#### NOTICE OF MEETING

#### There will be a meeting of the Senate Governance Committee

#### on Monday, January 21, 2019 at 2:30p.m.

#### Room 209/211 Assumption Hall

#### AGENDA

1	Approval of Agenda 1.1 Unstarring agenda items	
2	Approval of the minutes of the meeting of November 20, 2018.	SGCm181120
3	Business arising from the minutes	
4	Outstanding Business/Action Items	
	4.1 Report of the Review Committee on Employment Equity (RCEE)	Kaye Johnson-Information SGCa190121-4.1
	4.2 Research Ethics Board – Report 2017-2018	Suzanne McMurphy-Approval Sa190121-4.2
	*4.3 Senate Standing Committee Membership	Douglas Kneale-Approval SGCa190121-4.3
5	Bylaw Business	
	5.1 Bylaw 40, 44 and 51 – Revisions	Rick Caron-Approval SGCa190121-5.1

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

#### 4.1: Report of the Review Committee on Employment Equity (RCEE)

Item for: Information

See attached.

# Report of the Review Committee on Employment Equity (RCEE) September 2018

# 1 BACKGROUND

The RCEE was formed in 1987. The committee's terms of reference (ToR) are as contained in Article 30 of the Windsor University Faculty Association (WUFA) Collective Agreement. Specifically:

30:04 The Review Committee provided for in clause 30:03 shall be responsible for:
(i) identifying where there is a serious under-representation of members of the designated groups in any AAU and/or Library;
(ii) recommending reasonable goals and timetables for hiring by any AAU and/or Library where serious under-representation of members of the designated groups exists;
(iii) reviewing action taken within the University to achieve the hiring goals recommended under (ii).

The RCEE again expresses appreciation for the data provided for this report and throughout the year by the Employment Equity & Human Rights (EEHR) Manager. In addition, the manager carries out the central work for the implementation of the Diversity & Equity Assessment & Planning (DEAP) Tool Project and provides the required support to the units.

As explained in past reports, the DEAP Tool was created by Queen's University as a means for units to understand and use their specific demographic profiles, assess their diversity and climate, identify resources, and to develop, monitor and report on goals and timelines. As a response to feedback that had been provided to Queen's by way of the experiences of users, an enhanced DEAP Tool 2.0 was created, followed by a further enhanced 2.1 version. The University was able to transfer over to this updated version in winter 2018, and it is now in use. Information on the DEAP Tool can be found at <a href="http://www.uwindsor.ca/ohrea/95/deap-tool">http://www.uwindsor.ca/ohrea/95/deap-tool</a>.

# 2 ACTIVITIES AND KEY ISSUES FOR 2017-2018

The RCEE activities and key issues continued to be centered on 3 main areas. Firstly, the committee focused on *data*; specifically, acquiring and analyzing the data. Secondly, the committee explored possibilities for *enhancing equity* both campus wide and throughout the various AAUs. Lastly, RCEE examined options for *enhancing the equity infrastructure* of the University. RCEE discussed several issues which, although not part of its mandate, were considered to have an influence on the equity profile of the University community and ultimately on recruiting/attracting and hiring. The recommendations of this report are organized according to these three categories.

Agenda items addressed in committee meetings included:

- 1) Terms of Reference as Contained in WUFA CA, Article 30
- 2) Review 2017 EE Data on Faculty Members—Confirm Significant Under-Representation
- 3) Retirement & Termination Data
- 4) Discipline-Specific Availability Pool Data
- 5) Progression Charts for Designated Groups
- 6) SPF 50 Hires—Rounds 1, 2, & 3 and Regular New Faculty Hires
- 7) President's Indigenous Peoples Scholars (PIPS) Program
- 8) Proposed Job Ad Statement re EE Commitment
- 9) EE Data for Equity Assessors Assigned to a Committee
- 10) The DEAP Tool (Diversity & Equity Assessment & Planning) Updates
- 11) Follow-up with Provost Regarding Items from RCEE 2015 & 2016 Reports
- 12) Items for Provost's Council Discussion
- 13) Equity Assessor Service

RCEE obtains the new hires data from OHREA in the July 1 through September timeline in order to access the latest Human Resources Information System (HRIS) data available. This allows for the inclusion of the new hires in the system as per their start date.

The RCEE had recommended in the 2015 Report that "The University Administration explore specific initiatives such as the Academic Career Award to address extreme under-representation, particularly as found with Aboriginal faculty members and librarians." The University had followed up with the development of the President's Indigenous Peoples Scholars (PIPS) Program, resulting in the addition of five new Indigenous scholars. The program was an excellent example of an initiative that was the result of collaboration between the Administration and WUFA, in which many parties committed to and followed up on the idea.

Following the success of the PIPS program in increasing the representation of scholars in the designated group Aboriginal peoples, the RCEE recommends the University proactively move forward to consider a similar initiative in other academic areas to effectively enhance the equity profile.

**RCEE recommends** that the University explore the application of another program similar to PIPS or the Academic Career Award to address other areas of serious under-representation of certain designated groups in specific units, particularly women in units such as in the STEM fields.

RCEE noted that the issue of having more Equity Assessors serve a turn on a committee continues to be a challenge. As part of the ongoing discussion for proactive solutions, a discussion was held with the Deans at the Provost's Council. It was decided that it would be helpful if they received an annual list of the committees on which the faculty members in their unit served as an Equity Assessor.

**RCEE recommends** under Next Steps that OHREA provide the Deans and Heads a list of individual Equity Assessor activities at the end of each academic year.

RCEE has identified issues that while outside the scope of the committee's mandate, have an impact on recruitment and retention aspects of equity. These next two recommendations are under the category of equity items that are outside the mandate of the committee.

RCEE believes that the teaching and research excellence awards have been very successful in recognizing and encouraging excellence in these areas. The addition of academic service awards would send a message of the importance of service as the third pillar of professional responsibilities.

**RCEE recommends** the University explore the addition of academic service awards. Included would be recognition of service of Equity Assessors.

RCEE has discussed the ongoing anecdotal commentary that there are inequities that manifest in the committees on which various faculty members serve. In addition, there may be pressures to serve on many committees as a specific designated group representative.

**RCEE recommends** that as part of its commitment to equity, the University examine the composition of its committees in order to identify patterns of inequity. For example, which faculty members are serving and where, including on high profile committees or on committees with low impact for advancement, et cetera.

In last year's Report, RCEE had recommended that equity/diversity should appear more prominently and clearly in job advertisements. This was in addition to what present ads contain: "We are a welcoming community committed to equity and diversity in our teaching, learning, and work environments." It was noted that a clearer statement has been reflected in a few recent advertisements.

There has been a marked improvement in academic units using the equity data in the hiring process. An area that could be further enhanced is that some units could ensure more meaningful equity evaluation considerations at the pre-interview stage in order to have a better inclusion of under-represented designated group members at the interview stage.

It was noted that Recommendation 3a from the 2015 RCEE Report had been tied to the Provost's SPF 50 initiative. The recommendation was: "Equity goals of units be included in applications for new positions. Additional weight be given to applications that include a strategy for improving an AAU's current equity profile." Now that the SPF 50 has ended, this is no longer applicable. However, the University should seek other similar opportunities to proactively encourage equity.

# 3 PROMISING PRACTICES FEATURE – PRESIDENT'S INDIGENOUS PEOPLES SCHOLARS PROGRAM (PIPS)

The RCEE includes this short section in the annual report in which an academic unit is featured for an employment equity recruiting promising practice. This provides an opportunity to recognize the efforts that are being undertaken, enables units to serve as a resource for others, and shares ideas that may be adopted or adapted in other areas in the University. This year, the RCEE has elected to feature a program instead of a unit; specifically the President's Indigenous Peoples Scholars program (PIPS).

In the 2017-2018 academic year, the University successfully filled 5 tenure-track faculty positions as part of the President's Indigenous Peoples Scholars program (PIPS). Applications had been invited from Indigenous scholars (First Nations, Métis, or Inuit) from any discipline. In the end, the successful candidates for all 5 positions were in FAHSS. The specific AAUs were English, Philosophy, Political Science, Psychology, and Women's and Gender Studies.

The PIPS program was created as an initiative to further address the under-representation or absence of Indigenous faculty in almost all AAUs. In addition, the initiative represented the University's commitment to the Universities Canada Principles of Indigenous Education, and the recognition of the Truth and Reconciliation Commission (TRC) of Canada's reports and findings. For more information on the Universities Canada Principles of Indigenous Education, visit <u>https://www.univcan.ca/media-room/media-releases/universities-canada-principles-on-indigenous-education/</u>. More information on the TRC can be found in the website of the National Centre for Truth and Reconciliation at <a href="http://www.trc.ca/websites/trcinstitution/index.php?p=905">http://www.trc.ca/websites/trcinstitution/index.php?p=905</a>.

According to the University (see <u>http://www.uwindsor.ca/indigenous-peoples/297/presidents-indigenous-peoples-scholars-program</u>), the purpose of the PIPS program is to:

- Advance the academic careers of Indigenous scholars.
- Increase the strength and diversity of Indigenous voices and stimulate dialogue about indigeneity on our campus.
- Expand the community of qualified, promising Indigenous scholars on campus.
- Support and enhance Indigenous educational leadership at the University.
- Foster greater intercultural engagement among Indigenous and non-Indigenous students, faculty, and staff.

The University's Aboriginal Education Council (AEC) was involved in various stages of the hiring process, including meeting with each candidate for each of the positions and providing feedback to the various Appointments Committees. It was an excellent learning opportunity, as discussions took place regarding matters such as differences in expectations surrounding what constitutes consultation, as well as the various faculty hiring requirements. The AEC is leading an initiative that will review the consultation process and provide insight for future practices.

It is important to note that four other tenure-track positions, one visiting scholar, and two sessional instructor positions were filled within the last few years with Indigenous scholars outside of the PIPS program. Profiles can be found at <a href="http://www.uwindsor.ca/indigenous-peoples/299/indigenous-faculty-profiles">http://www.uwindsor.ca/indigenous-peoples/299/indigenous-faculty-profiles</a>.

The RCEE is pleased with the University's steps in increasing the representation, participation, and contributions of Indigenous scholars, while still encouraging ongoing efforts in this area. The impact of the PIPS program on representation in the designated group Aboriginal Peoples is not in the progression charts of this Report, as these charts are up to 2017, while the Indigenous scholars under the program were hired in 2018. However, the table and chart on page 9 do include the increased Indigenous representation in 2018.

