UNIVERSITY OF ONTARIO INSTITUTE OF TECHNOLOGY

1.0 Introduction
The Research Ethics Board, 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, 2013 until June 30, 2014.

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 (June 2013 until July 2014)

Membership	REB Position	Start Date	Faculty	Appointment
Bill Goodman	Chair	May 1st, 2013	Business & IT	Currently Appointed
Manon Lemonde	Vice-Chair	March 1st, 2013	Health Science	Currently Appointed
Joseph Krasman	General Member (*Vice Chair)	*June 27th, 2014	Business & IT	Currently Appointed
Shirley Van Nuland	General Member	May 1st, 2013	Education	Currently Appointed
John Samis	General Member	August 1st, 2013	Health Science	Currently Appointed
Toba Bryant	General Member	January 1st, 2013	Health Science	Currently Appointed
Natalie Oman	General Member	September 1st, 2013	Social Science & Humanities	Currently Appointed

Phillip Shon	General Member	August 1st, 2013	Social Science & Humanities	Currently Appointed
Leigh Harkins	General Member	March 1st, 2013	Social Science & Humanities	Currently Appointed
Glenn Brown	General Member	February 28th, 2014	Community Member	Currently Appointed
Susan Donaldson	General Member	March 1st, 2013	Community Member	Currently Appointed
Stephen Marsh	General Member	January 1st, 2013	Business & IT	Currently Appointed
Robin Kay	General Member	May 1st, 2013	Faculty of Education	Currently Appointed
Sascha Tuuha	ORS Administration	Ongoing	Ethics and Compliance Officer (ORS)	Ex-Officio

In the year, the Board met for monthly meetings 11 times where quorum was achieved at all meetings. Below is a list of all the dates the Board met:

- July 30th, 2013
- August 19th, 2013
- September 30th, 2013 (Supplemental)
- October 3rd, 2013
- October 24th, 2013
- November 5th, 2013 (Supplemental)
- November 26th, 2013
- January 30th, 2014
- February 12th, 2014
- March 28th, 2014
- June 26th, 2014

There were two reported unanticipated events during the year, one which was directly related to a human participant compliant. Both studies in question were temporarily suspended until the REB had an opportunity to complete an investigation and provide recommendations mitigating any further risk to study participations. Both studies satisfactorily met the REB's requirements and were subsequently re-approved.

4.0 Administrative Support

Administrative support for the Board is provided by the Office of Research Services, through funds provided from the Federal Indirect Costs Grant. There are multiple positions that function as Research Ethics Support:

- Ethics and Compliance Officer:
  The Ethics and Compliance Officer provides administrative support to the Board and is responsible for providing ongoing daily administrative support and ethical guidance to the Board and researchers in accordance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans and best practices.

- Research Ethics Administration:
  The Research Ethics Administration maintains all Research Ethics files through updating the Office of Research Services database daily to capture real time workflow, ensure accurate monthly reporting, and

to monitor all files are compliant. This position is also responsible for monitoring file renewals, and maintaining all renewals, amendments and closures.

The Ethics and Compliance Officer position is held by Sascha Tuuha.

5.0 Regulatory Updates

Research involving humans at the University is regulated by both the Canadian Tri-Council Policy Statement 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 15th, 2014, the REB participated in the Intragency Advisory Panel on Research Ethics' consultation process and submitted comments and concerns relating to proposed changes in the second Tri-Council Policy Statement.

5.1 Training

During the Fall/Winter Semester of 2013/2014, general workshops were held by the Ethics and Compliance Office 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, as follows:

> - September 16th, 2013
> - September 24th, 2013
> - October 8th, 2013
> - October 25th, 2013
> - November 28th, 2013
> - February 5th, 2014
> - February 11th, 2014
> - February 13th, 2014

### 5.2 Standard Operating Procedure Development

During this time, no additional SOP's were created. The SOP 104 "Membership, Composition, Roles and Responsibilities" was edited February 14th, 2013 and was revised as follows:

> - 5.2:"The Office of Research Services will approach a faculty member's Dean for endorsement of a nomination."

