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, 2015 until June 30, 2016.

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 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, 2015 until June 30, 2016)

Membership	REB Position	Start Date	Faculty	Appointment
Bill Goodman	Chair	May 1, 2013	Business & IT	Until July 2015
Joseph Krasman	Vice Chair	June 27, 2014	Business & IT	Until July 2015
Shirley Van Nuland	Chair	August 6, 2015	Education	Currently Appointed
Susan Donaldson	Community Member	March 1, 2013	n/a	Currently Appointed
Glenn Brown	Community Member	February 28, 2014	n/a	Until December 2015
Joan Young	Community Member	April 1, 2016	n/a	Currently Appointed
Toba Bryant	General Member	February 1, 2013	Health Sciences	Currently Appointed

Membership	REB Position	Start Date	Faculty	Appointment
Leigh Harkins	General Member	March 1, 2013	Social Science and Humanities	Until June 30, 2016
Jia Li	General Member	May 1, 2015	Education	Currently Appointed
Stephen Marsh	General Member	January 1, 2013	Business & IT	Until January 2016
Ruth Milman	General Member	January 5, 2016	Engineering and Applied Science	Currently Appointed
Laura Pinto	General Member	July 1, 2015	Education	Currently Appointed
Matthew Shane	General Member	April 1, 2015	Social Science & Humanities	Currently Appointed
Kamal Smimou	General Member	July 30, 2015	Business & IT	Currently Appointed
Serena Sohrab	General Member	July 30, 2015	Business & IT	Until May 10, 2016
Wendy Stanyon	General Member	July 3, 2014	Health Sciences	Currently Appointed
Sascha Tuuha	ORS Administration Ex-Officio		Research Ethics Officer	Until March 30 2016
Elisa Beverley	ORS Administration Ex-Officio	April 1, 2016	Interim Research Ethics Officer	Currently Appointed

Generally meetings are held the third Wednesday of each month from 11:00 a.m. to 1:00 p.m. alternating between the North and Downtown campuses. In December that meeting is held one week earlier and in February the meeting is held one week later. Eleven monthly REB meetings were scheduled and the Board met 11 times within the year. Quorum was achieved at all meetings. The scheduled dates when the Board met are:

- ❖ July 21, 2015*
- ❖ August 6, 2015
- ❖ September 24, 2015
- ❖ November 9, 2015
- ❖ December 7, 2015
- ❖ January 22, 2016
- ❖ February 26, 2016
- ❖ March 30, 2016
- ❖ April 20, 2016
- ❖ May 18, 2016
- ❖ June 15, 2016

* The July 21, 2105 meeting was devoted to meeting with Susan Marlin, the consultant responsible for conducting the External Review of Governance of and Administrative Support to the Research Ethics Board.

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 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).

Sascha Tuuha was the Ethics and Compliance Officer until her resignation on March 30, 2016. Elisa Beverley assumed the role and duties of the Ethics and Compliance Officer on March 31, 2016.

The Ethics and Compliance Officer 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 Ethics and Compliance Officer 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.

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.

5.1 Training

Throughout the year, presentations were given by 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.

❖ TCPS2 workshops were held on September 29, 2015 and January 19, 2016.
❖ The REB Chair presented to Kinesiology graduate students January 25, 2016.

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

❖ IRIS Research Portal update, demonstration and discussion by and with Research Data Coordinator at various REB meetings.

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 found in Table 1:

Table 1: REB Standard Operating Procedures and Date Approved

REB Standard Operating Procedures	Date Approved
SOP 101: REB Meeting Administration	April 20, 2016
SOP 102: Documentation and Document Management	May 18, 2016
SOP 103: Signatory Authority	April 20, 2016
SOP 105: Training and Education of REB Members and Staff	May 18, 2016

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

Discussion concerning a Reciprocal Research Ethics Board Review Agreement was ongoing between Durham College and UOIT. The agreement would 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. 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 or DC or both in order to qualify for BoR review.

6.0 Research Ethics Board Activities

In the 2015 – 2016 year, 133 applications were 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.

6.1 Reviewer Breakdown & Activities

Each Board member (full-time equivalency of 10.5), excluding the Chair, conducted on average 11 delegated reviews. The Chair reviews all applications and prepares letters of clarification.

The number of applications submitted on a monthly basis ranged from 7 - 21 per month, yielding an average of 11 applications per month (Table 2).