# **4 D**ATA

RCEE has been focusing on data relating to the faculty and librarian representation of designated groups over the years. Although the committee examines the available progression data for other faculty-related groups (i.e., LTA, AAS, Sessional Lecturers, and Sessional Instructors), the focus of this report is on tenured/tenuretrack professors and librarians. Data for the other faculty related groups are contained in the University's Annual Employment Equity reports.

The Overview and charts in this section were created for RCEE by the EEHR Manager. RCEE has reviewed unitspecific data, and individual AAUs will be provided with such data, however, the AAU data is not released to the wider University community. This is necessary due to the small numbers, which would present privacy and confidentiality concerns. The LGBTI data for individual Faculties is similarly not released. In addition, because the designated group sexual/gender minorities is not one of the four groups designated by the Employment Equity Act, the government does not generate the external workforce data required to determine the availability pool/comparators.

This section of the report starts with tables and charts that are specific to the SPF 50 positions. The charts provide the data regarding the designated group hires within this initiative, as well as the designated group hires through regular faculty hires in the year. As the SPF 50 initiative was completed in 2018, a final chart and table have been added for the years 2016-2019. This provides a view of the impact on designated group representation through hiring. In addition, it provides an ability to see the impact of the PIPS program on the representation in the Aboriginal designated group as of September 2018, without having to wait until next year for the 2019 progression reports.

#### OVERVIEW

The following charts provide information on the University of Windsor's internal representation within the academic ranks of: Assistant Professors, Associate Professors, Full Professors and Librarians. (NB: Assistant and Associate Deans and Deans are not included in these data.)

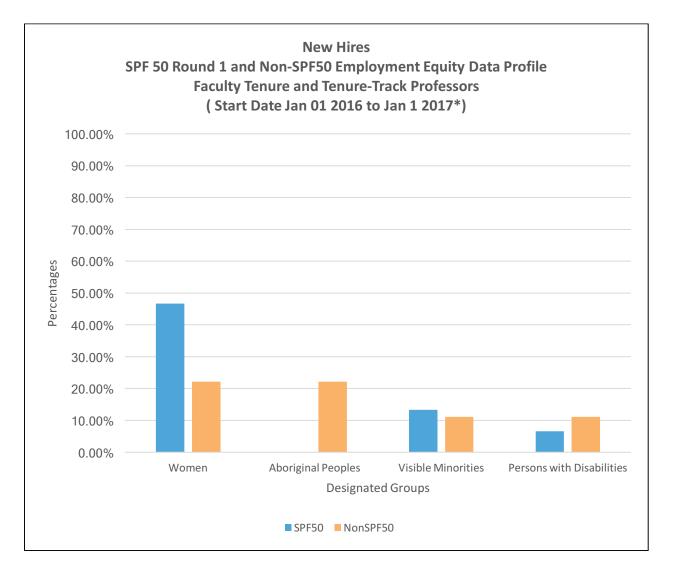
These data include information from the University of Windsor's Employment Equity Census 2006 and 2013, as well as updated information from the self-identification information up to and including December 2017.

The external data information for Women, Aboriginal Peoples and Visible Minorities are from Statistic Canada's 2006 National Census and 2011 National Household Survey. The external information for Persons with Disabilities is from the 2006 Participation and Activity Limitation Survey (PALS) and from Statistics Canada's Canadian Survey on Disability (CSD) (2012).

The University recognizes sexual/gender minorities as a fifth designated group. However, there are no available external data for comparison purposes.

#### New Hires - SPF 50 Round 1 and Non-SPF50 Faculty

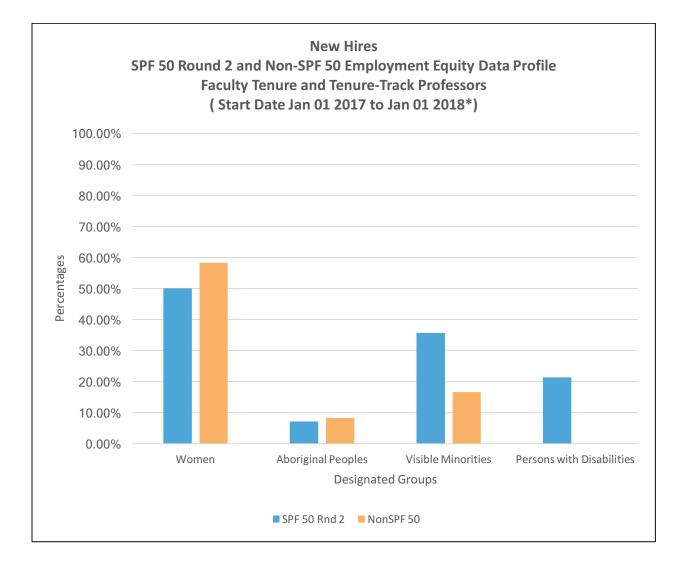
New Hires SPF 50 Round 1 and Non-SPF 50 Employment Equity Data Profile Faculty Tenure and Tenure-Track Professors ( Start Date Jan 01 2016 to Jan 01 2017*)							
	Women	Aboriginal Peoples	Visible Minorities	Persons with Disabilities			
SPF 50 Rnd 1	46.67%	0.00%	13.33%	6.67%			
NonSPF 50	22.22%	22.22%	11.11%	11.11%			



\* Includes 3 SPF 50 Round 1 new hires with start date of January 01/2017

#### New Hires - SPF 50 Round 2 and Non-SPF 50 Faculty

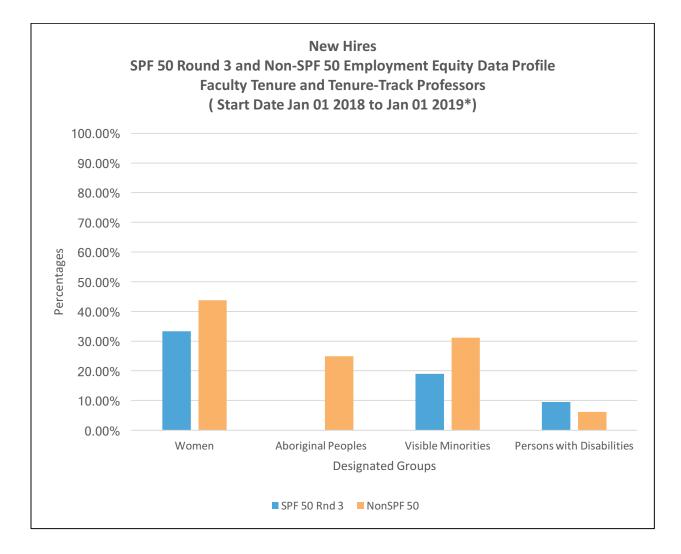
New Hires SPF 50 Round 2 and Non-SPF 50 Employment Equity Data Profile Faculty Tenure and Tenure-Track Professors ( Start Date Jan 01 2017 to Jan 01 2018*)								
	Women	Aboriginal Peoples	Visible Minorities	Persons with Disabilities				
SPF 50 Rnd 2	50.00%	7.14%	35.71%	21.43%				
NonSPF 50	58.33%	8.33%	16.67%	0.00%				



Includes 1 SPF 50 Round 2 new hire with start date of January 01/2018
 Includes 1 Non-SPF 50 new hire with start date of December 01/2017
 Does not include 3 SPF 50 Round 1 new hires with start date of January 01/2017, as they were included in the 2016 report

#### New Hires - SPF 50 Round 3 and Non-SPF 50 Faculty

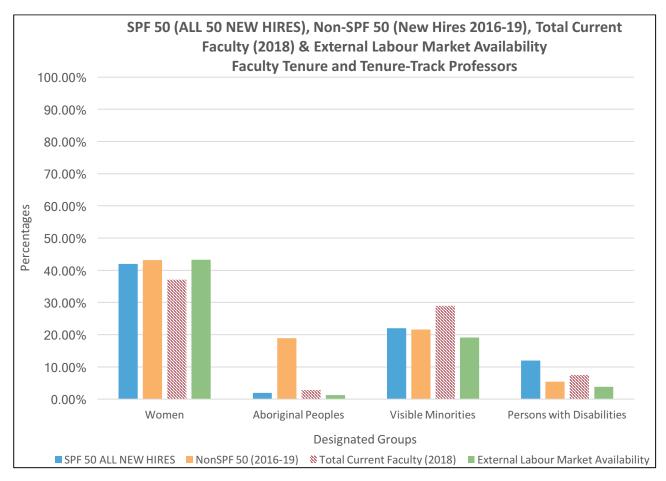
New Hires SPF 50 Round 3 and Non-SPF 50 Employment Equity Data Profile Faculty Tenure and Tenure-Track Professors ( Start Date Jan 01 2018 to Jan 01 2019*)								
	Women	Aboriginal Peoples	Visible Minorities	Persons with Disabilities				
SPF 50 Rnd 3	33.33%	0.00%	19.05%	9.52%				
NonSPF 50	43.75%	25.00%	31.25%	6.25%				



Includes 1 SPF 50 Round 3 new hire with start date of January 01/2019
 Includes 3 Non-SPF 50 new hire with start date of January 01/2019
 Does not include 1 SPF 50 Round 2 new hire with start date of January 01/2018, as they were included in the 2017 report

# SPF 50 (All 50 New Hires 2016-19), Non-SPF 50 (New Hires 2016-19), and Total Current Faculty & External Labour Market Availability

SPF 50 (All 50 New Hires), Non-SPF 50 (New Hires 2016-19), Total Current Faculty Employment Equity Data Profile & External Labour Market Availability Faculty Tenure and Tenure-Track Professors								
	Women	Aboriginal Peoples	Visible Minorities	Persons with Disabilities				
SPF 50 (All 50 New Hires)	42.00%	2.00%	22.00%	12.00%				
NonSPF 50 (New Hires 2016-19)	43.24%	18.92%	21.62%	5.41%				
Total Current Faculty (2018)*	37.15%	2.81%	28.94%	7.56%				
External Labour Market Availability**	43.3%	1.3%	19.1%	3.8%				



\* Total current faculty as of Sept 2018 (tenure and tenure-track faculty only). Adjusted to exclude faculty that resigned in 2016-19

\*\* National Household Survey (NHS 2011) & Canadian Survey on Disabilities (CSD 2012)

