

## 1.0 Introduction

The Research Ethics Board (REB), as part of its responsibilities, is required to provide an annual activities report to the President and Academic Council. This report covers the Research Ethics Board’s activities from July 1, 2017 until June 30, 2018.

## 2.0 Research Ethics Board Responsibilities

The primary mandate of the Research Ethics Board is to ensure the ethical conduct of research involving human participants. The Research Ethics Board reports directly to the President and is responsible for the following:

- Developing and applying policies regarding the ethical conduct of research involving human participants;
- Reviewing all research projects requiring the use of human participants;
- Ensuring that all policies regarding the ethical conduct of research involving human participants remain current;
- Dealing with ethical matters concerning human-based research;
- Ensuring that researchers receive education on the ethical conduct of research involving human participants;
- Providing an annual report on its activities to the President and Academic Council; and
- Participating in continuing education organized by University Research Administrators for the University community in matters relating to research ethics.

## 3.0 Membership and Meetings (July 1, 2017 until June 30, 2018)

Membership	REB Position	Start Date	Faculty	Appointment
Shirley Van Nuland	Chair	August 6, 2015	Education	Until June 30 2018
Susan Donaldson	Community Member	March 1, 2013	n/a	Currently Appointed
Joan Young	Community Member	April 1, 2016	n/a	Currently Appointed
Toba Bryant	General Member	February 1, 2013	Health Sciences	Until June 30 2018
Joseph Eastwood	General Member	April 18, 2018	Social Science and Humanities	Currently Appointed
Shanti Fernando	General Member	September 1, 2016	Social Science and Humanities	Currently Appointed
Jia Li	General Member	May 1, 2015	Education	Until

Membership	REB Position	Start Date	Faculty	Appointment
				June 30 2018
Ruth Milman*	General Member	January 5, 2016	Engineering and Applied Science	On research leave
Natalie Oman	General Member	September 1, 2013	Social Science & Humanities	Until October 18 2017
Jen Rinaldi	General Member	October 18, 2017	Social Science & Humanities	Currently Appointed
Matthew Shane	General Member	April 1, 2015	Social Science & Humanities	Until September 28/17
Kamal Smimou	General Member	July 30, 2015	Business & IT	Until September 15/17
Wendy Stanyon	General Member	July 3, 2014	Health Sciences	Currently Appointed
Ying Zhu	General Member	December 6, 2016	Business & IT	Currently Appointed
Janice Moseley	ORS Administration	August 30, 2016	Research Ethics Officer	Ex-Officio

\* Dr. Milman is on research leave and will resume her duties on the REB July 1 2018.

Twelve monthly REB meetings were scheduled; the Board met 11 times within the year. The Board did not meet in July; no REB application received required full board review. Quorum was achieved at all meetings.

Below is a list of all the scheduled dates and when the Board met:

- ❖ July 19<sup>th</sup>, 2017 – no meeting
- ❖ August 16, 2017
- ❖ September 20, 2017
- ❖ October 18, 2017
- ❖ November 15, 2017
- ❖ December 13, 2017
- ❖ January 17, 2018
- ❖ February 28, 2018
- ❖ March 21, 2018
- ❖ April 18, 2018
- ❖ May 16, 2018
- ❖ June 20, 2018

#### 4.0 Administrative Support

Administrative support for the Board is provided by the Office of Research Services (ORS). There are several positions that function to support the Research Ethics Board:

➤ Research Ethics Officer:

The duties of the Research Ethics Officer are divided between the Research Ethics Board (with 80% responsibility) and the Animal Care Committee (with 20% responsibility). The workload, however, increases due to compliance and regulatory audits.

Janice Moseley, as the Research Ethics Officer and principal liaison between the REB and the researchers, is responsible for providing ongoing daily administrative support and ethical guidance to the Board and researchers in accordance with the Tri-Council Policy Statement 2: Ethical Conduct for

Research Involving Humans, university policies, and best practices. These activities includes providing guidance to researchers in the understanding of TCPS2. In addition, other duties of the Research Ethics Officer include accurate record keeping of all paper copy and electronic research ethics files through the ORS database (ROMEO) and compliance monitoring which involves oversight of file renewals, closures, amendments, and unanticipated problem reports.

➤ Data Coordinator / Research Business Analyst:

Nicole Boivin, as Data Coordinator, provided monthly statistical reports to the REB on new applications, change requests related to current applications, yearly renewal of applications and closure of applications until she left her position in November 2017. In February 2018 Sanjana Pillai became the Research Business Analyst which included the duties of described above.

