University of Ontario Institute of Technology (Ontario Tech)

Research Ethics Board (REB)

Annual Report

July 1, 2018 to June 30, 2019

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Section 1: About this Report

The University of Ontario Institute of Technology (Ontario Tech) Research Ethics Board (REB) publishes this report annually to inform the Ontario Tech University President, University members, research staff and other interested stakeholders of the REB's activities throughout the year. This report covers the REB's activities from **July 1, 2018, to June 30, 2019,** fiscal year.

Section 2: Overview of Research Ethics at Ontario Tech

The Ontario Tech REB is committed to upholding the highest ethical standards for the University community, which includes its faculty, staff, students and those holding an appointment with the University. The Ontario Tech REB reports directly to the President and was established to ensure that all research involving human participants meets the research ethics standards in accordance to the most recent Tri-Council Policy Statement 2: Ethical Conduct for Research Involving Humans (TCPS2), associated regulations (TCPS2 2014, Article 6.1) and applicable University policies. The TCPS2 is a joint policy of Canada's three federal research agencies: 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). The REB endorses the core ethical principles of the TCPS2: Respect for Persons, Concern for Welfare, and Justice.

Section 3: REB Responsibilities

The primary mandate of the REB is to ensure the ethical conduct of research involving human participants conducted within the University's jurisdiction and/or under the auspices of the University, which includes off-site and multi-site jurisdiction research.

Other REB responsibilities include:

- 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;
- managing and providing advice on ethical matters concerning human-based research;
- educating the University community on the ethical conduct of research involving human participants;
- providing an annual report on its activities to the President and University members; and
- participating in continuing education organized by the University in matters relating to research ethics.

Section 4: REB Membership

The REB members are essential to the successful operations of the Board and timely ethical research reviews. Appointments of general members are for three-year terms and are renewable once. Initially, appointments range from two to three years to allow for continuity of membership during transition periods among member(s). Appointments for the Chair and Vice-Chair are for two years, renewable for one additional term.

Over the 2018-2019 fiscal year, the Ontario Tech REB experienced a high number of turnover in membership. At the beginning of the fiscal year, the terms of the REB Chair and two general members ended on July 1, 2018. As a result, the REB was without a Chair or Vice-Chair from July 1, 2018, to September 12, 2018. During this transition period, the Chair's workload was equally distributed to the existing REB members; decisions on study files were assigned to available REB members in rotation. In the absence of a Chair, a senior REB member was available to address urgent matters such as adverse events, complaints, ethical breaches, non-compliance, reconsiderations and appeals.

The President's Office and Office of Research Services (ORS) were instrumental in replenishing vacancies in the REB by recruiting a Chair, Vice-Chair and several general members. In June 2018, the President's Office sent a University-wide call to all University faculty members to encourage applications for memberships to the REB. In particular, faculty members with knowledge and experience in the following areas were encouraged to apply:

- computer science, app development, artificial intelligence, augmented reality, crowdsourcing;
- health sciences, medical health research, exercise physiology, clinical trials;
- socio-behavioural research; and
- Indigenous studies.

The President's call for membership resulted in the appointment of a new Vice-Chair (this role was vacant since August 2015) and five new general members to the REB with research disciplines in computer science, engineering and health science.

In parallel, the REB successfully recruited five new community members to fill various roles:

- one legally trained member to serve as a legal member;
- one member with tertiary care healthcare clinical trial experience; and
- three members with Indigenous family roots to provide input on Indigenous focussed research proposals.

Table 1 lists the membership throughout the fiscal year. Below are definitions of the membership status as of June 30, 2019:

- "Currently appointed" means the member remained in their role.
- "On sabbatical" means the member was on leave from their role.
- "Term ended" means the member's appointment concluded.
- "Resigned" means the member stepped down from their role prior to the conclusion of their term.

Table 1. REB membership

Name	Role	Appointment Date	Faculty	Status
Joeann Argue	Community Member	April 1, 2019	n/a	Currently appointed
Jeremy Bradbury	General Member	September 13, 2018	Science	Currently appointed
Sylvia Coleman	Community Member	March 14, 2019	n/a	Currently appointed
Susan Donaldson	Community Member	March 1, 2019	n/a	Currently appointed
Joseph Eastwood	General Member	April 18, 2018	Social Science and Humanities	Currently appointed
Shanti Fernando	General Member	September 1, 2016	Social Science and Humanities	Term ended
Tina Li	Community Legal Member	November 21, 2018	n/a	Currently appointed
Jennifer McKellar	General Member	August 27, 2018	Engineering Systems and Nuclear Science	Currently appointed
Ruth Milman	General Member	January 5, 2016	Engineering and Applied Science	General member until Chair appointment
	Chair	September 12, 2018	Engineering and Applied Science	Currently appointed
Efrosini Papaconstaninou	General Member	August 27, 2018	Health Science	Currently appointed
Shahryar Rahnamayan	General Member	August 27, 2018	Engineering and Applied Science	Resigned
Jen Rinaldi	General Member	October 1, 2017	Social Science and Humanities	Currently appointed
Peggy Shaughnessy	Community	January 3, 2019	n/a	Resigned
Wendy Stanyon	General Member	July 4, 2017	Health Science	Currently appointed
Paul Yielder	Vice-Chair	September 12, 2018	Health Science	Currently appointed
Joan Young	Community Member	March 31, 2019	n/a	Currently appointed
Loutfouz Zaman	General Member	September 17, 2018	Business and Information Technology	Resigned

Name	Role	Appointment Date	Faculty	Status
Kim Zetazate	Community Member	July 27, 2018	n/a	Currently appointed
Ying Zhu	General Member	December 6, 2016	Business and Information Technology	Resigned
Janice Moseley	ORS Ex-Officio	n/a	Research Ethics Officer	Current
Emma Markoff	ORS Ex-Officio	n/a	Research Ethics Assistant	Current
Yusuf Rahaman	ORS University Work Study Student	n/a	n/a	Completed

Section 5: REB Meetings

The REB meets monthly throughout the fiscal year to review all proposals involving human participants that require a full board review. In addition, the REB meetings provide professional development to the REB members related to research ethics and discussion of any pertinent REB matters that require the attention of the full board. It is important to note that quorum was maintained during all meeting decisions, and conflicts of interest were disclosed and mitigated prior to the REB meetings.