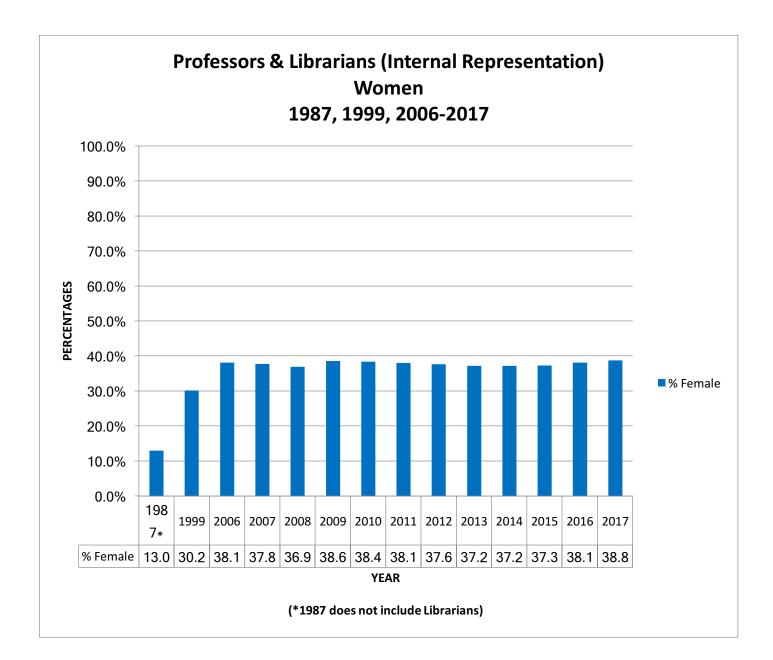
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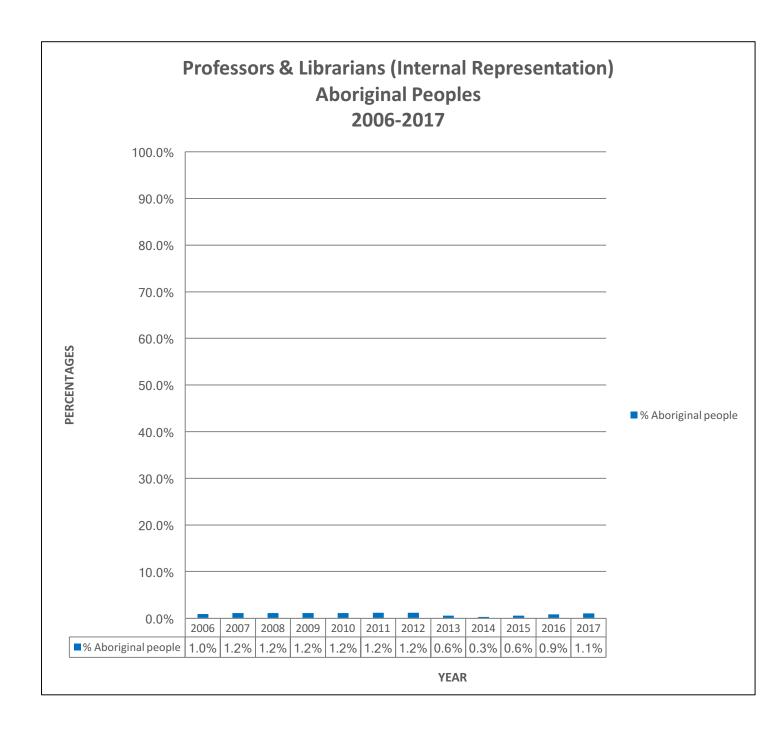
	Professors and Librarians – Internal Representation													
	1987 *	1999	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Total	484	431	514	508	515	503	498	486	481	470	454	483	462	464
Male	421	301	318	316	325	309	307	301	300	295	285	303	286	284
Female	63	130	196	192	190	194	191	185	181	175	169	180	176	180
Female	13.0	30.2	38.1	37.8	36.9	38.6	38.4	38.1	37.6	37.2	37.2	37.3	38.1	38.8
%	%	%	%	%	%	%	%	%	%	%	%	%	%	%
* 1987 da	* 1987 data does not include librarians													

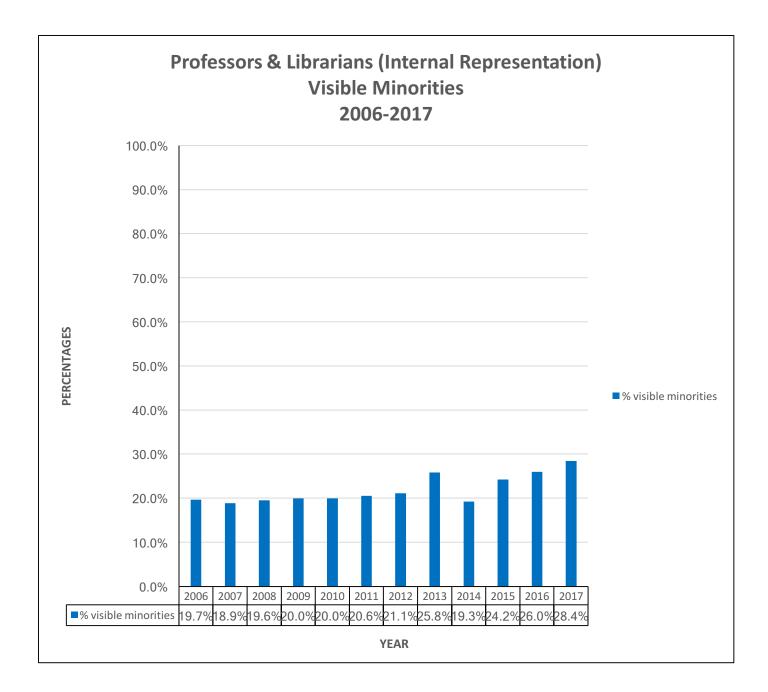
#### Professors and Librarians – Internal Representation

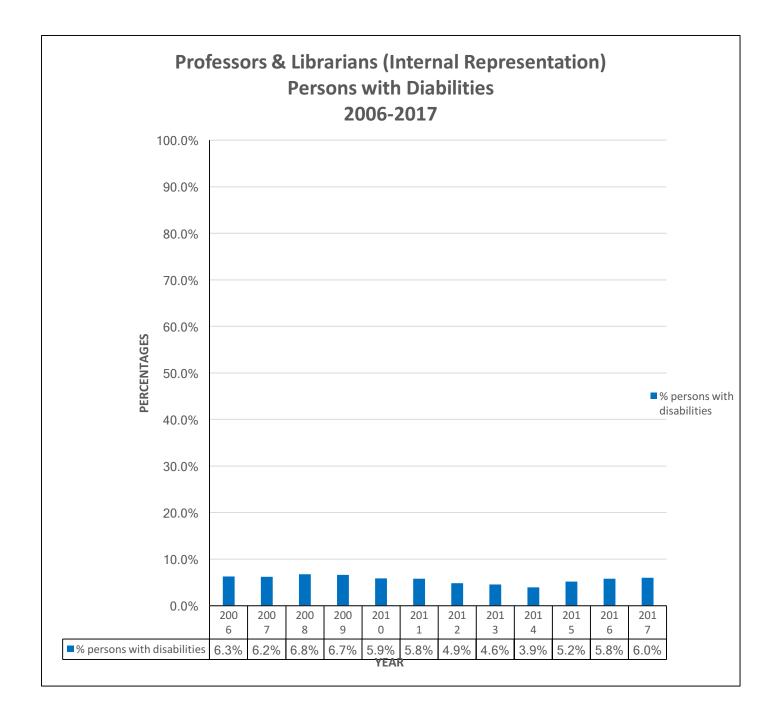
## **Professors (Excluding Librarians) – Internal Representation**

	1987	1999	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Total	484	409	490	482	490	478	477	465	460	449	433	461	440	444
Male	421	292	309	307	318	302	302	296	294	289	279	296	282	280
Female	63	117	181	175	172	176	175	169	166	160	154	165	158	164
Female	13.0	28.6	36.9	36.3	35.1	36.8	36.7	36.3	36.1	35.6	35.6	35.8	35.9	36.9
%	%	%	%	%	%	%	%	%	%	%	%	%	%	%