> - 5.2.1: "All nominations (whereby the nominee has expressed interest) and supporting documentation will be brought to the REB for discussion and vote. Potential members may choose to provide documentation of their experience (e.g., their resume). Nominees may not be present during the discussion or decision".

> - 5.3: Assignment of Roles: The REB will appoint the Chair & Vice-Chair from its current academic membership. A faculty member may self-nominate by sending a letter to the Chair or the Ethics and Compliance Officer. The Office of Research Services will approach a faculty member's Dean for endorsement of a nomination.

- 5.3.1: All nominations (whereby the nominee has expressed interest) and supporting documentation will be brought to the REB for discussion and vote. Nominees may not be present during the discussion or decision.

- 7.2: Leave of Absence of REB Members: Members who plan to resign go on a temporary leave of absence (e.g., sabbatical, medical leave or extended vacation), in duration must inform the REB Chair or designate and Ethics and Compliance Officer as soon as possible in writing. During a leave of absence, the member will be considered as continuing in active member of the board until they return to the board or expiration of their term or they resign.

- 7.3: Resignation of REB Members: Members who plan to resign must inform the REB Chair or designate and the Ethics and Compliance Officer as soon as possible in writing. Individuals listed in the appointment letter will be notified by the Ethics and Compliance Officer.

- 7.4: Expiration of Term: Upon the expiration of a term, a thank you letter will be sent to the member on behalf of the REB and the President.

6.0 Research Ethics Board Activities

In the 2014 fiscal year, there was a 5.55% increase from 2013 to 2014 in the overall number of Applications received. Faculty research has been steadily increasing, with an increase of 23.3% from 2013 to 2014. Graduate Research has increased from 2013 to 2014 by 14.7%, however Undergraduate research has been in decline due to the changes in fourth year thesis projects, primarily fourth year Capstone.

Application Submissions by Type
June 2010 - July 2014
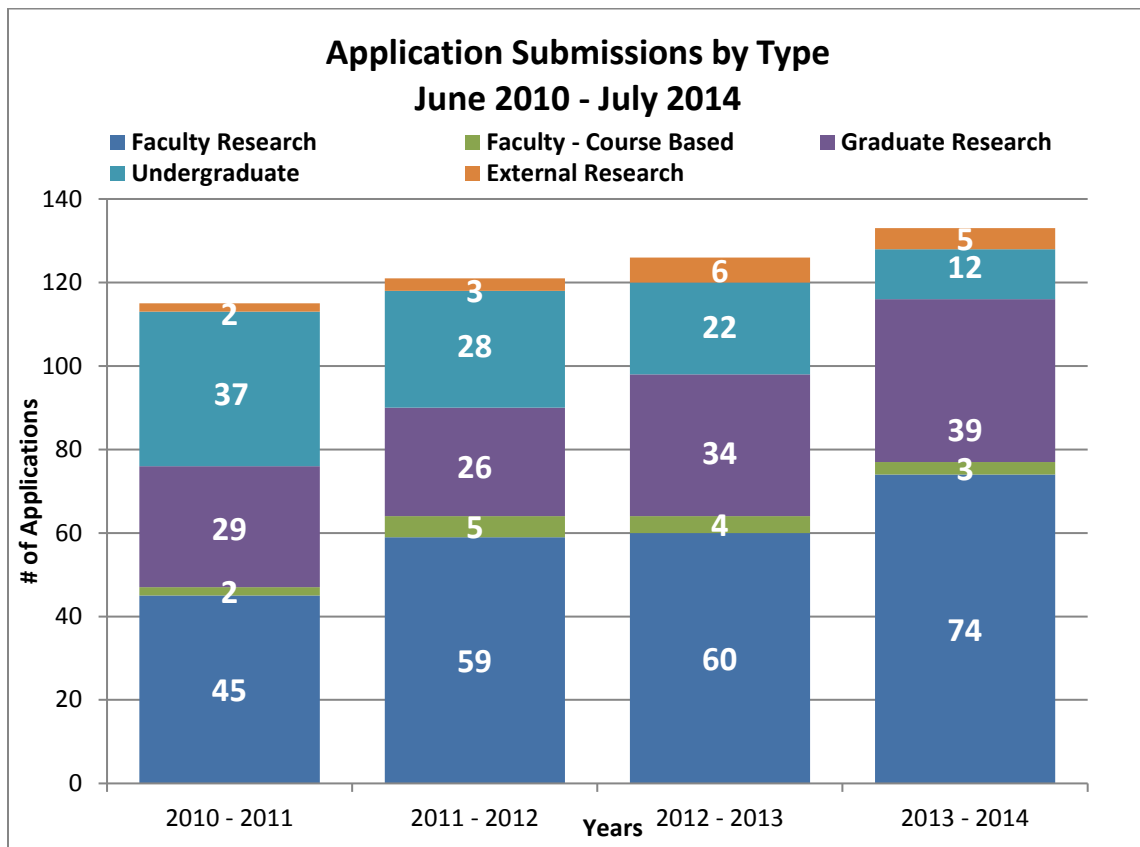
Research Ethics Administration Workload:

The Office of Research Services processes both new applications 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 7, 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 seven touch points in the current review system for new applications:
1) Application received and processed,
2) Sent to delegated reviewer,
3) Draft clarification letter,
4) Chair approves clarification letter,
5) Researcher receives clarification letter,
6) Researcher responds to clarification letter, and
7) Chair approves application.

➢ By the end of the 2014 fiscal year, there were 133 new applications and 130 requests for ongoing research received. Based on the touch points metrics system, a rough estimate of the volume of applications processed in 2014 is: (133 x 7) +130 = 1061. Based on the number derived from the previous year, the volume of applications processed in 2014 decreased by a total of 2.03%.

➢ 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.

6.1 Reviewer Breakdown & Activities

During the 2014 fiscal year, each Board member conducted on average 10 delegated reviews. In the 2014 fiscal year, the number of application submitted on a monthly basis ranged from 5-22 per month, yielding an average of 11 application per month. The time to first decision, in the form of a clarification letter (including two weeks holiday in December) is on average 12.91 days. This sharply contrasts the total review time which was on average 39.75 days (range 27-53 days), allotting 26.84 days in the post clarification phase (touch points 6 and 7). As seen in Table 1.0, compared to the 2013 fiscal year, the number of applications per month is almost identical; the time to first review is less by almost a day, however the number of days spent in post clarification is greater by almost 4 days. Reasons for this may include complexity of research, multiple iterations required, and time required for the researcher to respond. Figure 2.0 (below) details the median time for new applications to be reviewed and approved.

Table 1: 2013 – 2014

	2013	2014
Number of Applications per Month	10.5	10.91
Time to First Review (in days)	13.95	12.91
Total Review Time (in days)	36.6	39.75
Time Spent in Post Clarification (in days)	22.65	26.84