REB meetings are held on the third Wednesday of each month from 11:00 am to 1:00 pm, alternating between North Campus and Downtown Campus locations. However, the REB will meet on the fourth Wednesday of the month during reading weeks and on the second Wednesday of the month in December due to the University closure.

The REB met on:

1. July 18, 2018,
2. August 15, 2018,
3. September 26, 2018,
4. October 17, 2018,
5. November 21, 2018,
6. December 12, 2018,
7. January 16, 2019,
8. February 27, 2019,
9. March 20, 2019,
10. April 17, 2019,
11. May 15, 2019, and
12. June 19, 2019.

Section 6: REB Administration and Operations

The REB administration and operation unit within the Office of Research Services (ORS) provides administrative and operational support to the REB. A full-time continuing Research Ethics Officer, Research Business Analyst and limited-term Research Ethics Assistant currently staff the REB administration.

The Research Ethics Officer has a dual role of supporting the REB (with 80% responsibility) and the Animal Care Committee (with 20% responsibility). However, during times of compliance and regulatory audits, the Research Ethics Officer's ratio shifts to accommodate the increased workload for the Animal Care Committee. The Research Ethics Officer is the primary liaison between the REB, researchers and the University, and is responsible for providing ongoing daily operational support, research ethics education, subject matter advice and ethical guidance to the Board and researchers in accordance with the TCPS2. In addition, the Research Ethics Officer also ensures accurate record keeping of all paper 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. In the last fiscal year, the Research Ethics Officer portfolio has expanded to include policy development and implementation, process improvement, strategic planning on education initiatives and oversight of the Research Ethics Assistant, who was hired this year to take over the administrative tasks from the Research Ethics Officer.

The Research Business Analyst provides business solutions and technical support to all functional units within ORS. For the REB, the Research Business Analyst provides monthly statistical reports on new applications, modification requests related to applications submitted in the IRIS Research Portal, yearly renewal of applications and closure of applications. In addition, the Research Business Analyst provides technical support and training on the use of the Integrated Research & Innovation System (IRIS) Research Portal to the REB members and researchers.

For a six-month period from July to December 2018, ORS hired a Work Study Student to provide administrative support for the Research Ethics Officer in the form of pre- and post-REB meeting organization and preparations, as well as managing office tasks such as filing REB and other research compliance committee documents in paper and electronic files. In December 2018, a Research Ethics Assistant was hired for a two-year limited term contract to continue the administrative support for the Research Ethics Officer, REB and other compliance committees. With the addition of a Research Ethics Assistant, the Research Ethics Officer was available for strategic planning, process improvement, policy and procedure development, Board member recruitment, training and education, and outreach to the research community.

Section 7: Electronic System

The IRIS research portal (referred to as "IRIS") was launched in November 2016 and now is used exclusively for the submission of REB applications and managing of communications between the

researchers and REB related to study negotiations and approvals. In addition, IRIS enables researchers to:

- view their own research files, stored in the administrative research management system;
- create and submit new applications related to research projects;
- update current research files;
- collaboratively develop human ethics applications with their research teams;
- experience a streamlined approach to respond to requests for clarification and update applications as needed; and
- renew, request changes and close active files, and view the history of all such requests.

ROMEO is the backend of IRIS; it is an internal REB database that is used by the REB administration for daily operations to capture real-time workflow, ensure accurate monthly reporting, monitor files for compliance, and communicate with the project team members on their study file.

Section 8: Regulatory and Governance Updates

8.1 Tri-Agency Research Data Management Policy (Draft)
In July 2018, the Tri-Agency circulated a draft Research Data Management Policy (DMP) that aims to support Canadian research excellence by fostering sound digital data management and data stewardship practices. The policy includes suggested requirements related to institutional data management strategies, researcher data management plans and data deposit. The REB reviewed the draft Tri-Agency DMP at the July 2018 meeting and submitted joint comments with ORS for the public consultation period in August 2018.

8.2 REB Governance Documents
The President, having the overall authority of the REB, created an independent REB Task Force ("Task Force") to collaboratively and collegially work with the REB to refine the research ethics framework at the University, implement applicable external review recommendations and make decisions on the administrative operations of research ethics processes at Ontario Tech. Specifically, in November 2018, the Task Force critically reviewed and revised the Policy for Research Involving Human Participants (formerly the UOIT Research Ethics Policy) and the REB Terms of Reference. These documents were peer reviewed by the REB, Task Force and two external REB subject matter consultants. As a next step, the documents will undergo a review and consultation through the University governance framework in fall of 2019.

8.3 Policy framework for interventional/clinical trials
The REB Chair and Vice-Chair met with the President and the deans of the faculties of Social Science and Humanities and Health Sciences to discuss the creation of a policy regarding interventional/clinical trials involving a health outcome, in which the study procedures/interventions pose "above minimal" risk. The Research Ethics Officer, in consultation with the REB Chair, Vice-Chair, REB members, faculty deans, institutional representatives and other ad hoc experts, will develop this policy over the next fiscal year.