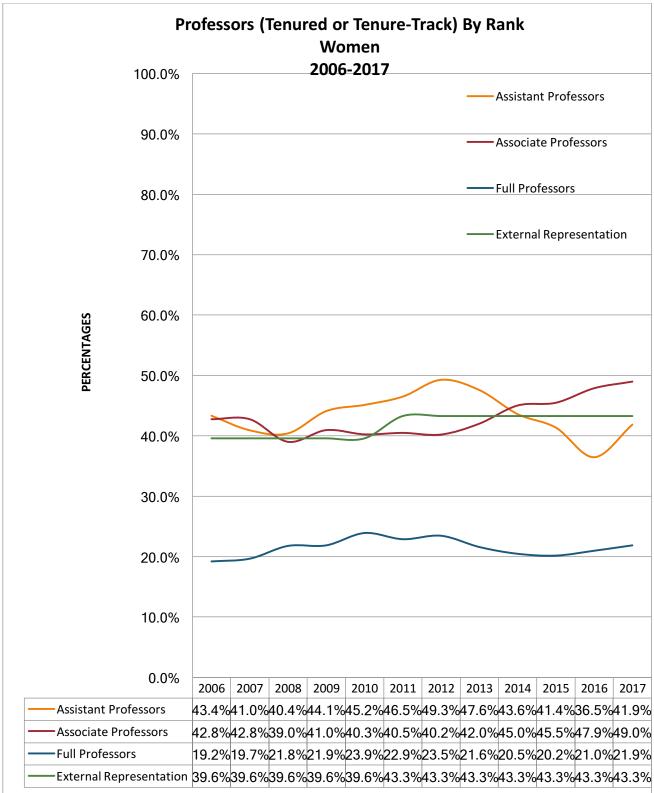






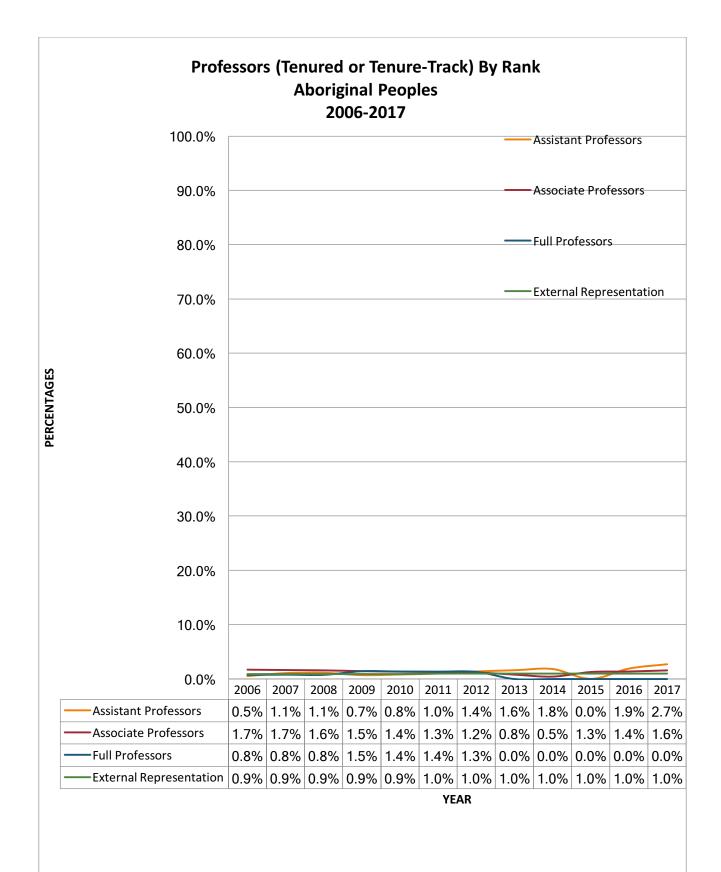


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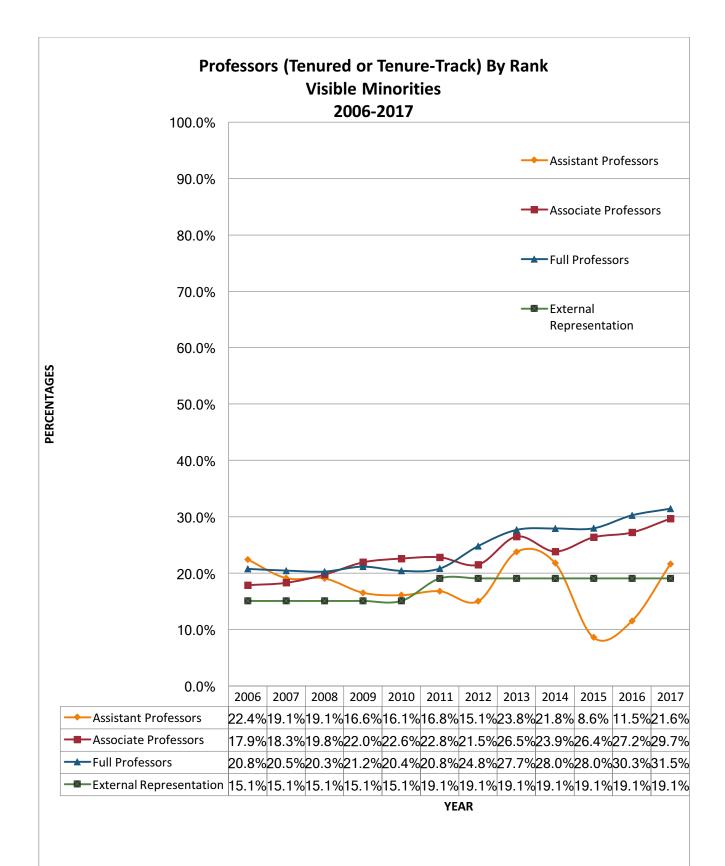


YEAR

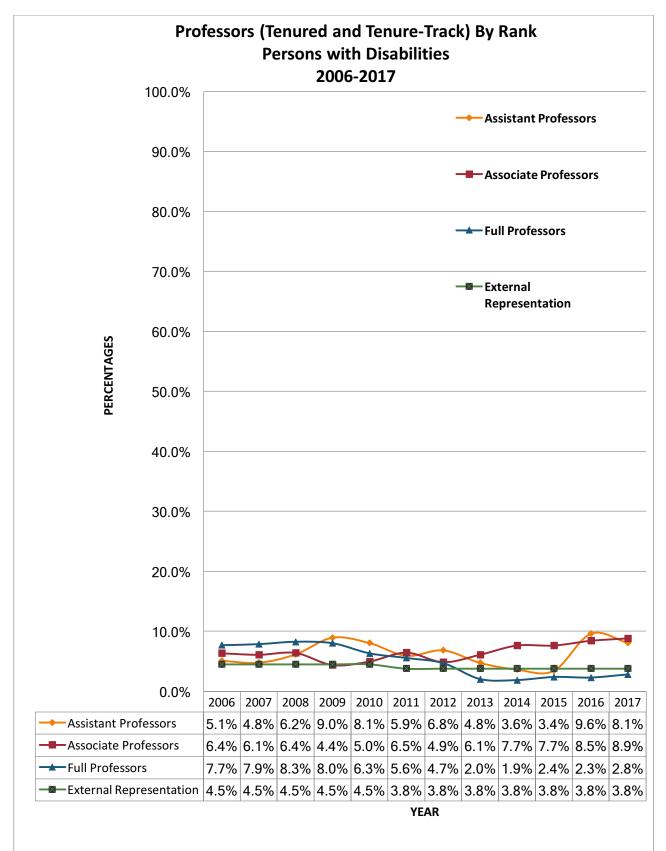
\*2006-2010 external representation is based on Statistics Canada's 2006 National Census data. 2011-2017 external representation is based on Statistics Canada's 2011 National Household Survey data.



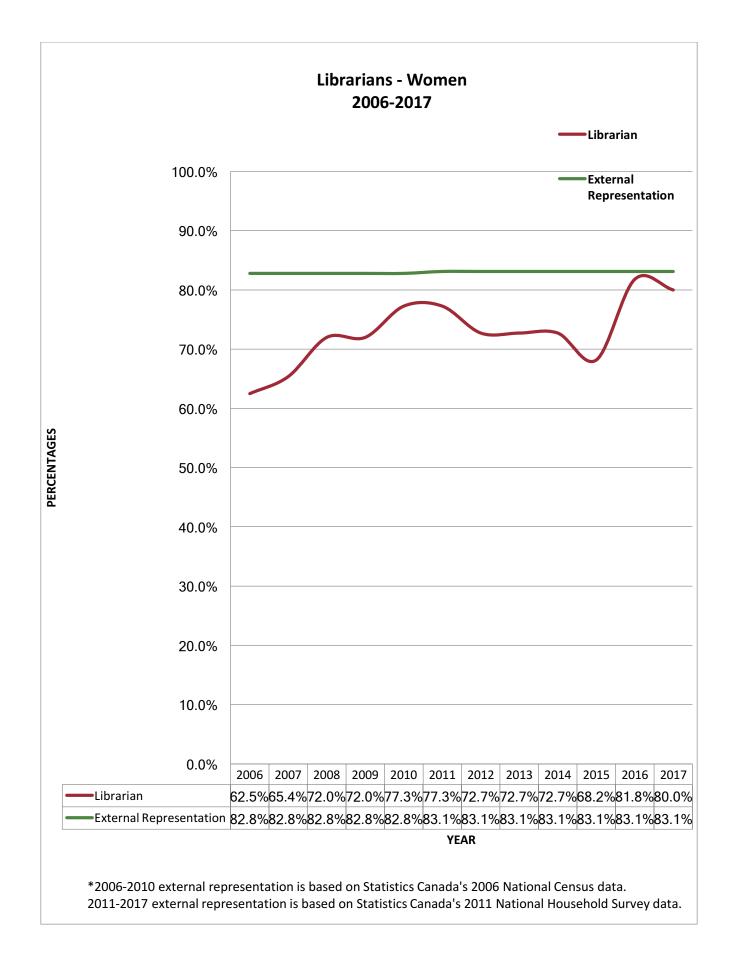
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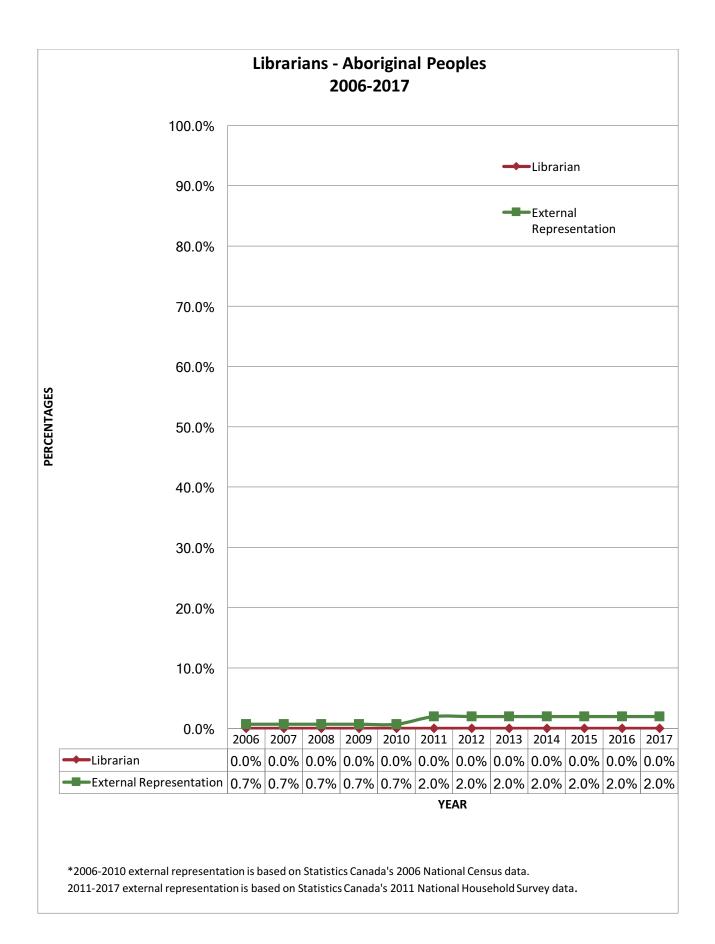


