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, 2016 until June 30, 2017.

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, 2016 until June 30, 2017)

Membership	REB Position	Start Date	Faculty	Appointment
Shirley Van Nuland	Chair	August 6, 2015	Education	Currently Appointed
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	Currently Appointed
Shanti Fernando	General Member	September 1, 2016	Social Science and Humanities	Currently Appointed
Jia Li	General Member	May 1, 2015	Education	Currently Appointed

Membership	REB Position	Start Date	Faculty	Appointment
Ruth Milman	General Member	January 5, 2016	Engineering and Applied Science	Currently Appointed
Natalie Oman*	General Member	September 1, 2013	Social Science & Humanities	Currently Appointed
Laura Pinto	General Member	July 1, 2015	Education	Until July 8, 2016
Matthew Shane	General Member	April 1, 2015	Social Science & Humanities	Currently Appointed
Kamal Smimou	General Member	July 30, 2015	Business & IT	Currently Appointed
Wendy Stanyon	General Member	July 3, 2014	Health Sciences	Currently Appointed
Ying Zhu	General Member	December 6, 2016	Business & IT	Currently Appointed
Elisa Beverley	ORS Administration Ex-Officio	April 1, 2016	Interim Research Ethics Officer	Until August 29, 2016
Janice Moseley	ORS Administration	August 30, 2016	Research Ethics Officer	Ex-Officio

* Dr. Oman resumed her duties on the REB on October 29, 2016.

In the year, 12 monthly REB meetings were scheduled and the Board met 8 times within the year. The Board did not meet in July, December, February and June as the REB applications received for those months did not require a review by the full board. Quorum was achieved at all meetings.

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

- ❖ July 20th, 2016 – no meeting
- ❖ August 17, 2016
- ❖ September 21, 2016
- ❖ October 19, 2016
- ❖ November 16, 2016
- ❖ December 14, 2016 – no meeting

- ❖ January 18, 2017
- ❖ February 22, 2017 – no meeting
- ❖ March 15, 2017
- ❖ April 19, 2017
- ❖ May 17, 2017
- ❖ June 21, 2017 – no meeting

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:

➢ Ethics and Compliance Officer / Research Ethics Coordinator:
  The duties of the Ethics and Compliance Officer (later renamed Research Ethics Coordinator) are divided between the Research Ethics Board (with 80% responsibility) and the Animal Care Committee (with 20% responsibility).

Elisa Beverley assumed the role of the Ethics and Compliance Officer on the resignation of Sascha Tuuha (March 30, 2016) until Janice Moseley was appointed as the replacement the Research Ethics Coordinator effective August 30, 2016.

The Research Ethics Coordinator 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. The Research Ethics Coordinator is the principal liaison between the REB and the researchers. In addition, other duties 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:
Nicole Boivin is the Data Coordinator and provides monthly statistical reports to the REB on new applications, change requests related to current applications, yearly renewal of applications and closure of applications.

The ROMEO database is updated daily to capture real time workflow, ensure accurate monthly reporting, and monitor files for compliance.

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.

On January 31st, 2017, the REB reviewed and provided comments to the Intra-agency Advisory Panel on Research Ethics (PRE) for the proposed changes to the TCPS2. The REB's comments have been posted on the PRE website, which can be found here.

5.1 Training

Throughout the year, presentations were given by the Research Ethics Coordinator 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. Presentations were given to the graduate students on September 23rd, 2016; and on May 24, 2017 as part of the Grad Pro Skills workshop. Ongoing research ethics consultations are scheduled regularly with researchers upon request.

❖ REB Chair presented on Research Ethics to the University of the West Indies Research Ethics Committee and senior administration (July 14, 2016 a.m.) and to Education graduate students (July 14, 2016 p.m.) based on the process that the UOIT REB uses.

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

- ❖ IRIS Research Portal demonstration and training by Research Data Coordinator, Nicole Boivin, at October 19, 2016 REB meeting.
- ❖ Igor Gontcharov from the Osgoode Hall Law School, York University and University of Canterbury, presented his research on the ethical framework in social science research: "Regulatory Capture of the Social Sciences and Humanities by the Institutions of Prospective Ethics Review: Challenges and Perspectives" at the March 15, 2017 REB meeting.
- ❖ Presentation by Research Ethics Coordinator on U.S. Common Rule changes at the April 19, 2017 REB meeting.

5.2 Standard Operating Procedure Development

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

Table 1: REB Standard Operating Procedures and Date Approved

REB Standard Operating Procedures	Date Approved
SOP 104: Membership, Composition, Roles and Responsibilities	October 19, 2016
SOP 106: Disclosure and Documentation of Conflicts of Interest	November 16, 2016
SOP 201: Research Submission Requirements	September 21, 2016
SOP 202: Criteria for REB Approval	September 21, 2016
SOP 203: Activities Requiring REB Review	September 21, 2016
SOP 204: Delegated Review	October 19, 2016
SOP 205: The Full Review Process	October 19, 2016
SOP 207: Ongoing Review of Approved Research	October 19, 2016
SOP 209: Study Completion	January 18, 2017
SOP 210: Non-compliance	January 18, 2017

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

On October 5, 2016, a Reciprocal Research Ethics Board Review Agreement was fully executed between Durham College and UOIT. The agreement establishes 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. As part of the BoR review process, a lead REB (also known as the BoR) will be designated to oversee the review and approval of the project, without having to submit to each REB. The PI must be affiliated with UOIT or DC or both in order to qualify for BoR review. Accompanying SOPs were created for the initial and ongoing review of studies accepted for review under the BoR model. The review and approval of these SOPs are still pending.