Section 9: Research Reciprocal Agreements

9.1 Ontario Tech and Durham College

On September 1, 2016, Durham College (DC) and Ontario Tech established a framework to coordinate research ethics reviews for joint research and research activities conducted by members at each institution through a reciprocal research ethics review agreement. The agreement established a Board of Record (BoR) review between DC and Ontario Tech to streamline research ethics review and eliminate the need to submit ethics applications to both institutions. Under the DC-Ontario Tech BoR review, a BoR designation will be assigned to either DC or Ontario Tech REB. The BoR will carry the responsibility for the initial review, approval and ongoing ethical review of the study; while the other REB, known as the Delegated REB (DREB), defers the all aspects of the ethics review to the BoR. In order to qualify for a BoR, the Principal Investigator (PI) must be affiliated with Ontario Tech or DC, or both, and the project must be deemed as minimal risk research. Over the course of the year, Ontario Tech deferred the REB review to DC as the BoR for two studies.

The two institutions renewed the reciprocal agreement in December 2017, and again for another two years in September 2019.

9.2 Ontario Tech and Lakeridge Health

Discussions continue with Lakeridge Health (LH) and Ontario Tech regarding a similar BoR agreement for research ethics reviews and research activities being conducted at LH and/or Ontario Tech by University faculty members and/or LH employees. The LH-Ontario Tech BoR will be similar to the agreement with DC and Ontario Tech. The Ontario Tech REB and Office of Research Services are working closely with LH REB to finalize the agreement and create the procedures by the end of 2019.

Section 10: Training, Education and Consultations

10.1 University community

The REB is committed to providing training, education and consultations to the University research community and REB members. Throughout the fiscal year, the REB and REB administration launched several initiatives with the goals of:

- promoting research ethics;
- enhancing communication through the provision of research ethics advice on REB submissions;
- providing guidance on the REB submission process and how to answer decision letters from the REB; and
- providing updates on research ethics trends and research ethics best practices.

Faculty and students frequently contact the REB Chair, REB Vice-Chair and/or Research Ethics Officer with research ethics questions related to specific projects or to determine whether their research requires an ethics review and to seek advice on ethical issues. In addition, the Research Ethics Officer provides guidance to faculty on submitting their applications to the REB and on responding to REB decision letters. Over the last year, the Research Ethics Officer responded to and resolved the majority

of the consultations; however, she consulted the REB Chair and REB Vice-Chair for more complex research ethics matters.

The Research Ethics Officer also educates the University community about the importance of considering ethics in research and research ethics best practices. Over the course of the last fiscal year, the Research Ethics Officer presented to students, staff and faculty at:

1. Health Research Approaches (HLSC 5010G) – September 26, 2018,
2. Survey of Computer Science Research Topics and Methods (CSCI 5010G) – October 24, 2018, and
3. "The Art of the Research Deal" at HR's Skill 'n Tell Lunch 'n Learn – November 7, 2018.

In the same period, the REB Chair, REB Vice-Chair and Research Ethics Officer were active participants in sixty-six (66) one-on-one scheduled consultations with the PI and/or project team members. The REB consultations were the highest in February and May as seen in Figure 1. At the beginning of the fiscal year, the number of consultations were low, with a drop in consultations in January. Figure 1 and Table 2 do not include the ad hoc consultations that frequently occurred throughout the year.

On May 23, 2019, the REB sent its first University-wide communication with information about the availability of in-person or remote consultations. This communication may be a cause of the increase in REB consults at the end of the fiscal year in May and June.

Figure 1: Number of scheduled REB consultations in a year
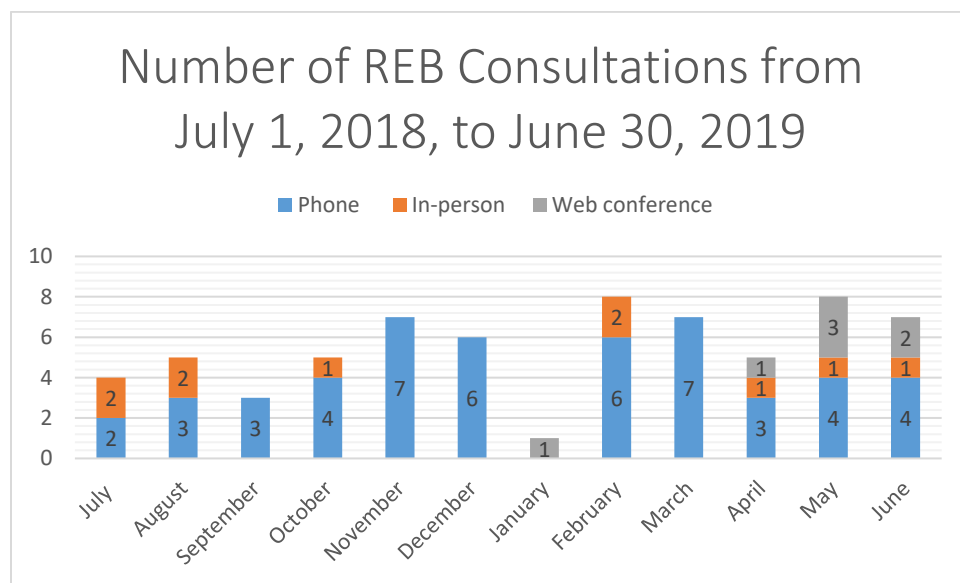
Over 70% of the scheduled consultations occurred over the phone (49) followed by in-person (10) and web conference (7) as seen in Table 2. The REB introduced the web-conference as a new method of consultation in January and was quickly found to be the preferred method of communication for many faculty and students who work off-campus.