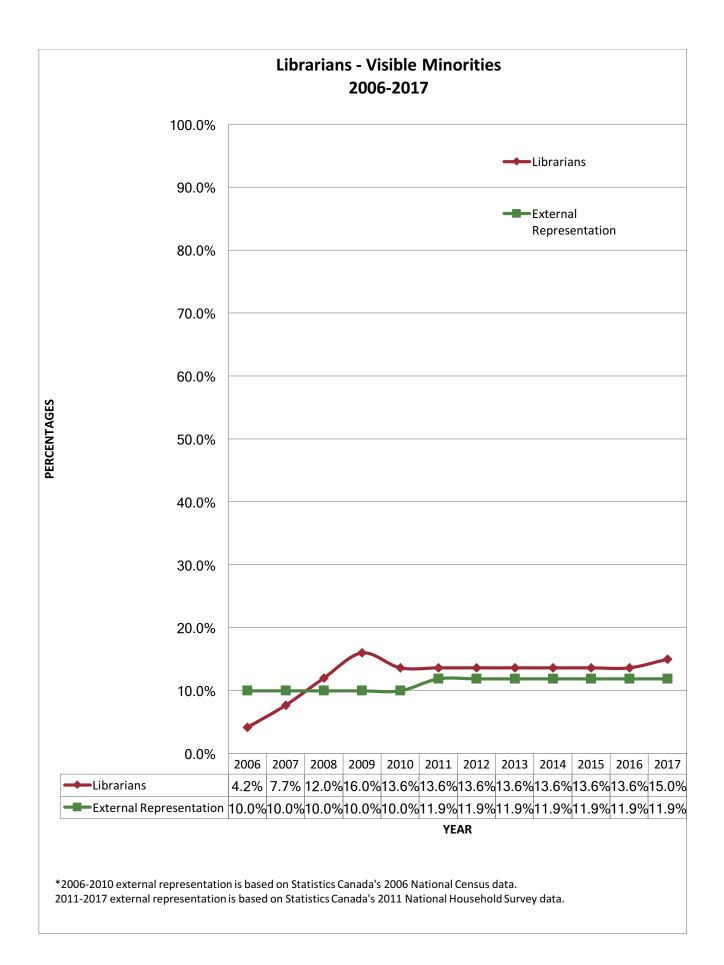
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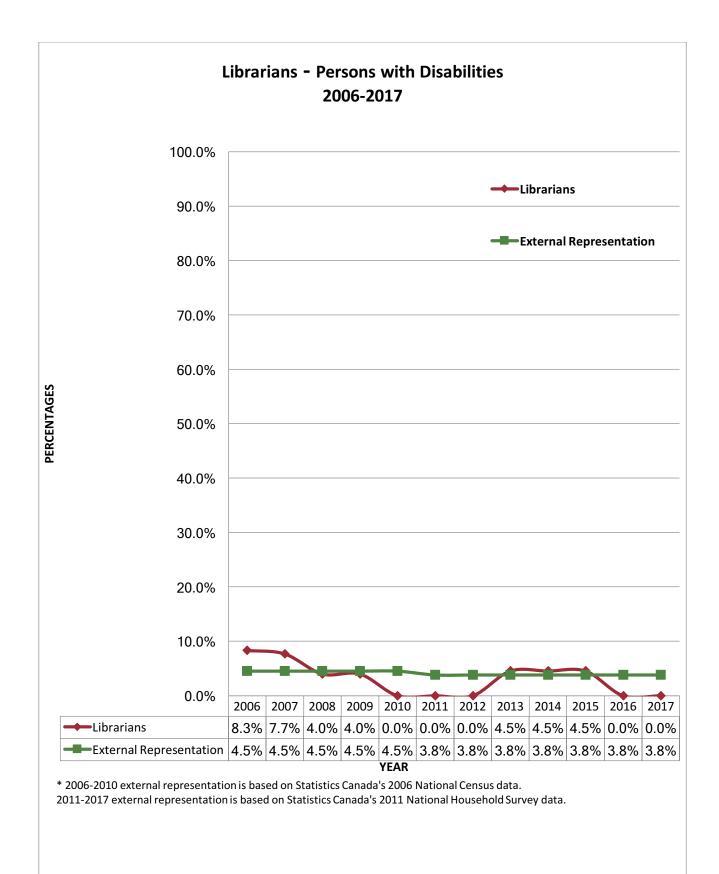


\* 2006-2010 external representation is based on Statistics Canada's 2006 National Census data. 2011-2017 external representation is based on Statistics Canada's 2011 National Household Survey data.









# 5 UPDATE ON OUTSTANDING RECOMMENDATIONS FROM THE 2015, 2016 & 2017 REPORTS

This section of the RCEE Report provides an update on the outstanding *next steps* and recommendations that were in the previous RCEE Reports. The *next steps* and recommendations were organized within 3 categories: Data, Enhancing Equity, and Enhancing the Equity Infrastructure.

ltem	2017 Report Next Steps and Recommendations	Status
1.	<b>RCEE recommends</b> that the University declares the valuing of equity/diversity more prominently and clearly in job advertisements such as in the example on the website for the SPF 50 positions.	In Preliminary Use
2.	<b>RCEE recommends</b> that the University ensures equity is weighted on all hiring grids.	Not Yet Completed
ltem	2016 Report <i>Next Steps</i> and Recommendations	Status
3.	<b>RCEE recommends</b> that Deans and Heads work collaboratively and proactively with Equity Assessors from their units to ensure the EAs are meeting their commitments to actively serve on a committee. An example of a proactive approach might be for EAs to report annually their EA service as part of workload considerations.	In Progress
Item 4.	Follow-up Items from the 2015 RCEE Report:RCEE will follow up with Administration for an update on the status of Recommendations 3a and 3b from the 2015 Report:3a. Recommendation: Equity goals of units be included in applications for new positions. Additional weight be given to applications that include a strategy for improving an AAU's current equity profileNote: This recommendation was specifically tied to the three	Status No Longer Applicable
	<ul> <li>year SPF 50 initiative. As the SPF 50 program has ended, this is no longer applicable.</li> <li>3b. Recommendation: Inclusion of a sentence in all job ads stating the expectation of candidates to have a level of proficiency and/or commitment to equity in their practice. Such proficiency and/or commitment would be considered and weighted in all grids.</li> <li><u>Note</u>: A basic sentence is in ads of the University's commitment. A few units have begun using more prominent and clearly defined language.</li> </ul>	Partially Completed

# 6 SUMMARY OF CURRENT *NEXT STEPS* AND RECOMMENDATIONS

This section of the RCEE Report includes *next steps* and recommendations towards enhancing equity on campus. The *next steps* and recommendations are organized within 4 categories: Data, Enhancing Equity, Enhancing the Equity Infrastructure, and Equity Items Outside RCEE Mandate.

#### Data

No new recommendations in this area.

#### Enhancing Equity

 RCEE recommends that the University explore the application of another program similar to PIPS or the Academic Career Award to address other areas of serious under-representation of certain designated groups in specific units, particularly women in units such as in the STEM fields.

#### Enhancing the Equity Infrastructure

The following recommendations or *next steps* are following up on items from the 2015 and 2016 RCEE Reports:

2) **RCEE recommends** under *Next Steps* that OHREA provide an annual list of individual Equity Assessor activities to the Deans and Heads at the end of each academic year.

#### Equity Items Outside RCEE Mandate

The following items deal with issues outside RCEE's mandate, but have an impact on enhancing the equity practices of the University community, including its hiring practices. As such, the following are suggested for further exploration:

- 3) **RCEE recommends** the University explore the addition of academic service awards. Included would be recognition of service of Equity Assessors.
- 4) RCEE recommends that as part of its commitment to equity, the University examine the composition of its committees in order to identify patterns of inequity. For example, which faculty members are serving and where, including on high profile committees or on committees with low impact for advancement, et cetera.

#### **RCEE Committee Members:**

Kaye Johnson Victoria Paraschak Vicki Jay Leung Alison Samson

#### University of Windsor Senate Governance Committee

#### 4.2: Research Ethics Board – Report 2017-2018

Item for: Approval

Forwarded by: Suzanne McMurphy, Chair, Research Ethics Board

# MOTION: That the proposed revisions to the Guidelines for Research Involving Humans (Appendix B) be approved.

#### **Rationale:**

- The Guidelines for Research Involving Humans has not been updated since 2009. This updated document aligns the REB Guidelines with the *Tri-Council Policy Statement 2 (2014)*.
- The proposed revisions have been approved by the REB Board.
- The annual report is provided for information.

\*see attached



# UNIVERSITY OF WINDSOR RESEARCH ETHICS BOARD Report to Senate January 1, 2017 – December 30, 2018

# **INTRODUCTION**

The University of Windsor Research Ethics Board (REB) operates in accordance with the *Tri-Council Policy Statement 2 (2014)*. 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 Chair of the Research Ethics Board and staffed by the Research Ethics Coordinator. 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 phone and walk-in 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 the Full Research Ethics Board which meets monthly. Protocols determined to be *minimal risk* are reviewed by the Delegated Review Committee which is comprised of four Full Board members who are specifically assigned as delegated reviewers. The Delegated Review Committee meets once a week during the academic year and bi-weekly over the summer, unless the number of protocol submissions requires additional meetings. Two new Delegated Review Committees were created in 2017-2018—the REB for Education and Learning and Administrative Research 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 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 Committee 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 new Delegated Review Committees do not receive compensation and only meet when a relevant protocol is assigned to them for review. The REB Chair facilitates all review meetings of the REB including the Full Board and Delegated Review Committees, except for the REB for Education and Learning.

