) the researchers will comply with any known preferences previously expressed by individuals about any use of their information;
- e) it is impossible or impracticable to seek consent from individuals to whom the information relates; and
- f) the researchers have obtained any other necessary permission for secondary use of information for research purposes.

In the case of secondary use of identifiable information, researchers must obtain consent unless the researcher satisfies requirements a through f listed above.

"Impracticable" refers to undue hardship or onerousness that jeopardizes the conduct of the research; it does not mean mere inconvenience.

Right to provide permission for secondary use

At the time of initial collection, individuals may have had an opportunity to express preferences about future uses of information, including research uses. Data stewards have an obligation to respect the individual's expressed preferences. For example, where an individual does not want information used for future research, data stewards shall remove this information from any datasets used or made available for research.

Researchers shall seek REB review, but are not required to seek participant consent, for research that relies exclusively on the secondary use of non-identifiable information, where the data have been anonymized and it is not possible to identify any specific participant or their data.

When secondary use of identifiable information without the requirement to seek consent has been approved, researchers who propose to contact individuals for additional information shall, prior to contact, seek REB approval of the plan for making contact (TCPS2, 2022, 5.6).

Data linkage

Researchers who propose to engage in data linkage shall obtain REB approval prior to carrying out the data linkage, unless the research relies exclusively on publicly available information. The application for approval shall describe the data that will be linked and the likelihood that identifiable information will be created through the data linkage (*TCPS2*, 2022, 5.7).

Where data linkage involves or is likely to produce identifiable information, researchers shall satisfy the REB that: the data linkage is essential to the research; and appropriate security measures will be implemented to safeguard information.

SUBMITTING RESEARCH FOR REVIEW: APPLICATION PROCESS

What to submit

All forms that researchers must file with the REB are available on the <u>REB</u> website (https://www.uwindsor.ca/research-ethics-board/).

The Office of Research Ethics can assist researchers with the completion of the application and with any questions relating to the ethics review process (519-253-3000 x3948; ethics@uwindsor.ca).

Other items to include in applications

One digital copy of the application form and all accompanying material must be

submitted including an original, signed signature page to the Office of Research Ethics.

Applications should be accompanied by: (where applicable)

- a copy of all questionnaires or test instruments;
- a copy of any recruitment notices, e-mails, advertisements or any other material to be used to solicit participation;
- a description of any verbal explanation to be given to participants before they are asked to consent to participate in the study;
- a transcript of any script(s) to be used;
- a copy of any consent form(s) to be completed;
- a copy of any debriefing script/research summary sheet or materials to be provided to the participants;
- copies of all contracts relevant to the conduct of the research
- copies of all letters of permission required to gain access to sites, participants, information, secondary data, etc.;
- any other material relevant to the REB decision.

REQUIREMENTS FOR ADDITIONAL CERTIFICATIONS AND APPROVALS

Researchers are responsible for obtaining any additional certifications or approvals that are required prior to conducting the research, and submitting copies of approvals to the REB. Such certifications may be internal to the University of Windsor, or from an external agency or authority.

REB clearance does not provide certification in any of the following areas, each of which requires review by another committee at the University, including but not limited to:

- Biosafety
- Radiation
- Chemical Control
- Animal Care

In addition, research involving human pluripotent or human totipotent stem cells that have been derived from an embryonic source, and/or that will be grafted or transferred in any other form into humans or non-human animals requires review and approval by the Stem Cell Oversight Committee (SCOC) as well as the REB. The researcher shall provide evidence of SCOC approval to the REB. SCOC reviews research involving human pluripotent and human totipotent stem cells that:

- have been derived from an embryonic source; and/or
- will be transferred into humans or non-human animals.

SCOC does not review research involving human pluripotent stem cells that come

from somatic (non-embryonic) tissue and that are not going to be transferred into humans or non-human animals (TCPS2, 2022, 12.10).

University of Windsor Senate Governance Committee

5.2: Report on Renewal, Tenure, and Promotion

Item for: **Information**

Background:

At the June 2022 meeting, Senate passed the following motion.