Table 2: Number of REB consultations per type in a year

Month	Phone	In-person	Web conference	Total
July	2	2		4
August	3	2		5
September	3			3
October	4	1		5
November	7			7
December	6			6
January			1	1
February	6	2		8
March	7			7
April	3	1	1	5
May	4	1	3	8
June	4	1	2	7
Total	**49**	**10**	**7**	**66**

10.2 REB Members and Staff

Training of REB members and the REB administration is critical to ensure that the REB fulfills its mandate of overseeing the ethical conduct of research involving human participants for studies conducted at the University. Training and education ensure that the REB members remain current with the most recent regulations, guidelines, ethical trends, and policies applicable to human participant research. The REB held the following training and education presentations and attended the following workshops throughout the course of the year:

1. October 9, 2018: **New REB member training session** facilitated by the REB Chair and Research Ethics Officer.
    ➢ This training session was an orientation for the new REB members followed by hands-on experience on reviewing and discussing an ethics application.
2. October 16, 2018: **"How to Review a Research Ethics Protocol**" facilitated by McMaster University.
3. May 15, 2019: External guest speaker on **REB Mission Creep**,
4. May 15, 2019: Updates from the **Canadian Association for Research Ethics Board (CAREB-ACCER) conference and annual general meeting** held on April 10-12, 2019.
    ➢ The Research Ethics Officer provided an update on research ethics trends, harmonization of research ethics review, and research exemptions. In addition, updates from the Tri-Agency's Research Data Management Policy were provided by SSHRC and the Secretariat from the Panel of Responsible Conduct of Research.
5. June 19, 2019: External guest speaker on **Ethical Data Management**.
6. June 19, 2019: External guest speaker on **Capacity Assessment and Consenting in a Major Pediatric Hospital in Ontario**.

External guest speakers with specialized knowledge in matters related to research ethics presented to REB members using web video conferencing for topics 3, 5 and 6 above. The web presentations reached an expanded audience of over thirty-nine attendees (39) directly involved in research ethics. Web participants included REB members and REB administrators from eight universities, one college, five hospitals and two provincial agencies across the county. This format allowed REB members and administrators to engage in research ethics discourse at the national level during the question and answer periods of the presentation. Most importantly, Ontario Tech REB led a valuable engagement opportunity with research ethics administrators and REB members across the country through the web presentations, which raised Ontario Tech's research ethics profile at the national level.

Section 11: REB Activities

11.1 Initial REB submissions

The REB received one-hundred and fifty-eight (158) new submissions (referred to as "initial submissions") throughout the year. Initial submissions types include Capstone, Faculty Course-Based, Faculty Research, Graduate Research, Post-Doc Research, Quality Assurance/Program Evaluation, Undergraduate Research and General Research projects. There was a +4.3% increase in initial submissions in 2017-2018 compared to the previous year, and +9.7% increase in initial submissions in 2018-2019 compared to the previous year (see Table 3). In 2018-2019, the REB observed peak submission periods in July (n=17), August (n=17) and October (n=16), while non-peak submissions were observed in September (n=9), March (n=10) and May (n=10) as seen in Figure 2.

Table 3.

Initial Applications Per Month for the Last Three Years			
Month	2016-2017	2017-2018	2018-2019
Jul 2018	12	12	17
Aug 2018	20	19	17
Sep 2018	6	12	9
Oct 2018	18	10	16
Nov 2018	16	7	15
Dec 2018	6	10	12
Jan 2019	10	12	13
Feb 2019	13	14	15
Mar 2019	12	6	10
Apr 2019	7	15	13
May 2019	10	14	10
Jun 2019	8	13	11
TOTAL	138	144	158

Figure 2.

Initial Applications per Month (2018-2019)
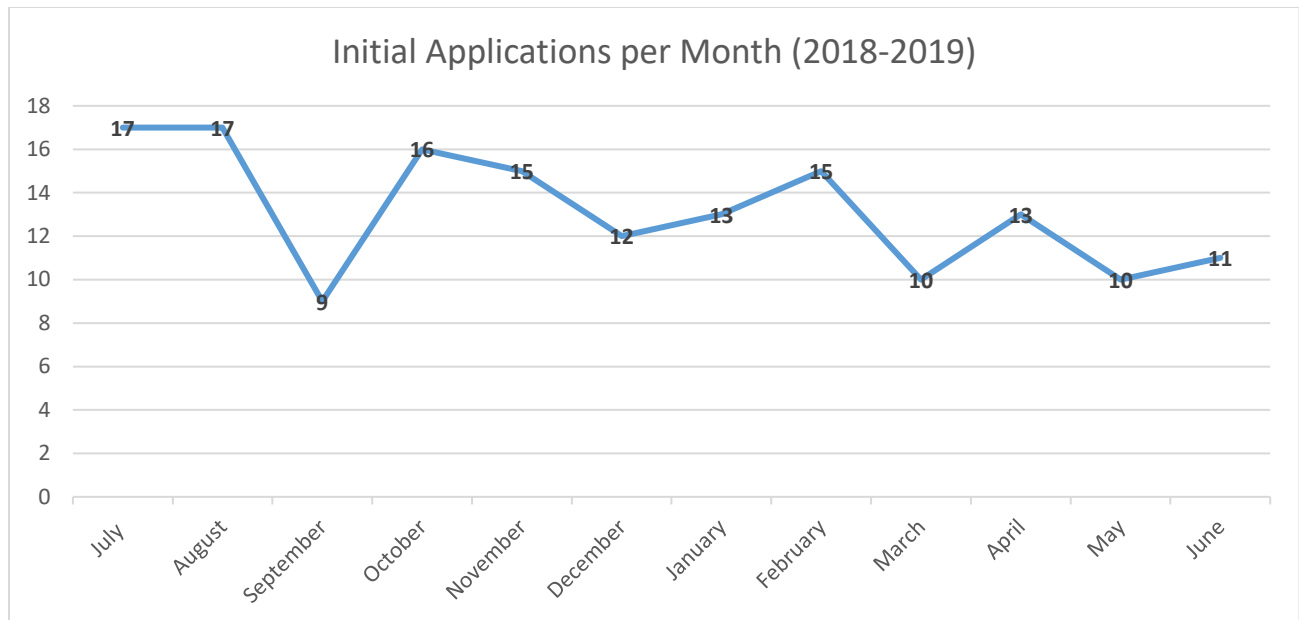
Figure 3 illustrates the trends from the last few years. Peak submission periods were observed in the summer for the last three years. In 2016-2017 and 2018-2019, another wave of initial submissions were observed during October, November and February. In 2017-2018 and 2018-2019, an additional peak submission period was observed in April.