#### **REB Members 2017 - 2019**

Dr. Suzanne McMurphy, Chair Sociology, Anthropology, and Criminology, Faculty Member

Mr. Abrahim Abduelmula (as of July 1, 2018)

Full Board; Nursing, Student Representative

#### Mr. Theimann Ackerson, M.S.W.

Full Board; Community Representative

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

Full Board; Community Representative (alternate for Cheryl Taggart)

#### **Dr. Pierre Boulos**

Special Advisor, Full Board, REB for Education and Learning Chair; CTL and Philosophy, Adjunct Faculty

#### Ms. Laura Chittle

REB for Education and Learning; Kinesiology, Student representative

#### Dr. Janice Drakich (as of July 1, 2018)

Full Board and Delegated Review Committee; Sociology, Anthropology, and Criminology, Emeritus

#### Mr. Frank Ely (as of July 1, 2018)

Full Board; Kinesiology, Student Representative

#### Dr. Laurie Freeman

Full Board; Nursing, Faculty Member

#### Dr. Nicole Freeman

Full Board; Windsor Regional Hospital, Medical Representative

Mr. Leo Gil, M.S.W. (as of July 1, 2018) Full Board; Community Representative

**Prof. Jeffery Hewitt (as of July 1, 2018)** Full Board; Legal Representative; Law, Faculty Member

Ms. Marla Jackson Full Board; Hôtel-Dieu Grace Healthcare Hospital, Representative

**Dr. Calvin Langton** Full Board and Delegated Review Committee; Psychology, Faculty Member

**Mr. Bryce Leontowicz (as of July 1, 2018)** Full Board; Medical Student Representative

**Dr. Saverpierre Maggio** Full Board; Windsor Regional Hospital, Representative

Dr. Scott Martyn Vice-Chair, Full Board and Delegated Review Committee; Kinesiology, Faculty Member

Ms. Sherri Lynne Menard Full Board; Health and Safety Representative

Ms. Ashlyne O'Neil REB for Education and Learning; Psychology, Student Representative

**Dr. Siyaram Pandey** Full Board; Chemistry & Biochemistry, Faculty Member

**Dr. Kathy Pfaff** Full Board and Delegated Review Committee; Nursing, Faculty Member

**Mr. Travis Reitsma** Full Board; Sociology, Anthropology, and Criminology, Student representative

**Ms. Ina Seviaryna (as of July 1, 2018)** Full Board; IDIR, Medical Devices

Dr. Allyson Skene, CTL REB for Education and Learning; CTL

**Dr. Clayton Smith** REB for Education and Learning; Education, Faculty Member

**Dr. Maureen Sterling** Full Board; Business, Faculty Member

Ms. Cheryl Taggart, M.S.W., R.S.W.

Full Board; Community Representative

#### **REB Full Review Board Members on Leave**

**Prof Reem Bahdi (Sabbatical)** Full Board and Delegated Review Committee; Law, Faculty Member

**Dr. Glynis George (Sabbatical)** Full Board; Sociology, Anthropology, and Criminology, Faculty Member

**Dr. Rosanne Menna (Sabbatical)** Full Board; Psychology, Faculty Member

**Prof. Kristen Thomasen (Leave)** Full Board; Legal Representative; Law, Faculty Member

#### **Ethics Coordinator**

Ms. Sarah Braganza

The Ethics Coordinator provides administrative assistance to the Office of the REB. She is the initial contact for researchers who call, drop-in, or e-mail the REB. She prepares REB files for the REB Chair and committee reviews, schedules and takes minutes at all REB meetings, sends communications to researchers and committee members, maintains protocol files and on-line records as well as the REB website.

## SPECIAL ADVISORS TO THE REB

Beginning in 2017, the REB 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.

<u>Clinical Research</u> Dr. Maher El-Masri, School of Nursing_	<u>Research Involving the First Nations, Inuit and Métis Peoples of Canada</u> <b>Dr. Harvey McCue,</b> Chair of the Ontario Heritage Trust <b>Dr. Brent Angell,</b> School of Social Work
Education and Local School Boards Dr. Geri Salinitri, Faculty of Education	Mr. Russell Nahdee, Aboriginal Education Centre
<u>Human Biological Materials</u> Dr. John Hudson, Biology Dr. Phil Karpowicz, Biology	<u>Research Using Deception</u> Dr. Josée Jarry, Psychology
<u>Medical Devices</u> Dr. Roman Maev, Diagnostic Imaging Centre Mr. Bartosz Slak, Diagnostic Imaging Centre	
Online Research Using social media	

Dr. Sarah Woodruff, Kinesiology

# **REB PROTOCOL REVIEW ACTIVITY July 1, 2017—December 30, 2018**

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; data entry and file processing; reviewing researchers' response to comments and clearance. Subsequent time with each cleared protocol can vary depending upon protocol modifications, unanticipated and adverse events; progress reports and file closures. 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 an overview of the REB structure and committees.

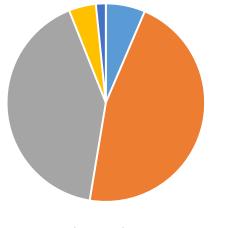
July 1, 2017-June 30, 202	18 (12 mos)	July 1, 2018-Decemb	er 31, 2018 (6 mos)
Full Board	3	Full Board	2
Delegated	144	Delegated	83
Executive	87	Executive	39
Withdrawn/Exempt	15	Withdrawn/Exempt	10
Total	249	Total	134

#### Table 1: New Applications by Level of Review

#### Table 2: New Applications by Principle Investigator Type

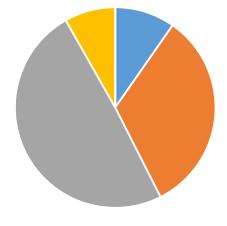
July 1, 2017-June 30,	, 2018 (12 mos)	July 1, 2018-Dece	July 1, 2018-December 31, 2018 (6 mos)			
Administrative	16	Administrative	13			
Faculty	115	Faculty	44			
Students	103	Students	66			
Community	11	Community	11			
Other	4	Other	0			
Total	249	Total	134			





Administrative Faculty Students Community Other

New Applications by Principal Investigator July 1, 2018-December 31, 2018



Administrative = Faculty = Students = Community = Other

Tables 1, 2 and 3, and the pie charts, identify the activity of the REB by level of review, principle 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 Committee level. Executive reviews are conducted by the Chair alone or together with another REB member. Table 2, and the corresponding pie charts, illustrate that the majority of protocols over the academic year are faculty-initiated research projects, followed by student applications which are primarily doctoral and master's level thesis projects. Community applications are from organizations that have contracted with the REB 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.

July 1, 2017-June 30, 2018 (1	.2 mos)	July 1, 2018-December 31, 2018 (6 mos)				
Business	8	Business	2			
CTL	9	CTL	5			
Community Partners	12	Community Partners	11			
Engineering	6	Engineering	4			
FAHSS	85	FAHSS	44			
Human Kinetics	51	Human Kinetics	29			
Law	3	Law	2			
Leddy Library	6	Leddy Library	2			
Nursing	15	Nursing	10			
Others	24	Others	2			
Science	12	Science	8			
University Administration	18	University Administration	15			
Total	249	Total	134			

#### **Table 3: New Applications by Faculty Unit**

#### 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 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 of the REB Chair's time in researcher communication and meetings, REB communication with participants, 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

July 1, 2017-June 30, 2018 (12 mos)		July 1, 2018-December 31, 2018 (6 mos)	
Files closed	91	Files closed	46
Final & Progress Reports	220	Final & Progress Reports	136
Requests to revise*	149	Requests to revise*	30
Unanticipated/Adverse	8	Unanticipated/Adverse	3
Events		Events	
Cleared	239	Cleared	134

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

# **REB INITIATIVES AND ACCOMPLISHMENTS 2017-2018**

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

#### **Audit Completion**

As part of the 2018-2019 University of Windsor Internal Audit Risk Assessment and Plan, the Office of Research Ethics and the REB were selected to undergo an audit by Price Waterhouse Cooper and the University of Windsor Office of Internal Audit. The audit commenced in August 2018 and was completed in November 2018. The results of the audit were positive, and no concerns were identified. The final report included four findings which require an action plan from the REB. These include: 1) Ensure that the new Standard Operating Procedures receive approval from the Full Board; 2) Review the TCPS2 certificates and confidentiality agreements and ensure they are up-to date for all REB members; 3) Inventory the RECs and their membership, develop standard documentation, and develop a formal policy for review scope, training, and reporting to the University REB; 4) Ensure that all protocol files are complete with all necessary documentation and signatures. Items 2 and 4 are complete and measures to ensure their on-going compliance are in place. Items 1 and 3 are on-going and are anticipated to be completed by September 2019.

#### **Collaboration with Windsor Regional Hospital (WRH)**

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. Dr. Suzanne McMurphy is now a full member of the WRH REB and 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 to establish a streamlined review process for secondary use of data and human tissue research protocols.

#### **Delegated Committee Expansion**

Two new Delegated Committees were formed to respond to specific types of research protocols and ethical review needs. The *REB for Education and Learning* reviews protocols that involve course-based research and scholarship of teaching and learning projects. Dr. Pierre Boulos chairs this Delegated Committee.

The Administrative Research Committee reviews administrative research protocols initiated by University of Windsor staff, external survey requests, and Ministry projects that require REB review. This Committee is formed in collaboration with Rosemary Zanutto, Executive Director of Institutional Analysis.

#### **Research Ethics Education**

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 will be promoting these courses and their availability to the community more broadly beginning in 2019.

The REB has recently established a partnership with the Faculty of Education to provide a series of monthly workshops on research ethics, research integrity, the REB review process, and specialized research ethics topics starting in 2019. The Chair of the REB and the Special Advisor to the REB will also continue to provide specific presentations as requested by individual faculty for their courses.

#### 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 has not been updated since 2009. This updated document aligns the REB Guidelines with the TCPS2 (2014). Special recognition is given to Dr. Alan Scoboria, past REB Chair, who worked with Dr. McMurphy to update the Guidelines, which have been approved by the REB Full Board. The areas in the new 2018 Guidelines which have been updated from the 2009 version are highlighted in the document attached in *Appendix B*.

#### Standard Operating Procedures for Office of Research Ethics and REB Review

As part of the improvement of the Office of Research Ethics and preparation for clinical trials certification, the REB Chair has written a set of standard operating procedures (SOP)—listed below--which reflect the organizational processes of the REB. To facilitate clinical trials certification, 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 REB Full Board by the REB Chair, discussed and approved by the Full Board. As the SOPs are approved, they will be posted to the REB website for public comment from the research community. The following SOPs, that have been developed by the REB Chair, are currently under review for approval by the Full Board:

#### **General Administration**

- 101 Authority and Purpose
- 102 Research Requiring REB Review
- 103 Training and Education
- 104 Management of REB Office Personnel
- 105A Conflict of Interest—REB Members and REB Office Personnel
- 105B Conflicts of Interest—Researcher
- 105C Conflicts of Interest—Organization
- 106 Signatory Authority
- 107 Use and Disclosure of Personal Information
- 108 Standard Operating Procedures Maintenance

#### **REB** Organization

- 201 Composition of the REB
- 202 Management of REB Membership
- 203 Duties of REB Members
- 204 REB Office of Research Ethics Personnel Serving as REB Members

#### Office of Research Ethics Functions and Operations

- 301 REB Submission Requirements and Administrative Review
- 302 REB Meeting Administration
- 303 Document Management

#### **Review of Research Protocols**

- 401 Delegated Review
- 402 REB Review Decisions
- 403 Initial Review-Criteria for REB Clearance
- 404 Ongoing REB Review Activities
- 405 Continuing Review
- 406 Research Completion
- 401 Suspension or Termination of REB Clearance

#### **Reviews Requiring Special Consideration**

501 REB Review During Publicly Declared University Closure or Emergency

- **REB** Communication and Notification
- 601 Communication—Researcher
- 602 Communication—Research Participants
- Informed Consent
- 701 Informed Consent Requirements and Documentation

Responsibilities of Investigators

801 Researcher Qualifications and Responsibilities

#### **Quality Management**

- 901 Quality Assurance Inspections
- 902 External Inspections or Audits
- 903 Non-Compliance

#### Updated US IRB Registration and Federal Wide Assurance Certification

The REB has updated its registration as a recognized Institutional Review Board (IRB) with the US Office of Human Research Protection. This allows the University of Windsor REB to act as an IRB for research conducted in the US, 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.