MOTION: That the University Committee on Academic Promotion and Tenure (UCAPT) report to Senate in the Fall and Spring, through the Senate Governance Committee (SGC), an aggregated update on the Renewal, Tenure, and Promotion (RTP) process for the current academic year. Respecting the required confidentiality, the report shall include, as appropriate:

- 1. Information concerning: revisions to UCAPT and AAU (Academic Administrative Unit) RTP content (e.g., to reflect Equity, Diversity, Inclusion, and Decolonizing [EDID] initiatives); dates on mandatory training sessions for Deans, Heads and Directors including list of attendees, relevant supports (e.g., faculty RTP ombudsperson), a performance assessment of personnel critical to the RTP process (e.g. heads, directors, and deans); and any issues identified, together with a plan for redress;
- 2. UCAPT identified Equity, Diversity, Inclusion, and Decolonizing (EDID) data to control for equity and parity;
- 3. Gross number of faculty submitting applications at each stage in the RTP process, with final outcomes as currently available;
- 4. Processing times between identified critical action points at each stage of the RTP process;
- 5. Results from an anonymous "Faculty Evaluation of Process" (FEP) survey to be offered to all faculty that have undergone a UCAPT process during the academic year;
- 6. Any other such relevant items as prioritized by the President, UCAPT, Vice-President EDI, or the SGC.
- 7. Recommendations for Senate Bylaw revision identified as necessary.

See attached.

SPRING 2023 REPORT to SENATE – UCAPT/RTP Process

This report summarizes UCAPT related information for the academic year 2022-2023 pertaining the motion of UCAPT reporting to Senate on aggregated RTP details for this academic year.

General Information

The University Committee on Academic Promotion and Tenure (UCAPT) normally meets regularly between November and June during the academic year (July 1 to June 30) to review and recommend applications for contract renewals; applications for tenure and promotion to associate professor; applications for permanence and promotion for AAS; applications for promotion to full professor or Level IV for AAS. UCAPT also reviews ongoing significant updates and changes to renewal-tenure-promotion (RTP) or renewal-permanence-promotion (RPP) criteria. UCAPT also provides commentary on general issues that may arise in the RTP/RPP process.

A parallel process governs advancement for University librarians and law librarians via the University Committee on Renewal, Permanence, and Promotion for Library Members (UCRPPLM). Where appropriate, data on advancement for UCRPPLM members is also reported.

As overall observations for 2022 to 2023, UCAPT notes that:

- AAUs are increasingly revising and submitting updated RTP/RPP criteria for their unit members. These
 criteria are moving towards a rubric based format for assessment.
- AAUs are increasingly addressing how equity, diversity, and inclusion, and Indigenization and Decolonization are being considered within their criteria.
- AAUs are now developing criteria appropriate for the new teaching intensive positions.
- AAUs are facing increasing challenges in securing the required 3 external reviews, particularly if the position is unique to Windsor (e.g., certain AAS positions).

Training and Information Sessions

A variety of information and outreach sessions were held during the Fall of 2022 to provide information about the RTP process in general.

- The RTP general information session is open to RTP committee members, UCAPT members, AAU Heads, candidates, and other members interested in more information about the RTP process. This was held on Thursday, September 29th with 34 individuals attending.
- 2. At the biweekly Deans Council meeting on Wednesday, October 19, an information session focussing on the new R TP "checkpoint" process being implemented by this motion was presented to all Deans or their representatives.
- 3. Using the AAU Heads Group network, an information session focussing on the new RTP "checkpoint" process being implemented by this motion for all AAU Heads was held on Tuesday, October 25th with 20 individuals attending.
- 4. On Tuesday, November 1st a session was held for all administrative assistants with 19 individuals attending.
- 5. Spring 2023 revision to the UCAPT evaluation form and the new Student Perceptions of Teaching form (former SET survey form). Separate sessions were scheduled for the following to discuss the revision of these new forms:
 - Deans Council March 1, 2023, with 14 individuals attending including guests.
 - Associate Deans Council March 9, 2023, with 19 individuals attending.
 - AAU heads March 9, 2023, with 27 individuals attending.
 - Student Senate Caucus March 22, 2023.
 - Provost's Council April 1, 2023, with 14 individuals attending.
 - UCAPT April 18, 2023, with 10 individuals attending.