The results from the major granting agencies such as NSERC Discovery, SSHRC Insight and CIHR are announced in the spring, which may explain the high number of initial submissions over the summer months.

Figure 3.
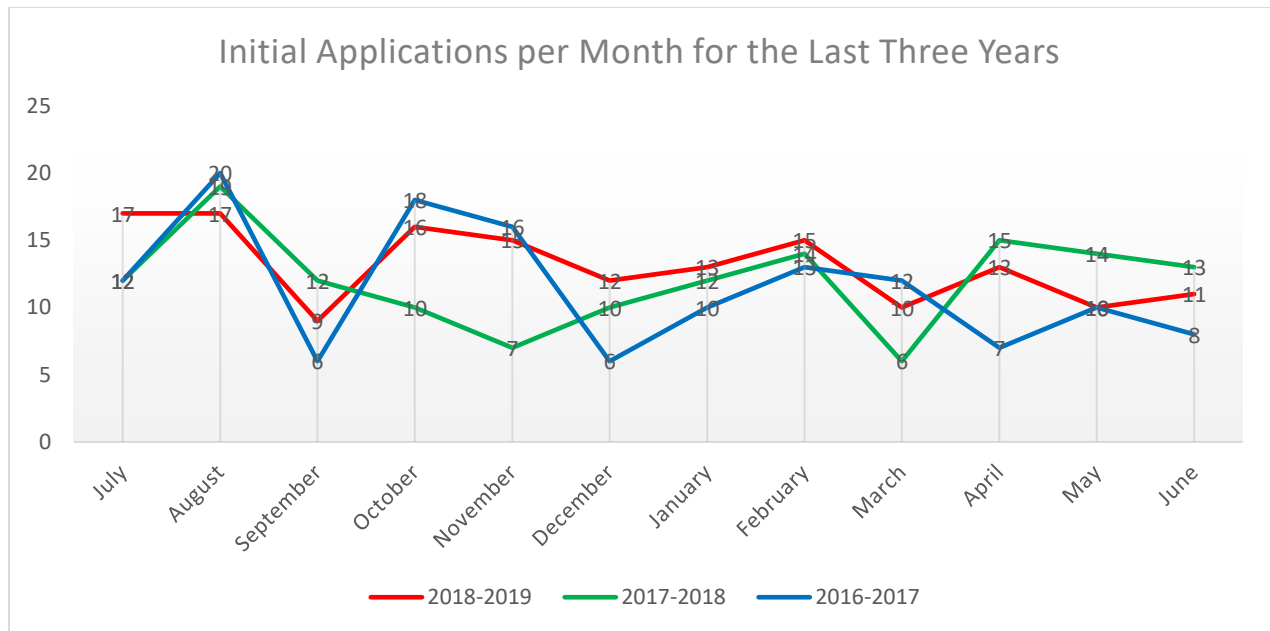
11.2 Initial REB Submissions by Research Type

In 2018-2019, the top three initial submissions involved graduate research (n=65), faculty research (n=50) and other (n=16) research proposals (see Figure 4).

Figure 4.

Graduate research proposals decreased by -9.8% in 2017-2018 compared to the previous year, and increased +41% in 2018-2019 compared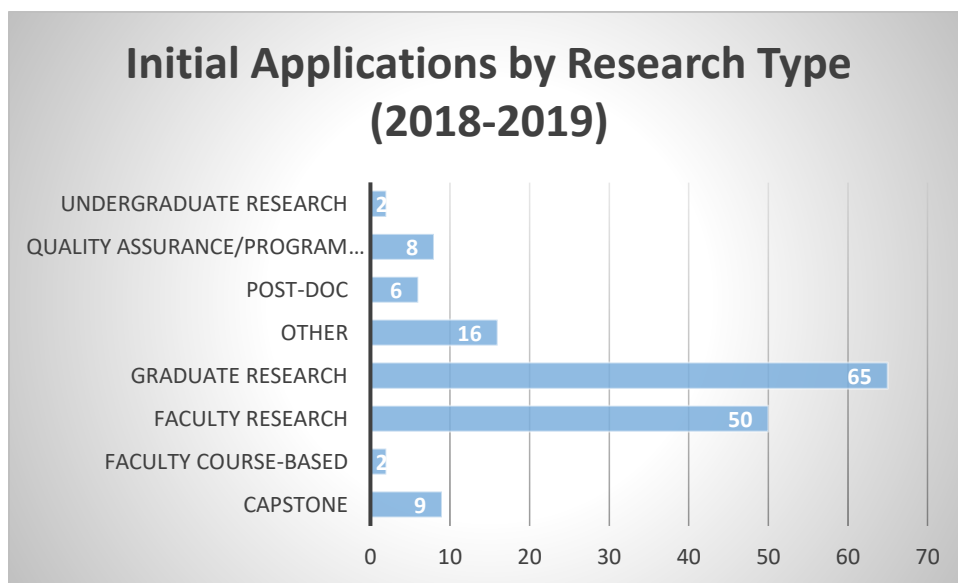 to the previous year. Faculty research proposals observed a +10% increase in 2017-2018 compared to the previous year, and a -9.1% decrease in 2018-2019 compared to the previous year (see Table 4).

Table 4.

Initial Applications by Type for the Last Three Years			
Research Type	2016-2017	2017-2018	2018-2019
Capstone	3	4	9
Faculty Course-Based	5	5	2
Faculty Research	50	55	50
Graduate Research	51	46	65
Other	17	21	16
Post-Doc	5	5	6
Quality Assurance/Program Evaluation	4	5	8
Undergraduate Research	3	3	2
TOTAL	138	144	158

11.3 Types of REB submission

The REB and REB administration review and decide on a number of initial applications, which include delegated, full board, multi-jurisdictional, secondary use of data and REB exemptions. In addition, the REB and REB administration review and decide on all post approval submissions, which include renewals, closures, change requests unanticipated events, and additional documentation.