Table 2: 2015 – 2016

Month	Applications Received
July	21
August	17
September	8
October	14
November	8
December	9

January	13
February	9
March	7
April	8
May	8
June	11
Average per month	**11**

The time to first decision by the first reviewer is 9.5 days (Table 3).

Table 3: 2015 – 2016

Month Sent	Average # Days to First Review
July	10
August	10
September	6
October	11
November	6
December	7
January	8
February	12
March	12
April	10
May	9
June	11
Average	**9.5**

6.2 Unanticipated Events

There were no reported unanticipated events during the year related to any protocols.

A complaint was filed against one application; the Chair met with the researchers concerning the issue. A letter of apology was sent to the complainant.

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. It was further appealed to UOIT's appeal board at Trent University. On its review of the original application along with the amendment, the documentation provided by the researcher, and the rationale provided by UOIT's REB, the Trent REB supported the original decision to deny the amendment change.

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,
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 2015 – 2016 year, 133 new applications and 87 change requests for ongoing research were received. Based on the touch points metrics system, a rough estimate of the volume of applications processed in 2016 is: (133 x 10) + 87 = 1417. This total does not include request for continuing research nor closure of files which have been completed.

➢ 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 Development of Integrated Research and Innovation System (IRIS) Submission and Review System

With the change of process of submission of applications to the REB moving from paper-based format to web-based format, Integrated Research and Innovation System (*IRIS*), the application form requires change. The content of the paper application is being developed to web-based for the REB Application for Ethical Review, Secondary Use of Data, Multi-Jurisdictional Research (MJR), Course-Based Research, and Human Tissue Samples in Research. The web-based for the REB Application for Ethical Review was developed and piloted first.

An IRIS pilot test online survey was developed to receive feedback as it was piloted; the questions were responsive; for example, if the participant responds that they had difficulty with logging into the system then another question will dynamically appear asking them to provide details and/or suggestions regarding the login process. The survey was related to contact details, experience, and satisfaction with survey responses housed internally here at UOIT.

To support the reviewers, a 17-page guide was developed to support the REB members in their use of the IRIS in reviewing applications.

6.6 External Review Governance of and Administrative Support to the Research Ethics Board Summary September 26, 2015

Preamble

The University of Ontario Institute of Technology (UOIT) commissioned an external review of the governance of and administrative support to the Research Ethics Board (REB). The review was conducted and the report prepared by Susan Marlin (consultant) in July and August 2015. The consultant was provided with the review terms of reference (TOR), relevant policy, procedures and other documentation. Meetings were arranged with key UOIT stakeholders.

The purpose of the review was communicated to the consultant by the provision of the Terms of Reference (TOR) by the Vice-President Research, Innovation and International. The consultant conducted interviews during the period of July 21st and July 22nd 2015.

The full report describes the purpose of the review and the review process, Governance of the REB, REB Operations, and REB Office Resources. Although there was an attempt to keep these sections separate, overlap was unavoidable. Each section begins with observations which are based on both documentary review and interviews, and is followed by discussion and recommendations.

Members of the UOIT community who participated in the review, without exception, did so in a constructive manner. A significant interest in REB activities and high quality and ethical research was evident throughout the review process.

Purpose of the Review

The purpose of the external review (see Appendix 1: External Review) was to review and assess the following:
1) The governance structure for the Research Ethics Board
2) The operations of the Research Ethics Board
3) The resources and administrative support provided to the Research Ethics Board by the University
Review Process

All university stakeholders were strongly encouraged to participate and were provided with the opportunity to attend open sessions, have one-on-one meetings and provide written feedback. A number of individuals were interviewed either by telephone or in person at UOIT on July 21st and 22nd, 2015. Several written submissions were reviewed as well as documents relating to research ethics review at UOIT. Additional details are provided here:

UOIT Interviewees:
   Past REB Chair and Past Vice- Chair;
   Current members of the REB (N = 4);
   Ethics and Compliance Officer;
   President;
   Provost & Vice-President Academic;
   Vice-President Research, Innovation & International;

Director of Research Services;
Research Services Staff (N = 6);
Senior administrators (Deans) (N = 7);
Faculty members (N = 3).