At the general RTP information session, the main topics for discussion focused on:

- The specifics of applying the various rules and procedures for candidates applying to the RTP process.
- A discussion for preparing a teaching portfolio.
- Feedback from Dean Ken Montgomery from Education about the RTP process.
- Discussion surrounding the upcoming RTP reporting checkpoint process introduced by this motion.

A conceptual workflow and reporting/tracking structure of key RTP related activities (including decisions) was developed and presented to the Deans; the AAU Heads Networking group; and the departmental administrative assistants for their feedback and commentary at the events noted above. Given the amount of work the RTP process entails, one key objective is to minimize the additional amount of time and effort necessary for reporting on the RTP process in any AAU and corresponding Faculty. As of this writing and based on the feedback received, the reporting process was envisioned as a combination spreadsheet / shared drive access as a preliminary tracking mechanism for key RTP activities. The initial attempt to create such a tool has proven to be technically challenging, and more assistance is being sought to develop this tool. There has also been some discussion into a future web-based approach for handling the RTP process for improved efficiency: this is commonplace among other institutions.

UCAPT identified Equity, Diversity, Inclusion, and Decolonizing (EDID) data

UCAPT does not receive applicant data that would identify if a member belongs to a designated group. Because of the confidential and sensitive nature of such data, there are strict measures on accessing such information. The Office of Human Rights, Equity, and Accessibility has been contacted to determine how such information can be compiled. As of the time of this writing, a solution is being actively explored with OHREA to provide the requested EDID data in aggregate.

Candidate Related Data and RTP/RPP Process

For the 2022-2023 academic year, we received the following applications from all Faculties:

- 17 contract renewals (15 faculty; 1 AAS; 1 Sessional Lecturer all completed)
- 27 tenure and promotion to associate professor (18 completed; 9 pending)
- 3 permanence and promotion to AAS III (2 completed; 1 pending)
- 9 promotions to full professor (5 completed; 4 pending)
- 4 promotions to Sessional Lecturer III (all completed)

For the 2022-2023 academic year, we received the following from the libraries:

- 1 contract renewal (completed)
- 1 permanence and promotion to Librarian III (completed)
- 1 permanence only consideration (completed)
- 2 promotions to Librarian IV (1 complete; 1 pending)

The feedback from both the Deans and AAU heads indicates that the current due dates for applications to be submitted to UCAPT are unrealistic; for example, most RTP committees cannot be formed until late September when faculty and student representatives are available. Current bylaw deadlines would require a much earlier start, which is impractical given the circumstances. Based on the various discussions with the Deans, Associate Deans, AAU Heads and the current membership of UCAPT, the dates for submission to UCAPT should be changed to improve the efficiency and effectiveness of the process. The suggested, revised dates are:

- Contract renewals December 15
- Tenure/permanence and promotion January 31
- Promotion Full professor, Librarian IV, AAS IV March 15

For 2022-2023, multiple AAUs have noted significant challenges in securing and receiving sufficient external referee letters. Of the pending applications still expected, the vast majority are awaiting a third and final reference letter to

allow the AAU to complete their assessment. After the RTP/RPP applications for 2022-2023 are completed, the Office of the AVPA will review the issues that arose and consider best practices for addressing this challenge.

Additional Items

In addition to the possible Bylaw changes for submission dates outlined previously, a revised UCAPT assessment form has been developed that closely aligns with the general format adopted by most updated AAU RTP/RPP criteria, and streamlines the documentation requirements. This new form has been demonstrated to multiple groups, and especially AAU heads who are the primary users of the form. The feedback about this new form has been very positive. The intent is to implement the revised form for the 2023-2024 academic year.

UCAPT has considered and discussed the items contained in the motion. UCAPT supports the intention for improved communications and reporting. However, it has raised concerns about multiple elements of the motion. In addition to the prior concerns about confidential or sensitive information, it is not clear what the scope of actions are being requested in some instances, nor what would be the measurable or demonstrated benefits in others. UCAPT is concerned that acting on elements within the motion may create unintended impacts; establish a process that is outside of Senate approved processes; or duplicate provisions already allowed for under the current, approved Senate bylaws and processes. As a result, UCAPT would like to refer this motion to Senate Governance for review.