As of July 1, 2018, two-hundred and forty-nine (249) studies were active within the REB database. This means that these studies have already undergone an initial review and are actively conducting research activities. In addition, active studies require on-going, post-review activities in the form of change requests, yearly reports and unanticipated problem/adverse event reports.

The REB receives various submission types throughout the year that require review and approval. In 2018-2019, the REB received 614 submissions in IRIS seeking review and approval (see Table 5). These submissions include initial applications, and several post-approval events consisting of:

- change requests for study modifications of previously approved proposal;,
- renewals for studies that seek ethics approval for another year;
- closures for studies that have concluded research activities;
- unanticipated problem reports for unanticipated study conduct, adverse events/issues or protocol deviations;
- additional documentation for review and acknowledgement; and
- administrative closures due to administrative non-compliance.

In 2018-2019, the REB received a high number of submissions for both initial and post-approval review, in August (n=61), September (n=60) and February (=62) as seen in Table 5.

Table 5.

Month	Additional Documents	Admin Closure	Change Request	Closure	New Applications	Other REB Review	Renewal	TOTAL
Type of REB Submission by Month (2018-2019)								
Jul 2018	4	0	6	8	17	0	15	**50**
Aug 2018	**4**	**1**	**9**	**4**	**17**	**0**	**26**	**61**
Sep 2018	**6**	**0**	**10**	**10**	**9**	**0**	**25**	**60**
Oct 2018	1	2	6	9	16	0	19	**53**
Nov 2018	3	2	8	3	15	1	11	**43**
Dec 2018	8	1	3	3	12	0	32	**58**
Jan 2019	5	0	9	6	13	0	19	**52**
Feb 2019	**3**	**0**	**10**	**8**	**15**	**0**	**27**	**62**
Mar 2019	0	1	6	5	10	0	25	**47**
Apr 2019	0	0	11	0	13	0	11	**35**
May 2019	1	0	11	9	10	0	28	**59**
Jun 2019	1	0	5	6	11	0	11	**34**
Total	**36**	**7**	**94**	**71**	**158**	**1**	**249**	**614**

The top three submission types included renewals (40.6%), new (initial) approvals (25.7%) and change requests (15.3%) as seen in Figure 5.

Other submissions such as additional documents, closures and renewals are considered post-approval events and are delegated to the REB administration level. In the last fiscal year, the REB administration received, reviewed and approved three-hundred and sixty-four (364) post-approval events. This demonstrates a need to ensure that the REB administration is adequately resourced at all times.

Figure 5.

NEW SUBMISSIONS BY TYPE (2018-2019)

- Additional Documentation Submitted by Researcher 5.9%
- Administrative Closure 1.1%
- Change Request 15.3%
- Closure 11.6%
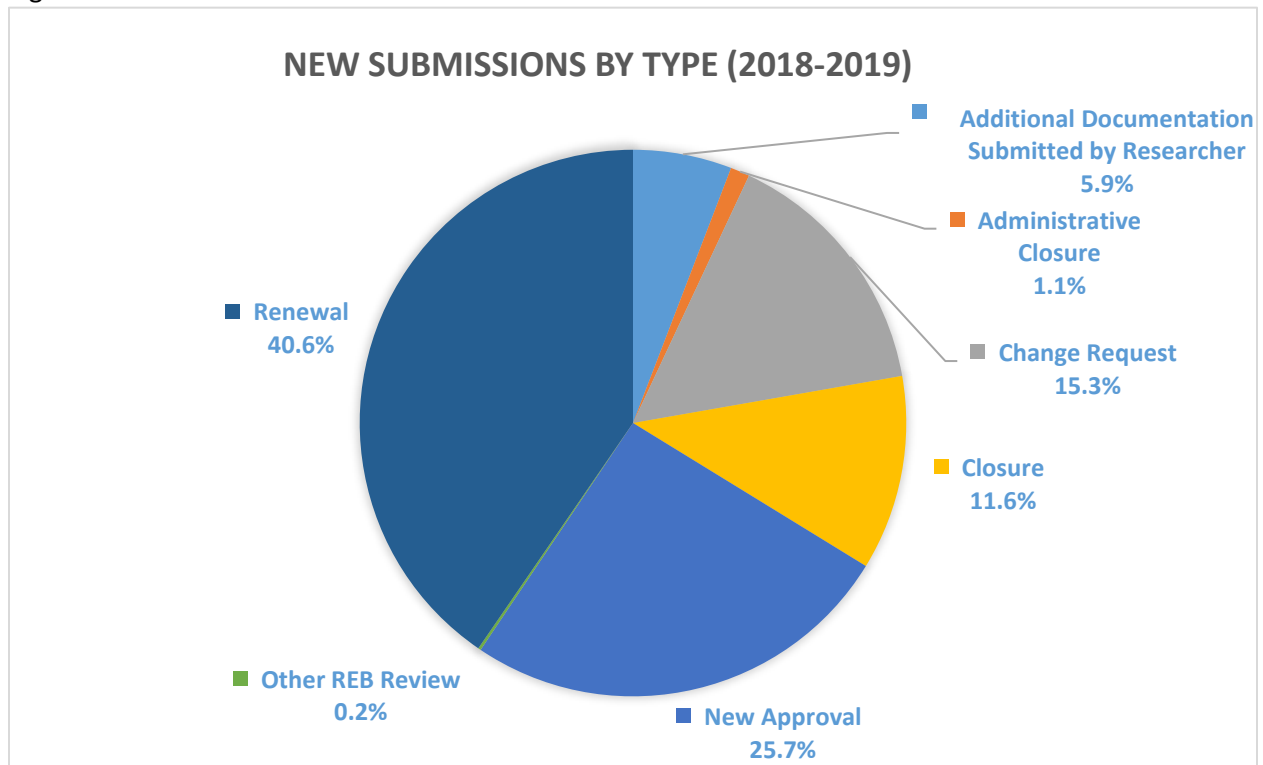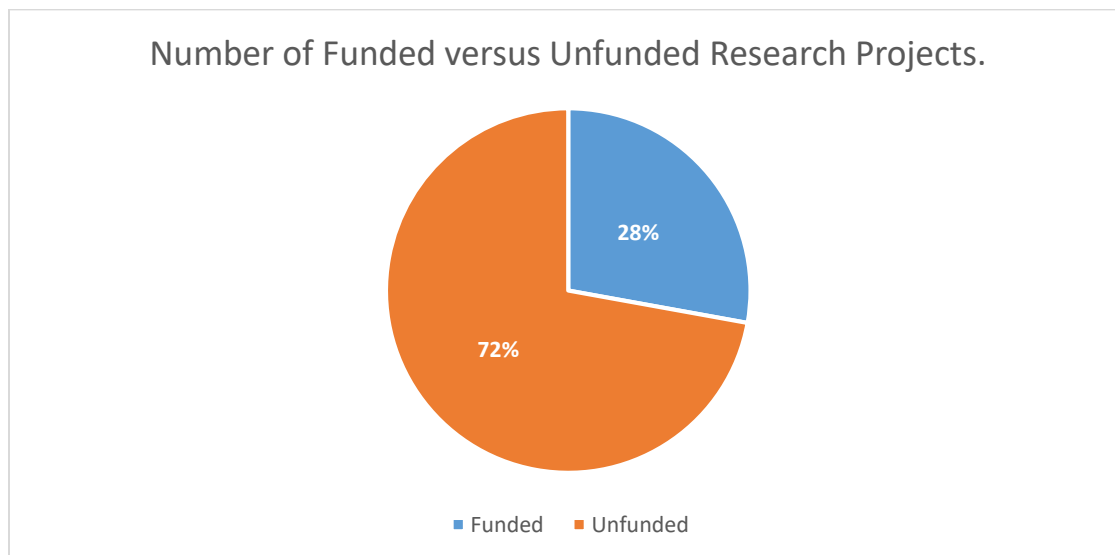- New Approval 25.7%
- Other REB Review 0.2%
- Renewal 40.6%