## LOOKING FORWARD 2019-2020

In addition to its regular work of conducting protocol reviews and monitoring, the REB and Office of Research Ethics will focus on these four areas of activity from January 1, 2019 through June 30, 2020.

#### **Implement Audit Recommendations and REB Action Plan**

#### Review of the Research Ethics Committees (REC)

Beginning in January 2019, The REB Chair will meet with all 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 develop and implement an annual training for all REC members on campus. 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

Recent training provided by the company that supports the on-line database used by the REB and ORIS for research file management revealed that the REB database had not been structured correctly at its inception and so the data being entered were not captured appropriately. As a result, we have been unable to produce benchmarking reports from the on-line database and have had to manually extract data from our paper files for reporting and analysis. We will restructure the database and re-enter data from all current open files over the next year.

When this clean-up of the database is complete, we will be able to conduct performance assessments of the REB operations and provide more accurate information to the research community on the timing of reviews, trends in

applications as well as identify areas for improvement. As recommended in the Audit Report, the REB will also explore on-line protocol submission options for researchers and a researcher dashboard for reporting timelines, such as progress reports and final report.

#### Standard Operating Procedures

In addition to the standard operating procedures listed in the Accomplishments section, several additional SOPs will need to be written, approved by the Full Board, and posted for researcher comment. Additional SOPs that will need to be developed include: operation and scope of the Research Ethics Committees; administrative research; criteria and procedures for determining projects exempt from REB review; course-based research; and multi-jurisdictional research.

# **Complete Clinical Trials Certification through Clinical Trials Ontario**

Preparation for application for clinical trials certification will be completed in 2019 and a pre-audit will be scheduled with Clinical Trials Ontario. Members for a new Biomedical Board have been identified and will formally meet in 2019.

Several additional activities related to clinical trials certification will also be accomplished in 2019 which includes developing specialized application forms for human tissues and biomedical research and training for the new Biomedical Full Board.

# **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 explore areas of reciprocity with Windsor Regional Hospital. The REB also plans to explore review mechanisms for researchers through Schulich Medical School, currently under the jurisdiction of Western University's REB.

# **Expand Educational Resources in Research Ethics**

Beginning in early 2019, in collaboration with the Faculty of Education, the REB will provide monthly workshops on current topics in research ethics, ethics review processes, and the REB. The REB will also provide monthly hands-on workshops on writing REB applications. The REB will continue to provide individual consultations through in-person meetings, phone and e-mail.

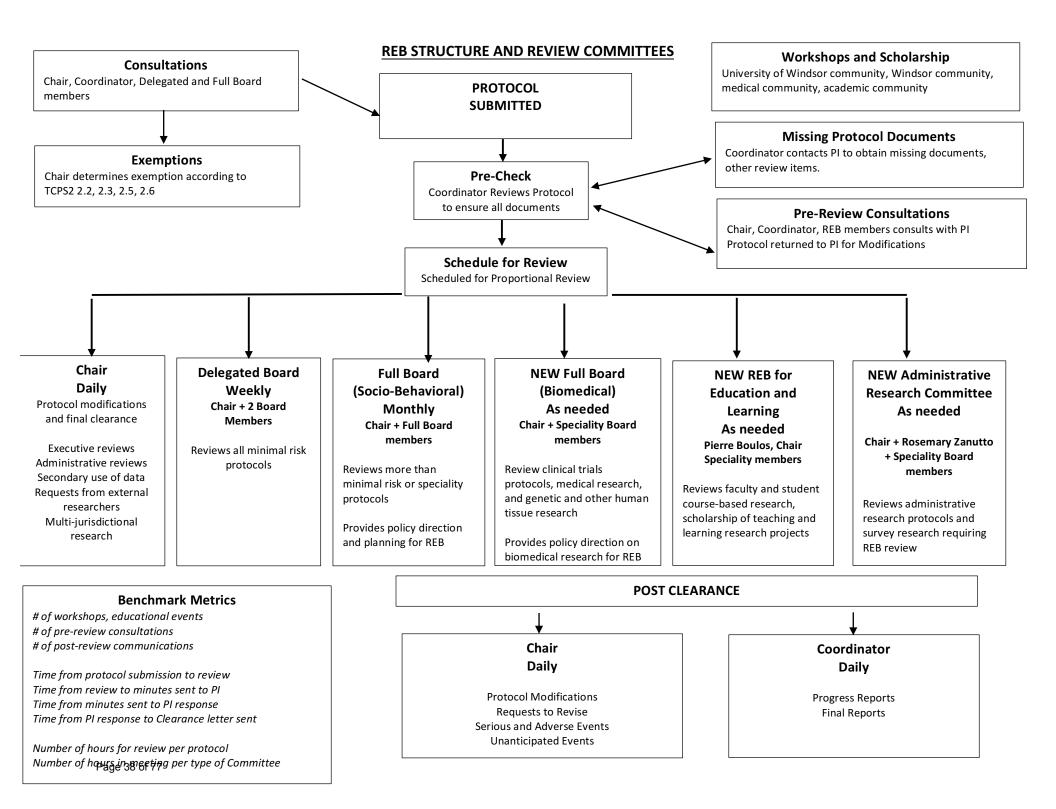
Finally, the REB will be monitoring the development of the Tri-Council Policy on research data management (RDM) and ways in which the REB can support researchers in complying with the new policy as it relates to research ethics. The REB will also continue to contribute to the efforts of the University as they relate to research ethics.

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

Suzanne McMurphy, REB Chair

# **APPENDIXES**

Appendix A: Flowchart of REB Structure and Review Committees Appendix B: University of Windsor, Guidelines for Research Involving Humans, November 2018



APPENDIX B Proposed revisions are highlighted in the document.



Guidelines for Research Involving Humans

Last Revised: June 2009

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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 twice, and the version at the time of preparation of these revised guidelines is the TCPS2 (2014). "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* (2017) are consistent with and reflect the adoption by the University of the *TCPS*, *TCPS2*, and the current *TCPS2* (2014) by the University. Some statements of the University of Windsor Guidelines are verbatim adoptions of the *TCPS2* (2014).

# **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*, 2014, 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.

University of Windsor, Guidelines for Research Involving Humans - 2019

#### <mark>Justice</mark>

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*, 2014, 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*, 2014, 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:

- a. 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;
- c. 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 Page 44 of 77

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;
- i. 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;
- I. 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;
- 0. 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 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 Principle 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.

# The University Administration

The TCPS2 (2014) states that 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*, 2014, 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*, 2014, 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 armslength to the University of Windsor (TCPS2, 2014, 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*, 2014, 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*, 2014, 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*, 2014, 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 10 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*, 2014, 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, 2014, 6.4):

- 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*, 2014, 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, 2014, 6.13).

Communications with the REB are treated as confidential. The contents of REB files are closed. Only members of the REB 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. The following requires ethics review and clearance by the REB before the research commences (*TCPS2*, 2014, 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*, 2014, 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*, 2014, 2.1).

Research involving human remains, cadavers, tissues, biological fluids, embryos or fetuses is subject to review by the REB (*TCPS2*, 2014, 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*, 2014, 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 (2014)* 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 Page 48 of 77

# 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, 2014, 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, 2014, <mark>2.3).</mark>

# 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, 2014, 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, 2014, 2.5).

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*, 2014, 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
  - 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;
  - 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;
  - whether the purpose of the study is fully outlined;
  - o 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;
  - 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;
- 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;
  - 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*, 2014, Chap1C). 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 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*, 2014, 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, 2014, Chap2).

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*;
- c. 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: Page 52 of 77 University of Windsor, Guidelines for Research Involving Humans - 2019

- 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

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*, 2014, 6.18).

The <mark>President or designate will, in consultation with the Chair of the REB,</mark> 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.

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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*, 2014, 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*, 2014, 2.8).

A 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*, 2014, 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 the 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,* 2014, 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) *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, 2014, 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 the exclusion of women or minorities, 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*, 2014, 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*, 2014, 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*, 2014, 4.4).

Research Involving the Elderly

Elderly people shall not be inappropriately excluded from research solely on the basis of their age (*TCPS2*, 2014, 4.5).

Research Involving First Nations, Métis, Inuit

Chapter 9 of the TCPS2 (2014) 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, 2014, 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*, 2014, 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 (2014) 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*, 2014, 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*, 2014, 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 participationrelated 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, 2014, 3.3).

# Incidental findings

Researchers have an obligation to disclose to the participant any material incidental findings discovered in the course of research (*TCPS2*, 2014, 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*, 2014, 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,* 2014, 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;
- b. Either no standard efficacious care exists or the research offers a realistic possibility of direct benefit to the participant in comparison with standard care;
- 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*, 2014, Chapter 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. 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*, 2014, 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.

# 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 decisionmaking 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*, 2014, 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*, 2014, Chap 5A).

Security. <mark>Security refers to measures used to protect information. It includes physical, administrative and </mark> 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. Information is identifiable if it may reasonably be expected to identify an individual. Information is identifiable 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*, 2014, 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*, 2014, 5.2).

Researchers shall provide details to the REB regarding their proposed measures and data management plan for safeguarding information, for the full life cycle of information: its collection, use, dissemination, retention and/or disposal (*TCPS2*, 2014, 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 Page 66 of 77 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 be 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, 2014, 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 to 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*, 2014, 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, 2014, 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 decisionmaking 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, 2014, 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*, 2014, 7.1).