5.4 REB Website

A stand-alone REB website was developed and launched in December 2016. The REB website 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. 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 2016 – 2017, five (5) files were closed for non-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 has begun between Lakeridge Health Centre and UOIT. Similar to the Durham College – UOIT agreement, 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 2016 – 2017 year, 138 applications were received (see Table 2), an increase of 4.5% from 2015 to 2016 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.

'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.

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 16	6	5					1	12

Aug 16	6	9	3				2	20
Sep 16	2	2					2	6
Oct 16	8	4	1	1			4	18
Nov 16	4	5		1	1	2	3	16
Dec 16	4	1					1	6
Jan 17	3	4	1			1	1	10
Feb 17	5	4			1	1	2	13
Mar 17	2	7		1		1	1	12
Apr 17	1	3					3	7
May 17	7	3						10
Jun 17	2	4			1		1	8

By month, Table 3 below summarizes when the applications are received.

Table 3 Applications by Month July 1 2016 – June 30 2016

Month	Number of Applications
July	12
August	20
September	6
October	18
November	16
December	6
January	10
February	13
March	12
April	7
May	10
June	8
Total	**138**

During the 2016 – 2017 year, each Board member (full-time equivalency of 10) conducted on average 13 delegated reviews. 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.

The number of application submitted on a monthly basis ranged from 6 – 20, yielding an average of 12 applications per month.

Table 4 Applications by Faculty

Faculty	Number of Applications (initial application)
Faculty of Business and Information Technology	12
Faculty of Education	16
Faculty of Engineering and Applied Science	1
Faculty of Engineering Systems and Nuclear Science	0
Faculty of Health Sciences	43
Faculty of Science	4
Faculty of Social Science and Humanities	40
External to UOIT	11
UOIT staff	1

6.2 Unanticipated Events

There were no reported unanticipated events during the year.

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 2016 – 2017 year, there were 138 new applications. The 75 change requests for ongoing research received showed a 13.7% decrease from the 2015 – 2016 year for change requests. Based on the touch points metrics system, a rough estimate of the volume of applications processed in 2016 - 2017 is: (139 x 10) + 75 = 1465.

➢ 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.

➢ 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

After many adjustments to IRIS to ensure that it would work well for UOIT's researchers and REB members reviewing the applications, the system became operational in November. The system supports 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.

For the researchers using IRIS, an expanding online information system was developed to answer questions and support the researchers as they develop their applications. Information may be found at IRIS. To support applicants, an IRIS resources and training 'How Do I' support pages were developed and can be accessed at IRIS User Guide. Further information is available at IRIS Research Support Portal.

For five months both paper and web-based applications were accepted. This dual process has increased the workload of the REB Ethics and Compliance Officer/Research Ethics Officer and all members of the REB in adjusting to the new process while continuing with the original process.

6.5 REB Member Workload Summary

This data was retrieved from April 1st, 2016 to March 31st, 2017 representing eight REB members (n=8). Three members were not included in the overall sample as these members joined in September-December.

REB members' regular time commitments include attending scheduled monthly meetings, participating in those meetings where application reviews are conducted and completing the assigned application reviews in the time period requested. Other factors have an impact on the members beyond their regular REB time commitments. For instance, a member may be asked to assume a specific role during a review related to the duties and functions of the Board. These duties include, but are not limited to:
- o Extra work that a member completes on the initial review for a full board review as Acting Chair when the Chair is not available;
- o Ethics consults with the REB Chair and REB Ethics and Compliance Officer/Research Ethics Officer to discuss an REB issue related to a study file;
- o Maintaining confidentiality on reviews since the member cannot discuss any review aspect with anyone outside the Board;
- o Review of SOPs on a detailed basis as needed;
- o Travel time between office and the meeting site for REB monthly meetings.

The results for general REB members on a yearly basis when 12 meetings are held are as follows (n=8):

REB Applications	
Average number of applications assigned per REB member	12/year
Average number of review hours per REB member	5 hours/application
Average number of hours spent reviewing applications per member	**60 hours/year**
REB Meetings	
Number of REB meetings per year per member	12
Number of hours per meeting per member	2 hours
Estimated number of hours for pre and post prep/meeting per member	2 hours
Estimated number of hours of meeting/prep time per member	**48 hours/year**

Total number of hours for REB work per member	108 hours/year (approximately 15 business days in a year).

Note: the estimated amount of time for REB work (103 hours/year) does not include the other factors that can impact a member's regular time commitment as outlined above.

The average number of new applications per REB member has increased from 11 in 2015 – 16 to 13 in 2016 – 2017. Several members resigned from the Board due to other commitments in their respective faculties or personal issues. Some members were not replaced.

7.0 Education and Training

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

- ➢ November 16, 2016: Presentation to REB members on the McMaster University REB Reviewer Workshop 'How to Review a Research Ethics Protocol'.
- ➢ November 16, 2016: Presentation to REB members on Research Involving First Nations, Inuit & Métis Peoples of Canada.
- ➢ April 19, 2017: Presentation to REB members on Common Rule Changes

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.

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. It is expected that the Office of Research Services will be updating its website accordingly to include additional educational resources and information for researchers as will the REB with its website.

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.