Figure 6 shows that 72% of the initial REB submissions were unfunded and 28% of submissions received funding from various granting agencies and external partners.

Figure 6.

Number of Funded versus Unfunded Research Projects.

- 28% Funded
- 72% Unfunded

11.4 Initial Submissions by Faculty

The faculties of Social Science and Humanities (FSSH), Health Sciences (FHS) and Business and Information Technology (FBIT) were the top 3 submitters to the REB for initial applications, with 59 from FSSH, 46 from FHS and 18 from FBIT (see Figure 7).

Figure 7.
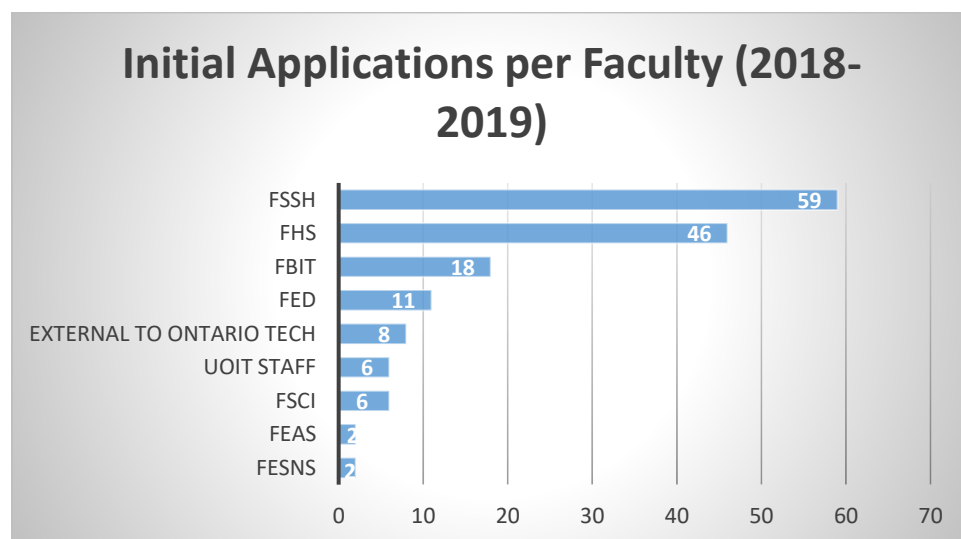
In 2017-2018, the number of initial submissions from the FSSH increased +27.5% from the previous year, and +15.7% in 2018-2019 from the previous year. The number of initial submissions from the FHS increased +20.9% in 2017-2018 compared to the previous year, and decreased by -11.5% in 2018-2019 compared to the previous year. The number of submissions from FBIT decreased by -25% in 2017-2018 from the previous year, and doubled in 2018-2019 (see Table 6). FSSH and FHS continue to be in the top three spots for frequent submitters of initial applications to the REB for the last three years. Based on the current trend, the REB revised the composition of the Board to recruit three new faculty members each from the FSSH and FHS to address the volume of submissions from these faculties and to ensure that the Board has the requisite knowledge in specific research areas.

Table 6.