University of Windsor Senate Governance Committee

5.3.1: Senate Standing Committees

Item for: Approval

Forwarded by: SGC Nominating Committee

MOTION: That the Senate Governance Committee recommend to Senate that the Senate Standing

Committees membership for 2023-2024 be approved.

*See attached.

Program Development Committee				
Member	Term	Notations		
Provost and Vice President, Academic (or designate) – Robert Aguirre	Ex-officio			
Dean of Graduate Studies (or designate) – Patti Weir	Ex-officio			
Vice-Provost, Teaching and Learning (or designate) – Erika Kustra (designate)	Ex-officio			
Faculty of Business Administration				
Fazle Baki (S.2024)	2023-2025			
Faculty of Education				
Zuochen Zhang (S. 2024)	2023-2025			
Faculty of Engineering				
Darryl Danelon (S. 2024)	2023-2025			
Faculty of Human Kinetics	,			
Sarah Woodruff Atkinson	2022-2024			
Faculty of Law				
Gemma Smyth	2022-2024			
Faculty of Nursing	,			
Eric Tanlaka (S.2024)	2022-2024			
Faculty of Science				
Arunita Jaekel	2023-2025			
Nurlan Turdaliev (S. 2024)	2023-2025			
Faculty of Arts Humanities & Social Science	ces (at least one from Social Scier	nce & one from Arts)		
Arts/Humanities –Jeremy Worth	2023- 2025			
Arts/Humanities – Lionel Walsh (Chair) (S.2024)	2022-2024			
Social Sciences – John Deukmedjian	2023-2025			
Librarian Representative				
Dave Johnston	2023-2025			
Student Representation (1 year terms)		-		

Student Representation (1 year terms)

Five students (including at least one graduate, one part-time undergraduate, two full-time undergraduates TBA (UWSA), TBA (UWSA), (GSS), TBA (OPUS), TBA Additional

^{*}At least three members must be members of Senate (SATISFIED)

Academic Policy Committee		
Member	Term	Notations
Associate Vice President Academic (or designate) Dr. Robert Aguirre	Ex-officio	
Vice-Provost, Teaching and Learning (or designate) Erika Kustra (designate)	Ex-officio	
Faculty of Business Administration		
Francine Schlosser (S. 2024)	2023-2025	
Faculty of Education		
Priscilla Correa	2022-2024	
Faculty of Graduate Studies		
Chitra Rangan	2023-2025	
Faculty of Engineering		
Niel Van Engelen (S. 2024)	2022-2024	
Faculty of Law		
Anneke Smit	2023-2025	
Faculty of Human Kinetics		
Sara Scharoun Benson	2023-2025	
Faculty of Nursing		
Debbie Rickeard	2022-2024	
Faculty of Science		
Isabell Barrette – NG Chair (S. 2024)	2022-2024	
Faculty of Arts, Humanities & Social Scio	ences (One from Social Science & c	ne from Arts/Humanities)
Arts/Humanities –Maureen Muldoon (S. 2024)	2023-2025	
Social Sciences – Lydia Miljan	2022-2024	
Librarian Representative		
Adam Mulcaster	2023-2025	
Student Representation (1 year terms) Four students (including one graduate, TBA (UWSA), TBA (GSS), T		full-time undergraduates).

^{*}At least three members must be members of Senate. (SATISFIED)

Senate Student Caucus				
Member	Term	Notations		
Associate Vice-President, Student Experience – Shetina Jones	Ex-officio			
Director, Campus Services (Acting) Shae Harasym	Ex-officio			
Faculty of Business Administration				
Ehab Elsaid (S. 2024)	2022-2024			
Faculty of Education		1		
Michael Macdonald	2023-2025			
Faculty of Engineering				
Jennifer Johrendt	2022-2024			
Faculty of Law				
Ruth Kuras (S. 2024)	2023-2025			
Faculty of Human Kinetics				
ТВА	2023-2025			
Faculty of Nursing				
Sherry Morrell	2023-2025			
Faculty of Science				
Dora Cavallo – Medved	2022-2024			
Faculty of Arts, Humanities & Social So	ciences			
Natalie Atkin (S.2024)	2023-2025			
Librarian Representative				
Sarah Glassford	2022-2024			