Written Submissions Received and Reviewed: REB member (N=1); Faculty (N=4)

UOIT Documentation reviewed included:
Research Ethics Policy, Approved June 2013, UOIT Board of Governors;
Research Ethics Board Standard Operating Procedures (SOPs):
      100 series (REB Administration)
      200 series (REB Operations);
UOIT Website – Research Ethics Board information (for Faculty and Students);
Research Board Terms of Reference, approved March 11, 2015;
Role of UOIT Board of Governors, UOIT website;
Academic Council mandate, UOIT website;
Job Information Questionnaire, Ethics Compliance Officer, date submitted April 21, 2015;
Job Posting, Ethics and Compliance Officer, posting date April 11, 2012;
Table comparing REB Workloads & Staffing, South Ontario REB Working Group (December 2014)
Memorandum from Chair and Vice-Chair REB to President dated April 24, 2015;
Slide Deck, REB Meeting with President dated November 26, 2014.

A. Governance Structure for the Research Ethics Board
Regarding the governance structure for the REB, the following recommendations are made:

Recommendation 1:
- *The President clarify and make explicit the roles and responsibilities of the VPR portfolio in determining resources and overseeing the operations of the Research Ethics Board.*

- *UOIT policies and procedures reiterate and clearly recognize the independence of the REB in decision making with respect to this relationship.*

Recommendation 2:
- *UOIT REB Conflict of Interest procedures be revised to recognize the potential for conflicts between the institution and REB decision making, and how potential conflicts will be investigated and managed.*

Recommendation 3:
- *An annual report of REB activities be prepared in a timely manner and be made available to the UOIT community.*

Recommendation 4:
- *UOIT consider implementing an annual researcher survey, or utilize other mechanisms, to solicit feedback regarding REB processes and institutional support for researchers conducting research involving human subjects.*

No Recommendation 5 was provided

Recommendation 6:
- *The REB work with university administration to develop a process for receiving and managing complaints from the UOIT community regarding REB processes.*

Recommendation 7:
- *The institution and the REB develop regular communication channels and reporting mechanisms. The development of these channels and mechanisms should include key parties such as the REB, REB Staff, Office of Research Services and the Vice-President Research and be reviewed and approved by the President.*

Recommendation 8:
- *SOP development and approval processes should consider the content of individual SOPs and consult appropriately to ensure responsible parties are engaged and SOPs are complaint with applicable internal procedures and internal and external standards.*

Recommendation 9:
- *The REB, through the Chair or Vice-Chair, contribute to clarifying performance and service expectations of key Research Ethics personnel.*

B. Operations of the Research Ethics Board

To support the effectiveness and efficiency of the Research Ethics Board review process, the following e recommendations may be considered:

Recommendation 12:
- *The process of reviewing and finalizing REB SOPs be clarified and codified. The CAREB/N2 Standard SOPs be consulted as part of this process.*

- *Once final, REB SOPs should be made accessible to the UOIT community (e.g., posted on an accessible website), and procedures relevant to researcher activities emphasized or further communicated in documents easily accessible to researchers.*

Recommendation 13:
- *The process for delegated review of initial applications be revisited with the objective of engaging REB members more effectively in the process and building their capacity. The roles and responsibilities of the REB Chair and Vice-Chair be reviewed to ensure responsibilities meet the needs of the REB and are allocated between the two positions, REB members and the ECO in a manner that respects the capabilities and time availability of each position.*

Recommendation 14:
- *Create additional educational and training opportunities/materials for the REB members to increase capacity and understanding of the TCPS and related ethical guidelines.*

- *Create pathways to provide learning opportunities for the REB, such as sharing the feedback from researchers in response to research ethics review.*

Recommendation 15:
- *Membership on the REB be reviewed to ensure there is a sufficient number of REB members, representing key areas of research.*

- *Contributions of REB members be recognized and supported within their Faculty, ensuring total service/administrative commitment is within the 20% allocated to service.*

Recommendation 16:
- *Research conducted within undergraduate and graduate courses, including FBIT Capstone program, be assessed to seek options for either significantly improving the content of REB applications before the ECO or REB is approached, or the implementation of an alternative approach to REB review at the Faculty level.*

Recommendation 17:
- *In keeping with the institution's responsibility for establishing an REB or REB(s) and arrangements/agreements to review research, a delegated Board of Record process be considered by UOIT, especially for projects primarily conducted in hospital settings or other institutions where the institution has signed the Agreement on the Administration of Agency Grants and Awards by Research Institutions.*

C. REB Office Resources

Taking into account the workload comparison, the valued contributed of the ECO towards quality and compliance, as well as measures recommended above to increase the quality of REB submissions and the effectiveness and efficiency of the REB, the following is recommended with regard to REB Office resources:

Recommendation 18:
- *The workload of the ECO be restructured by:*
    - *Removing the responsibility for the Animal Care Committee*
    - *Removing the responsibility for the administrative processing of annual renewal; however, oversight responsibility for the annual renewal process should remain*
    - *Distinguishing between coordination/administrative/screening back up for the ECO, and back up for REB substantive issues (e.g.. determining delegated/full board review, advising on applications, review comments or TCPS compliance).*
    - *Assign REB coordination/administrative back up to consistent administrative capacity in Research Services and back up for substantive issues to the REB Chair or Vice-Chair.*

Recommendation 19:
- *The role of the ECO outside of compliance be recognized by considering a title that better reflects the role, e.g., REB Coordinator.*

Recommendation 20:
- *Focussed, expert and temporary resource be hired to develop educational resources and tools to support the conduct and review of research involving human subjects at UOIT such as:*
    - *revised/updated SOPS.*

- *tools and resources such as consent templates and instructions for form completion.*
- *educational resources such as webinars, researcher/REB member TCPS guides.*
- *policy or guidance regarding specific issues as required.*

Appendix 1

**External review
of
Governance of and Administrative Support to the Research Ethics Board**

Consultant: Susan Marlin

UOIT will undertake an external review of the Research Ethics Board.

Purpose:
The purpose of the external review is to assess the governance structure and the operations Research Ethics Board. In addition, the external review will evaluate the resources and administrative support provided to the Research Ethics Board by the University.

Specifically, the external review will review and assess the following:
- Governance structure of the research ethics board
- Operations of the Research Ethics Board
- UOIT policies related to the Research Ethics Board
- Standard Operating Procedures of the Research Ethics Board
- Level of administrative support and resources provided to the Research Ethics Board.

Process:
The consultant will meet with the following UOIT stakeholders:
- Chair and Co-Chair of the Research Ethics Board
- Members of the Research Ethics Board, as available
- President and the Vice-President Research, Innovation & International
- Ethics and Compliance Officer
- Director, Research Services
- Faculty members/Deans/researchers, if available
- Research Data Coordinator (Research Services).

The consultant will review:
- UOIT research ethics policy
- UOIT research ethics web site
- UOIT research ethics Standard Operating Procedures
- Research Ethics Board Annual Report and other related documentation (e.g., minutes, sample of protocols and correspondence related thereto).

Deliverables:
- Provide a written report outlining the review and assessment conducted
- Provide recommendations to the university on ways that the University may improve the governance, operations, and administrative support of the Research Ethics Board.

6.7 UOIT Research Ethics Board Response to the Marlin Report

The review of the Governance of and Administrative Support to the Research Ethics Board was requested by the Vice-President Research, Innovation and International and conducted by Susan Marlin, an external consultant contracted to complete the review. She is the President and CEO of Clinical Trials Ontario (CTO) and a past president of the Canadian Association of Research Ethics Boards, among other boards and as a member of the Tri-Agency Panel on the Responsible Conduct of Research.

The REB discussed the Marlin Report at length at its February 26, 2016 meeting. While the Research Ethics Board was the subject of the review, it does not have the authority, capacity, or funding to implement many of the recommendations provided in the report. Some recommendations, the REB members believe impinge on the autonomy of the REB. The REB has, however, worked on the recommendations given its resources.

The REB has begun work on developing its own website independent from the Office of Research Services. The current website is embedded too deeply within ORS and does not provide sufficient information for researchers to develop their application.

7.0 Education and Training

Several training opportunities were offered for Board members and Board Aministration.
- ❖ Member attendance at McMaster University's REB Reviewer Workshop 'How to Review a Research Ethics Protocol' on October 16, 2015.
- ❖ Member attendance at Wilfrid Laurier's REB Workshop 'How to Review a Research Ethics Protocol' on October 16, 2015.
- ❖ Members attendance at Toronto Research Management Symposium 2015 St. Andrew's Club & Conference Centre on November 24, 2015.

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 will post its SOPs on its website, have a greater website presence, and provide 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 (when appointed), 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 the Vice-Chair duties (i.e., approval of change requests, multi-jurisdictional research applications, secondary use of data requests, and exemption requests) fall to the Chair.

There must be support from the Deans to ensure that their faculty members are given the required time to be members of the REB and that they are able to complete their term. Scheduling through the Registrar's Office has been requested to hold the meeting dates and times clear from the teaching schedules of the REB members. In some cases, the Faculties have not provided cleared schedules of members thus ensuring that some members are not able to attend meetings for a semester.

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.

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.

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.