Conflicts of interest will be managed per the guidance in the TCPS2 (2014), 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 (2014).

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 (2014).

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 (2014).

#### 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*, 2014, 2.3):

- 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.

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*, 2014, 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, 2014, 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,* 2014, 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;
- 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, 2014, 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*, 2014, 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 REB website: www.uwindsor.ca/reb.

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; <u>ethics@uwindsor.ca</u>).

# Other items to include in applications

One paper copy of the application form all accompanying material should be submitted including an original, signed signature page to the Office of Research Ethics. One electronic file that includes all components of the application must be emailed to the REB at ethics@uwindsor.ca, or brought to the REB office to be copied.

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

# University of Windsor Senate Governance Committee

\*4.3: Senate Standing Committee Membership

Item for: Approval

- Forwarded by: University Secretariat
- MOTION: That the Senate Governance Committee recommend to Senate the approval of the following Senate Standing Committee membership:

Dr. Kevin Milne – Faculty of Human Kinetics – Program Development Committee

# University of Windsor Senate Governance Committee

#### 5.1: Bylaw 40, 44 and 51 – Revisions

Item for: Approval

Forwarded by: SGC Bylaw Review Committee

MOTION 1: That the proposed revisions to Bylaws 40 and 44 be approved.

#### Proposed Revisions:

#### Bylaw 40:

4.1 Each AAU shall have a Council consisting of:

#### [...]

4.1.2 the sessional lecturers in the AAU have the option of participating on Council, subject to the limitations of 4.1.6. The AAU Office shall notify sessional lecturers of their right to participate on Council by August 1, with responses from sessional lecturers confirming or declining participation submitted to the AAU Office no later than August 15, for the coming academic year (September–August). Sessional lecturers understand that a decision to participate on Council is voluntary and represents a commitment to participate year-round.

# [...]

4.1.6 Members of Councils under 4.1.3 and 4.1.5 shall not participate in appointment procedures for new faculty, or in renewal, promotion and tenure procedures, or selection procedures (including Search Committee size, composition and membership) for Deans, Associate Deans, and AAU Heads, and Associate AAU Heads or stand for election to the Senate or the Faculty Coordinating Councils.

With the exception of external searches for Deans, Associate Deans, and AAU Heads, Mmembers of Councils under 4.1.2 shall not participate in appointment procedures for new faculty, or in renewal, promotion and tenure procedures, or selection procedures (including committee size, composition and membership) for Appointments Committees and RTP Committees.

#### Bylaw 44:

- 3 Faculty Coordinating Council
- 3.1 Each Departmentalized Faculty shall have a Coordinating Council consisting of:

[...]

3.1.8 Members of Faculty Coordinating Councils under 3.1.7, including the limited-term faculty members and ancillary academic staff appointed as learning specialists on temporary appointment, shall not participate in appointment procedures for new faculty, or in renewal, promotion and tenure procedures, or selection

procedures (including Search Committee size, composition and membership) for Deans, Associate Deans, **and** AAU Heads<del>, and Associate AAU Heads</del> or stand for election to the Senate.

With the exception of external searches for Deans, Associate Deans, and AAU Heads, Ssessional lecturers on Faculty Coordinating Councils shall not participate in appointment procedures for new faculty, or in renewal, promotion and tenure procedures, or selection procedures (including committee size, composition and membership) for Appointments Committees and RTP Committees.

#### **Rationale:**

- The current bylaws allow for sessional lecturers to participate in head searches but not appointments for new faculty, resulting in a discrepancy in the case of external searches.
- At the December 2018 meeting, concern was raised regarding permitting sessional lecturers to participate as they hold teaching only positions and their appointment process did not follow the same procedures as regular faculty members who have duties that include teaching, research/scholarship and creative activity, and service.
- As directed by Senate at its December 2018 meeting, the Bylaw Review Committee revised the proposal allowing
  sessional lecturers to participate in all appointments to allowing sessional lecturers to participate only in
  appointments which are a result of external searches for heads, associate deans and deans. This addresses the
  discrepancy between the bylaws in the case of external searches for heads, associate deans, and deans, while
  continuing to limit sessional lecturer participation in other appointments.

# MOTION 2: That the proposed revisions to Bylaw 51 be approved.

# Proposed Revisions:

# Bylaw 51

- 1.5.2 A student who has three or more final examinations scheduled or due in consecutive time slots over a 24hour period or three or more final examinations scheduled or due in one calendar day may apply<del>, no later than October 31<sup>st</sup> for the Fall Semester, February 28<sup>th</sup> for the Winter Semester, and June 30<sup>th</sup> for the Summer Semester, to have one of their examinations rescheduled on a supplemental examination day. The determination of which examination shall be rescheduled and the date of the supplemental examination (normally the last possible day of the examination period) shall be made by the Associate Vice-President, Student Experience<del>, by November 15<sup>th</sup> for the Fall Semester, March 15<sup>th</sup> for the Winter Semester, and July 15<sup>th</sup> for the Summer Semester. Where permission has been granted, instructors shall provide an alternate examination at the rescheduled time. Where other arrangements cannot be made, invigilation and administration of final examinations held on the supplemental examination day will be managed by the Office of the Registrar. Applications and notification of decisions shall made in accordance with the deadlines listed in Appendix A.</del></del>
- 1.5.3 A student who has three or more major in-term evaluations scheduled or due within a 24-hour period may apply, no later than the fourth week end of the first quarter of classes, to seek an appropriate accommodation (such as a due date modification, alternative assignment, or rescheduled test). Such a request shall not be unreasonably denied. In the case where the matter cannot be resolved between the instructor and the student, the final determination will rest with the Head of the Department offering the course, in consultation with the faculty member(s).

[...]

# ADD to Graduate Section of Bylaw 51

#### 2.2 Other Evaluative Procedures

- 2.2.1 A student who has three or more final examinations scheduled or due in consecutive time slots over a 24hour period or three or more final examinations scheduled or due in one calendar day may apply to have one of their examinations rescheduled on a supplemental examination day. The determination of which examination shall be rescheduled and the date of the supplemental examination (normally the last possible day of the examination period) shall be made by the Associate Dean, Faculty of Graduate Studies. Where permission has been granted, instructors shall provide an alternate examination at the rescheduled time. Where other arrangements cannot be made, invigilation and administration of final examinations held on the supplemental examination day will be managed by the Office of the Registrar. Applications and notification of decisions shall made in accordance with the deadlines listed in Appendix A.
- 2.2.2 A student who has three or more major in-term evaluations scheduled or due within a 24-hour period may apply, no later than end of the first quarter of classes, to seek an appropriate accommodation (such as a due date modification, alternative assignment, or rescheduled test). Such a request shall not be unreasonably denied. In the case where the matter cannot be resolved between the instructor and the student, the final determination will rest with the Head of the Department offering the course, in consultation with the faculty member(s).

[renumber paragraphs of bylaw 51 accordingly]

[...]

3 Alternative Examinations (applicable to students in all Faculties)

Students who wish to request an alternative examination date in accordance with 1.5.2 and 1.5.3 above shall make such a request within the timelines specified in 1.5.2 and 1.5.3 above and as set out below.

Students who are unable to write a final examination during the regularly scheduled time slot due to a conflict arising from a religious observance shall be given the opportunity to write an alternative examination during another time slot within the regularly scheduled examination period.

Students must submit an application for an alternative examination to the Office of the Registrar as indicated below: in accordance with the deadlines listed in Appendix A.

One term (twelve week) course offered during Fall, Winter or Summer Semesters – by October 31<sup>st</sup> for the Fall Semester, February 28<sup>th</sup> for the Winter Semester and June 30<sup>th</sup> for the Summer Semester.

Two term course by October 31<sup>st</sup>, February 28<sup>th</sup>, or June 30<sup>th</sup> of the second term, as the case may be.

Three week course offered during Intersession or Summer Session by May 12<sup>th</sup> for Intersession or July 2<sup>nd</sup> for Summer Session.

Six week course offered during Intersession or Summer Session by May 30<sup>th</sup> for Intersession or July 20<sup>th</sup> for Summer Session.

Eight week course offered during Intersession or Summer Session – by May 30<sup>th</sup> for Intersession or July 20<sup>th</sup> for Summer Session.

The Office of the Registrar is required to contact the instructors involved for the preparation of an alternative examination, to reschedule the examination in another time slot within the regularly scheduled examination period, and to notify students of their new examination schedule approximately three quarters into the semester in accordance with the deadlines listed in Appendix A.

# Appendix A Deadlines for Alternative Examinations Pursuant to Bylaw 51: 1.5.2, 2.5.2, and 3

TERM	Posted Exam Schedule	Application Deadline	Notification of Decision Deadline
Fall Semester (12 weeks)	October 15	October 31	November 15
Winter Semester (12 weeks)	February 15	February 28	March 15
Summer Semester (12 weeks)	June 15	June 30	July 15
Fall-Winter Semesters (24 weeks) (2 term course)	February 15	February 28	March 15
Winter-Summer Semesters (24 weeks) (2 term course)	June 15	June 30	July 15
Summer-Fall Semesters (24 weeks) (2 term course)	October 15	October 31	November 15
Inter-Session (3 weeks)	May 8	May 12	May 16
Inter-Session (6 weeks)	May 15	May 30	June 5
Inter-Session (8 weeks)	May 15	May 30	June 5
Summer Session (3 weeks)	June 28	July 2	July 6
Summer Session (6 weeks)	July 5	July 20	July 26
Summer Session (8 Weeks)	July 5	July 20	July 26
For all other courses	By the end of the first quarter of the course	By the end of the second quarter (halfway through the course)	By the end of the third quarter of the course

# **Rationale:**

- At the December 2018 Senate meeting, it was suggested that it would be best to be proactive in establishing deadlines for any and all types/lengths of courses to come. The last row of the paragraph addresses this request.
- It was also noted at the Senate meeting that many graduate students find themselves with three or more exams in 24 hours (or may find themselves in this scenario), particularly with the growth of course-based Masters program where the regular course load is 5 courses per semester. The stressors for these students are the same, if not greater than, those for undergraduate students. The paragraph on multiple exams in one day was therefore added to the graduate section of bylaw 51.
- For clarification and streamlining, the Bylaw Review Committee opted to represent these deadlines in a table and to refer to the table in the appropriate bylaw 51 paragraph.