Student Representation (1 Year Terms)

Eleven Students (2 graduate students, 2 part-time undergraduate, 4 full-time undergraduate, 1 international, 1 residence student, 1 student at large) (1 student from this group would be elected co-chair) TBA (GSS), TBA (GPUS), TBA (OPUS), TBA (UWSA), TBA (UWSA), TBA (UWSA), TBA (UWSA), TBA (International), TBA (Residence), TBA (Student At-Large)

^{*}At least three members must be members of Senate (Satisfied)

Senate Governance Committee		
Member	Term	Notations
President (Chair) – Rob Gordon	Ex-officio	
Provost and Vice President, Academic (or designate) – Dr. Robert Aguirre	Ex-officio	
Vice-President Equity, Diversity and Inclusion – TBA	Ex-officio	
Faculty of Business Administration		
Dave Bussiere	2023-2025	
Faculty of Education		
Darren Stanley	2022-2024	
Faculty of Engineering	1	
Ofelia Jianu (S.2024)	2022-2024	
Faculty of Law		
Reem Bahdi (S. 2024)	2022-2024	
Faculty of Human Kinetics	•	
Jess Dixon	2023-2025	
Faculty of Nursing	.l	
Laurie Freeman (S.2024)	2022- 2024	
Faculty of Science	Д	
Luis Rueda (S.2024)	2022-2024	
Faculty of Graduate Studies		<u>'</u>
Debbie Kane (S.2024)	2022-2024	
Faculty of Arts, Humanities & Social Science	es	
Beth Daly (S. 2024)	2022-2024	
Cheryl Collier (ex- officio)	2022-2024	
Representative – at- Large		
Nick Baker (S. 2024)	2022-2024	
Librarian Representative		
Selinda Berg (ex- officio)	2023-2025	
	erms)	ne part-time undergraduate,

undergraduates).

TBA (UWSA), TBA (UWSA), TBA (GSS), TBA (OPUS).

^{*}At least half must be members of Senate. (SATISFIED)

University of Windsor Senate Governance Committee

5.3.2: Discipline Appeal Committee, Procedures and Discrimination Committee, SGC Nominating

Committee, SGC Special Appointments Committee, SGC Bylaw Review Committee)

Item for: Approval

Forwarded by: SGC Nominating Committee

MOTION: That the Discipline Appeal Committee, Procedures and Discrimination Committee, Special

Appointments Committee, Nominating Committee, and Bylaw Review Committee memberships be

approved.

Discipline Appeals Committee (2023-2024)

Chair: David Tanovich (2022-2024)
Faculty Member: Patti Fritz (2022-2024)

2 Faculty Alternates

Dima Alhadidi (2023-2025) Gina Pittman (2023-2025) **3 Student Representatives**

TBA GSS (2023-2024) TBA OPUS (2023-2024) TBA UWSA (2023-2024)

Procedures and Discrimination Committee (2023-2024)

Chair: Jasminka Kalajdzic (2022-2024)

Faculty Member: Sung Hyun Yun (2022-2024) Student Member: TBA UWSA (2023-2024)

2 Faculty Alternates

Rajesh Seth (2022-2024) Patti Fritz (2022-2024)

2 Student Alternates

TBA OPUS (2022-2023) TBA GSS (2022-2023)

SGC Special Appointments Committee (2023-2024)

Core Membership

Robert Gordon, President and Chair

Robert Aguirre, Provost and Vice-President Academic

Nihar Biswas, Senior Faculty Representative (Engineering)

Lionel Walsh, Senior Faculty Representative (FAHSS)

Lisa Porter, Senior Faculty Representative (Science)

Myra Tawfik, Senior Faculty Representative (Law)

TBA, Student Representative

TBA, Alternate Student Representatives

TBA, Alternate Student Representatives

TBA, Equity Assessor (Non-voting)

In the case of Honorary Degrees 1 Board of Governor member is included

Irene Moore Davis, Board of Governor Representative (term continues, as appointed by Board)