The ROMEO database is updated daily to capture real time workflow, ensure accurate monthly reporting, and monitor files for compliance. IRIS (Integrated Research and Innovation System) is the element of ROMEO that allows for uploading of documentation to support the researcher's REB application and provides for system-generated communications (clarifications requests, renewal notifications, etc.) and for post-approval events (change requests, renewals, closures, etc.). Post-approval events (change requests, renewals, closures, etc.) can be returned to the researcher for edits/clarifications in IRIS.

## 5.0 Regulatory Updates

Research involving humans at the University is regulated by both the Canadian Tri-Council Policy Statement 2 (TCPS2): Ethical Conduct for Research Involving Humans; and the United States Federal Wide Assurance program. Research conducted under the auspices of the University is guided by a set of regulations and responsibilities for protecting the rights and welfare of human subjects.

The REB is reviewing and providing comments to *Tri-Agency Research Data Management Policy* as suggested by the the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC) (due August 31, 2018).

## 5.1 Training

Throughout the year, presentations and many one-on-one consultations were given by the Research Ethics Officer to familiarize the research community with the need for research ethics, as well as educating the research community about the research ethics review process at the University. Ongoing research ethics consultations are scheduled regularly with researchers upon request.

- ❖ REB Chair presented on Research Ethics to Master of Health Science students on September 27, 2017 and Master of Education students on February 5, 2018.
- ❖ Research Ethics Officer presented to Master of Science students on September 26, 2017.
- ❖ Research Ethics Officer presented to Master of Social Science students on September 29, 2017.
- ❖ Handout from Panel of Research Ethics (PRE) PRE on Taking Part in Research – PRE created a hand out for study participants about key questions to ask about participating in a research study. This is a useful handout

that could researchers should consult when creating consent materials for participants. Available on REB website.

## 5.2 Standard Operating Procedure Development

The REB reviewed, revised, and approved existing Standard Operating Procedures (SOP) during the monthly meetings throughout the year. The revised SOPs are:

**Table 1: REB Standard Operating Procedures and Date Approved**

<b>REB Standard Operating Procedures</b>	<b>Date Approved</b>
SOP 201: Research Submission Requirements	October 18, 2017
SOP 301: Coordinated Initial and Ongoing Review Process Durham College and UOIT Board of Record	January 17, 2018

Related to UOIT Expense Procedure: Payments to Research Participants, the Board discussed the Procedures that set out steps in respect of Payments to Research Participants and provided feedback specific to support documents and confidentiality of participants.

## 5.3 Reciprocal Research Ethics Board Review Agreement between Durham College and UOIT

On October 5, 2016, the Reciprocal Research Ethics Board Review Agreement was fully executed between Durham College and UOIT to establish a Board of Record Review (BoR) model for research involving human subjects at DC and UOIT to streamline research review and eliminate the need to submit ethics applications to both institutions. This agreement was renewed in December 2017.

## 5.4 REB Website

A stand-alone REB website (<https://sites.uoit.ca/reb/index.php>) supports the REB and researchers; it contains pertinent information, tools, and resources for the research community such as:

- ❖ REB meeting dates
- ❖ List of REB members
- ❖ REB terms of references
- ❖ REB SOPs and policies
- ❖ Annual and external reports
- ❖ Frequently asked questions
- ❖ Sample consent forms and confidentiality agreements
- ❖ Links to important resources and documents

## 5.5 Suspension of Files

Effective January 1, 2017, research ethics files are promptly suspended when a progress report (renewal or closure application) is not submitted prior to the expiry date of the study. Prior to suspension of a file, the Principal Investigator receives three (3) courtesy emails beginning 30 days before the application renewal date, seven (7) days before the renewal date and the day of expiry to remind the Principal Investigator to renew followed or close their study prior to expiry as required by TCPS2. This is followed by another email and

telephone contact by the Research Ethics Officer usually within a few days post expiry. REB approval is suspended the day after the study expires. For studies suspended after 30 days post expiry, the REB will bring a motion to terminate the study following REB review at a convened meeting. During the 2017 – 2018 year, six (6) files were closed for none-compliance.