Figure 2.0: 2014 Median Time for Approval Process (Delegated Reviews)
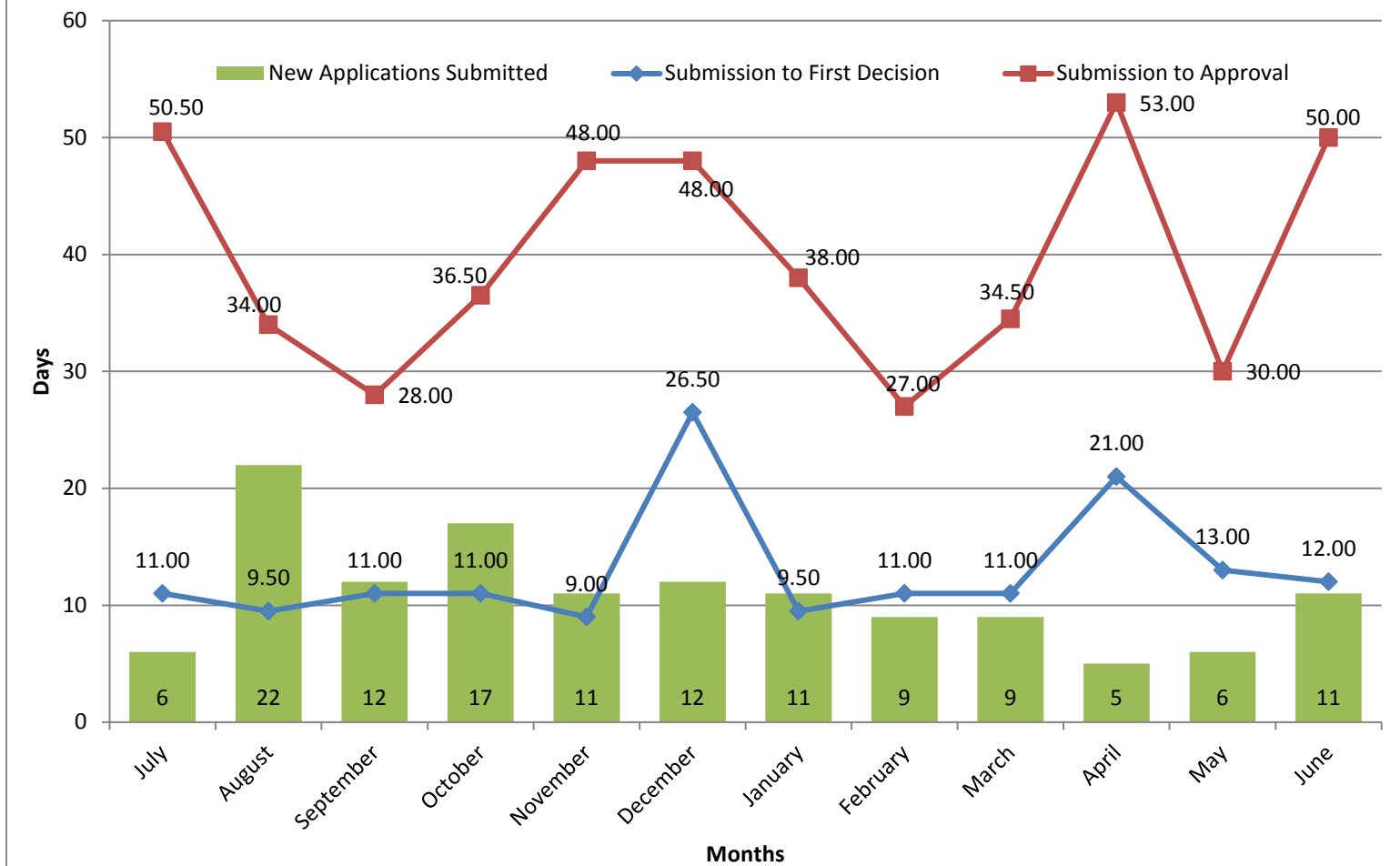
7.0 Education and Training

Several training opportunities were offered for Board members (e.g., provincial and national CAREB conferences, as well as a Regional Conference). The majority of conferences were attended by Board Administration, and/or Board members.

- ➢ CAREB Provincial, St. Michael's Hospital, December 2013
- ➢ Regional Research Ethics Meeting, University of Waterloo, March 27th, 2014
- ➢ CAREB National, Montreal, April 2014

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 (including the posting of SOP's on the

website, greater website presence, and 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. workshop, online tool or 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 Ethics and Compliance Officer during the clarification phase if he/she does not how to respond to the REB's clarification request. Seeking clarification on these issues can greatly expedite the post clarification review phase.

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.