In the case of University Professors two senior members of the teaching staff of other universities are included

Bernhard Schlegel (Science, Wayne State University)

Charmaine Dean (VP, Research and International, University of Waterloo)

SGC Nominating Committee (2023-2024)

Robert Gordon Robert Aguirre Isabelle Barrette-NG Tom Najem Andrew Ward – Student TBA – Student Alternate

SGC Bylaw Review Committee (2023-2024)

Jess Dixon (Chair)
Bonnie Stewart
Phil Dutton
Ghallia Hashem (Student Representative)
Ms. Renée Wintermute (University Secretariat)

University of Windsor Senate Governance Committee

5.3.3: Senate Membership (2023-2024)

Item for: Information

Forwarded by: University Secretariat

SENATE MEMBERSHIP 2023-2024

Updated: May 8, 2023

Ex officio members

- 1. R. Gordon-President (Chair)
- 2. R. Aguirre Provost and Vice-President, Academic
- 3. S. Jones Associate Vice-Provost, Student Experience
- 4. L. Chandler Registrar (Acting)
- 5. S. Johnson Vice-President Research and Innovation
- 6. TBA Vice-President Equity, Diversity and Inclusion
- 7. C. Collier Dean, Faculty of FAHSS
- 8. C. Houser Dean, Faculty of Science
- 9. TBA Dean, Odette Schoole of Business
- 10. K. Montgomery Dean, Faculty of Education
- 11. B. Van Heyst Dean, Faculty of Engineering
- 12. L. Rohr Dean, Faculty of Human Kinetics
- 13. R. Bahdi Dean, Faculty of Law
- 14. D. Sheppard LeMoine Dean, Faculty of Nursing
- 15. D. Kane Dean, Facutly of Graduate Studies
- 16. S. Berg University Librarian
- 17. J. Cappucci President of Assumption University
- 18. G. Drake Principal of Canterbury College
- 19. N. King Principal of Iona College
- 20. G. Hashem President, University of Windsor Students Alliance (UWSA)
- 21. C. Baillargeon President, Organization of PartTime University Students (OPUS)
- 22. A. Ward President, Graduate Students Society (GSS)
- 23. E. Tam Associate Vice-President, Academic (Acting)
- 24. P. Dutton Academic Colleague to COU

Elected representatives of Faculties

Faculty of Arts, Humanities and Social Sciences

- 1. N. Atkin [to Sept 2024]
- 2. R. Sharma-Persaud [to Sept 2024]
- 3. V. Sevillano Canicio [to Sept 2024]
- 4. B. Daly [to Sept 2024]
- 5. M. Muldoon [to Sept 2025]
- 6. G. Salvato [to Sept 2025]
- 7. L. Walsh [to Sept 2025]

- 8. J. Luft [to Sept 2025]
- 9. TBA [to Sept 2025]
- 10. TBA [to Sept 2025]
- 11. TBA [to Sept 2025]
- 12. TBA [to Sept 2025]

Odette School of Business

- 1. F. Schlosser [to Sept 2024]
- 2. E. Elsaid [to Sept 2024]
- 3. F. Baki [to Sept 2025]
- 4. J. Pathak [to Sept 2025]

Faculty of Education

- 1. Z. Zhang [to Sept 2024]
- 2. M. MacDonald [to Sept 2025]

Faculty of Engineering

- 1. E. Abdel Raheem [to Sept 2024]
- 2. O. Jianu [to Sept 2024]
- 3. B. Minaker [to Sept 2024]
- 4. A. Abdulhussein [to Sept 2025]
- 5. N. Van Engelen [to Sept 2025]

Faculty of Human Kinetics

- 1. F. Biondi [to Sept 2024]
- 2. TBA [to Sept 2025]

Faculty of Law

- 1. W. Aoun [to Sept 2024]
- 2. R. Kuras [to Sept 2024]

Faculty of Nursing

- 1. L. Freeman [to Sept 2024]
- 2. E. Tanlaka [to Sept 2024]