## 5.6 Development of Reciprocal Research Ethics Board Review Agreement between Lakeridge Health Centre and UOIT

Discussion concerning a Reciprocal Research Ethics Board Review Agreement continues between Lakeridge Health Centre and UOIT. Similar to the Durham College – UOIT agreement (October 5, 2016), a Board of Record Review (BoR) model for research involving human subjects at Lakeridge Health Centre where UOIT researchers are involved would be established. This agreement would streamline research review and should eliminate the need to submit ethics applications to both institutions. A lead REB (also known as the BoR) would oversee the review and approval of the project, without researchers having to submit to each REB as is currently the case. The PI must be affiliated with UOIT in order to qualify for BoR review.

## 6.0 Research Ethics Board Activities

### 6.1 Reviewer Breakdown and Activities

In the 2017 – 2018 fiscal year, there were 144 applications received (see Table 2), an increase of 3.6% from 2016 to 2017 in the overall number of Applications received. Faculty research has been steadily increasing as has graduate student research. Undergraduate research has been in decline due to the changes in fourth year thesis projects, primarily fourth year Capstone. Since July 2015, there has been an 8.3% increase in applications.

‘Other’ refers to request for review for those conducting research but are not faculty or students at UOIT. These include UOIT staff conducting research related to studies for organizations, multi-jurisdictional review which involves multiple institutions and/or multiple REBs (i.e., not intended to apply to ethics review mechanisms for research involving multiple REBs within the jurisdiction or under the auspices of a single institution) and exemption requests. In several instances the indication of research type was left blank by the researcher completing the application.

**Table 2: Type of Research Applications Received by Month**

	Faculty Research	Graduate Research	Faculty Course - based Research	Capstone	Undergraduate Research	Post-Doc	Other	Total
Jul 17	8	3		1				12
Aug 17	8	3	1			2	4	19
Sep 17	4	3		1	1	1	1	12
Oct 17	1	4			1		4	10
Nov 17	2	5						7
Dec 17	4	2			1		3	10
Jan 18	2	5		1			4	12
Feb 18	5	4	1		2		2	14
Mar 18	3	2					1	6
Apr 18	8	3		1		1	2	15

May 18	6	5				3	14
Jun 18	3	7				2	13

Table 3 below summarizes when the applications are received by month.

**Table 3 Applications by Month July 1 2017 – June 30 2018**

Month	Number of Applications
July	12
August	19
September	12
October	10
November	7
December	10
January	12
February	14
March	6
April	15
May	14
June	13
<b>Total</b>	<b>144</b>

During the 2017 – 2018 year, each Board member (full-time equivalency of 9) conducted on average 14 delegated reviews. The average number of applications per REB member requiring review has increased from 11 in 2015 – 16 to 14 in 2017 – 2018. Several members resigned from the Board due to other commitments in their respective faculties or personal issues. Some members were not replaced. In addition to REB member reviews, ad hoc reviewers have been required to assess those applications where there was not sufficient expertise on the Board to complete the reviews.

In this year, the number of applications submitted on a monthly basis ranged from 6 – 19, with an average of 12 applications per month.

**Table 4 Applications by Faculty**

Faculty	Number of Applications (initial application)
Faculty of Business and Information Technology	9
Faculty of Education	9
Faculty of Engineering and Applied Science	3
Faculty of Engineering Systems and Nuclear Science	1
Faculty of Health Sciences	52
Faculty of Science	9
Faculty of Social Science and Humanities	51
External to UOIT	7
UOIT staff	3

## 6.2 Unanticipated Events

There were no reported unanticipated events during the year.

One amendment to an application was denied. An appeal was brought forward which was sent for full board consideration; the REB upheld the original decision to deny the amendment.

### **6.3 Research Ethics Administration Workload:**

The Office of Research Services processes both new applications (i.e. delegated, full board, multi-jurisdictional, and secondary use of data), unanticipated events, research exemption requests, as well as requests for ongoing research (renewals, amendments, and closures). To better understand the workload of the Research Ethics Administration, the number of new applications needs to be multiplied by 10, which is the average number of touch points an application is handled by the Research Ethics Administration before approval is granted.

The Touch Points system can provide a snapshot of the workload of the Research Ethics Administration and the Board. There are on average ten touch points in the current review system for new applications:

1. Application received and pre-screened,
2. Application is processed, including a review of the application's completeness and extent to which the application involves a 'vulnerable population' of human participants,
3. Application is sent to primary reviewer for review and comments,
4. Application sent to Chair with primary reviewer comments,
5. Draft clarification letter created by Chair,
6. Clarification letter finalized and sent to Researcher,
7. Researcher responds to clarification letter,
8. Clarification response pre-screened,
9. Clarification response sent to Chair,
10. Chair approves application.

- By the end of the 2017 – 2018 year, there were 144 new applications and 91 change requests (increase of 21% from 2016 – 17) for ongoing research received. Based on the touch points metrics system, a rough estimate of the volume of applications processed in 2017 – 2018 is:  $(144 \times 10) + 91 = 1531$ .
- The "Touch Points system", however, does not capture the complexity of applications received, the amount of time that it takes the researcher to respond, if multiple iterations are required prior to approval, or the amount of time spent with the researcher in the pre-review stage. Change requests at times involve additional issues than the one touch point allocated to the change request.
- The "Touch Points system" does not capture the added time that may be required for a Full board review which was required on several applications.

### **6.4 Continued Development of Integrated Research and Innovation System (IRIS) Submission and Review System**

IRIS has been available since November 2016 and now is used exclusively for submission of REB applications and as the vehicle to provide feedback to UOIT's researchers and for REB members reviewing the applications. The system supports uploading of documentation of the researcher's REB application and provides for system-generated communications (clarifications requests, renewal notifications, etc.) and for post-approval events

(change requests, renewals, closures, etc.). Post-approval events (change requests, renewals, closures, etc.) can be returned to the researcher for edits/clarifications in IRIS.

For the researchers using IRIS, an expanding online information system answers questions and supports their development of applications. Information may be found at [IRIS](#). IRIS resources and training ‘How Do I’ support pages were available at [IRIS User Guide](#) and at [IRIS Research Support Portal](#).

## **7.0 Education and Training**

Several training opportunities were offered for Board members and Board Administration.

- October 18, 2017: Members were presented with professional development online webinar materials on “Embracing Social Media in Research” by Quorum IRB.
- November 15, 2017: Presentation to REB members on the McMaster University REB Reviewer Workshop ‘How to Review a Research Ethics Protocol’.
- New REB members receive one-to-one support on the process in reviewing REB applications.

Training and development of REB members are scheduled during the monthly meetings. Training and development events include:

- Full board reviews, where required, allow for training and development of REB members on issues identified during member reviews;
- Review of Durham College (DC) and UOIT Board of Record (BoR) SOP;
- Discussion of risk assessment, crowd sourcing.

## **8.0 Ongoing Issues and Actions:**

Despite the fact that the Board has focused on improving the transparency of its processes and establishing standards to maintain consistency with the development and use of Standard Operating Procedure, greater outreach and training to the research community is recommended. To assist with this need, the REB has posted its SOPs on its website, has a greater website presence, and provided tools for researchers, including the posting of all meeting/submission dates.

## **9.0 Concerns and Recommendations**

As there are many first-time researchers applying to receive ethics clearance at the University, the Board recommends that there be more training resources made available to the new researchers (including workshops, online tools, educational pamphlets, etc.). As the complexity of research projects increase, it is important that the research community seek to engage the advice of the Research Ethics Board and administrative support well in advance of an application submission to ensure that applications being received are high quality, adequately addressing the requirements of the TCPS2. This in turn will facilitate an effective and efficient review process. Additionally, researchers are advised to seek the advice of the Chair, Vice-Chair, or Research Ethics Officer



during the clarification phase if he/she does not understand how to respond to the REB's clarification request. Seeking clarification on these issues can greatly expedite the post clarification review phase.

There is a great need to increase the number of REB general members and for the appointment of a Vice-Chair to the Board. Currently all the Vice-Chair duties fall to the Chair. To address this concern the President sent a general call in May 2018 to faculty for applications for the positions of Chair, Vice-Chair, and general members.

## **10.0 Future Directions and Considerations**

The Board continues to grow in its capacity as an Institutional Research Ethics Board in promoting research excellence and upholding the standards of the TCPS2, including implementing ongoing changes introduced to the TCPS2 to improve its overall policies.

Ongoing workshops will continue to be held by the Research Ethics Administration to address the need for research and ethics training within the research community. This training should be considered mandatory to meet the compliance requirements as outlined by TCPS 2 (2014). It is expected that the Office of Research Services will be updating its website accordingly to include additional educational resources and information for researchers.

It is anticipated that future initiatives will continue to refine and consolidate best practices, to ensure a consistent, high quality, efficient review process in addition to ongoing engagement with the research community.