Faculty of Science

- 1. A. Swan [to Sept 2024]
- 2. D. Marquardt [to Sept 2024]
- 3. X. Yuan [to Sept 2024]
- 4. I. Barrette Ng [to Sept 2024]
- 5. C. Ragan [to Sept 2024]
- 6. N. Turdaliev [to Sept 2025]
- 7. K. Drouillard [to Sept 2025]
- 8. K. Granville [to Sept 2025]

Library Representatives

- 1. J. Soutter [to Sept 2024]
- 2. R. Reka [to Sept 2025]

Elected representatives-at-large (1 year terms)

- 1. N. Baker [to Sept 2024]
- 2. J. Bornais [to Sept 2024]
- 3. D. Danelon [to Sept 2024]

- 4. N. Fujita [to Sept 2024]
- 5. E. Kustra [to Sept 2024]
- 6. L. Rueda [to Sept 2024]

Academic Support

Academic Professional [1 year term]

1. Kristen Morris [to Sept 2024]

Elected representative of the Faculty Association

1. TBA [to Sept 2024]

Elected representative of the Aboriginal Education Council

1. TBA [to Sept 2024]

Board of Governors Representatives

- 1. M. Evans [until Nov 2024]
- 2. S. Williams [until Aug 2024]

Appointed by the Alumni Association

1. TBA [to Sept 2025]

Student Representatives (1 year term)

- 1. A. Jain (UWSA) [to April 2024]
- 2. V. lannetta (UWSA) [to April 2024]
- 3. S. Khan (UWSA) [to April 2024]
- 4. L. Pupulin (UWSA) [to April 2024]
- 5. W. Rischke (UWSA) [to April 2024]
- 6. S. Randhawa (UWSA [to April 2024]
- 7. B. Singh (GSS) [to April 2024]
- 8. H. Sindhu (GSS) [to April 2024]
- 9. TBA (OPUS) [to April 2024]
- 10. TBA (OPUS) [to April 2024]
- 11. TBA (OPUS) [to April 2024]

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University of Windsor Senate Governance Committee

5.4: Senate and Senate Standing Committee Diversity Report (2023-2024) - Updated

Item for: Information

Updated: as of May 11, 2023

	Current Survey # Self-		# Self-	50/30	hallenge
	Voting Members	Responses	Identified	50% Women- identified Persons	30% other designated group members
Senate	72 (of 86)	43 ^{1,2}	30	12.5%	19.3%
Academic Policy Committee	13 (of 18)	12 ^{1,3,4}	8	46.1%%	0%
Program Development Committee	14 (of 19)	13 ^{1,3,4}	12	42.1%	49.9%
Senate Governance Committee	13 (of 19)	13 ^{1,3,4}	12	38.5%	46.1%
Senate Student Caucus	9 (of 21)	7 ^{1,3,4}	6	55.6%	11.1%

¹ still awaiting responses from members.

NB: # of designated group members may not equal the number of individuals who self-identified, as individuals may have self-identified under more than one category. Responses are still coming in. It is difficult to know or be able to report that the University is meeting the federal 50/30 challenge (of which it is a signatory), without active participation by members. Efforts to gather responses will continue over the summer. The report will be updated and a more complete report will be presented to SGC and Senate in the F2023.

² twelve stated that they did not wish to self-identify.

³one did not wish to self-identify.

⁴ students responses TBA

University of Windsor Senate Governance Committee

5.5: Strategic Items for Senate Discussion

Item for: **Discussion**

Preliminary discussion on possible SIS topics for 2023-2024.

Confirmed Upcoming Senate Information Sessions

May 19, 2023: Accessibility for Ontarians with Disabilities Act (AODA) Compliance by 2025

Current list of possible Strategic Items for Senate discussion

Additional suggestions? Suggestions for order/scheduling of the following items?

- 1) University and College Partnerships
- 2) Work Integrated Learning
- 3) Curriculum Development
- 4) Individual Faculty plans and strategies moving forward
- 5) Entrepreneurship
- 6) Knowledge mobilization
- 7) Continuing Education
- 8) Future of Education (open discussion on differing approaches to teaching, learning, and evaluations; the purpose of education; and what student success means)
- 9) Strategic Enrolment Management Strategy
- 10) Internationalization planning