Initial Applications Per Faculty for the Last Three Years			
Faculty	2016-2017	2017-2018	2018-2019
FESNS	0	1	2
FEAS	1	3	2
FSCI	4	9	6
Staff	1	3	6
External PI	11	7	8
FED	16	9	11
FBIT	12	9	18
FHS	43	52	46
FSSH	40	51	59
Total	**128**	**144**	**158**

11.5 Type of Submissions by Faculty

Similarly, the FHS and FSSH take the top two spots in terms of frequent submitters to the REB for all submission types, which include additional documentation, closures, renewals, change requests and initial applications. Of all submissions received at the REB, FHS submitted 33.6% of all submission types to the REB, FSSH submitted 32.1% and FED submitted 12.9% (see Figure 8).
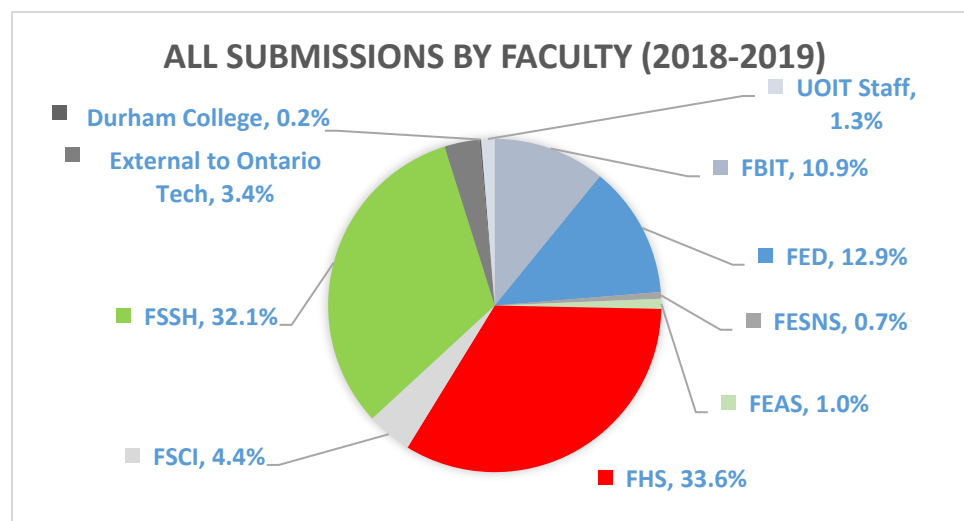
Figure 8.

ALL SUBMISSIONS BY FACULTY (2018-2019)

- UOIT Staff, 1.3%
- Durham College, 0.2%
- FBIT, 10.9%
- External to Ontario Tech, 3.4%
- FED, 12.9%
- FSSH, 32.1%
- FESNS, 0.7%
- FEAS, 1.0%
- FSCI, 4.4%
- FHS, 33.6%

Table 7.

Type of Submissions by Faculty (2018-2019)								
Faculty	Additional Documents	Admin Closure	Change Request	Closure	New Approval	Other REB Review	Renewal	TOTAL
Durham College	0	0	0	0	0	0	1	**1**
FESNS	1	0	1	0	2	0	0	**4**
FEAS	0	0	1	0	2	0	3	**6**
Staff	0	0	0	0	6	0	2	**8**
External PI	1	0	0	4	8	0	8	**21**
FSCI	1	0	3	0	6	0	17	**27**
FBIT	0	1	6	4	18	0	38	**67**
FED	3	2	13	8	11	0	42	**79**
FSSH	12	2	27	33	59	0	64	**197**
FHS	18	2	43	22	46	1	74	**206**
Total	**36**	**7**	**94**	**71**	**158**	**1**	**249**	**616**

11.6 REB Timelines: First Clarification letter

The Ontario Tech REB strives to communicate a written decision letter for initial applications to the researchers within 24 to 42 calendar days (4 to 6 weeks) upon acceptance of the original ethics application through the IRIS Research Portal. However, some applications may take longer due to the additional information, clarifications that the Board may require or during peak submission periods in the summer and fall.

In order to understand the workload of the REB, the number of new initial applications must be multiplied by 10, which is the average number of times an REB member and REB administration "touch" a single application before approval is granted.

There are on average ten "touch points" in the current review system for new applications:

1. Application is received and pre-screened;
2. Application is processed, including a review of the application's completeness and extent to which the application involves study procedures that are above minimal risk and pose vulnerable circumstances to study populations;
3. Application is sent to reviewer sub-committee 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 if PI response is satisfactory.

The REB had a tumultuous start to the fiscal year as the Board was without leadership from July 1 to September 12, 2018, and was absent two REB members due to terms ending, and planned sabbaticals. In addition, many REB members were away from June to August due to planned absences which posed extreme challenges for the REB to maintain a 24-to-42-calendar-day (4-6 weeks) turnaround time due to the high volume of submissions received in July to August (see Figure 2 above). The limited availability of REB reviewers resulted in a backlog of initial applications.

The REB Chair and Vice-Chair were appointed September 12, 2018, and new members were appointed on August 27, 2018. At the time of appointment, the REB Chair and Vice-Chair inherited a three-month backlog of initial applications that accumulated in July and August due to lack of REB reviewers. Over the course of a seven-month period, the REB and REB administration worked diligently to overcome the summer and fall backlog in order to return review timelines to the normal 24-to-42-calendar-day window. The review timelines normalized in February, when the average turnaround time for the first clarification letter was 32 calendar days (see Figure 9 and Table 8). The REB turnaround times continued to improve throughout the year; the average clarification letter was sent 25 calendar days from when the initial application was received in May. Throughout the fiscal year, the REB and REB administration

introduced several process initiatives to facilitate the review process and provide support to the REB members and researchers. Sections 14 and 15 of this report describe in detail these initiatives:

- new REB leadership and expansion of general members,
- revisions to REB delegated full board and review process,
- new consent form templates,
- REB reviewer ethical merit assessment form,
- IRIS pre-submission checklist,
- quarterly communications, and
- REB consultations.

To maintain and continually improve response time, it is important to ensure that the REB is sufficiently resourced with a REB Chair, Vice-Chair, and REB members during peak submission periods in the summer and fall. In addition, constant monitoring of REB membership is essential in order to replenish vacancies due to terms ending and planned leaves. Most importantly, the support of the President and Deans is critical for the recruitment of new REB members and to demonstrate support for the REB.
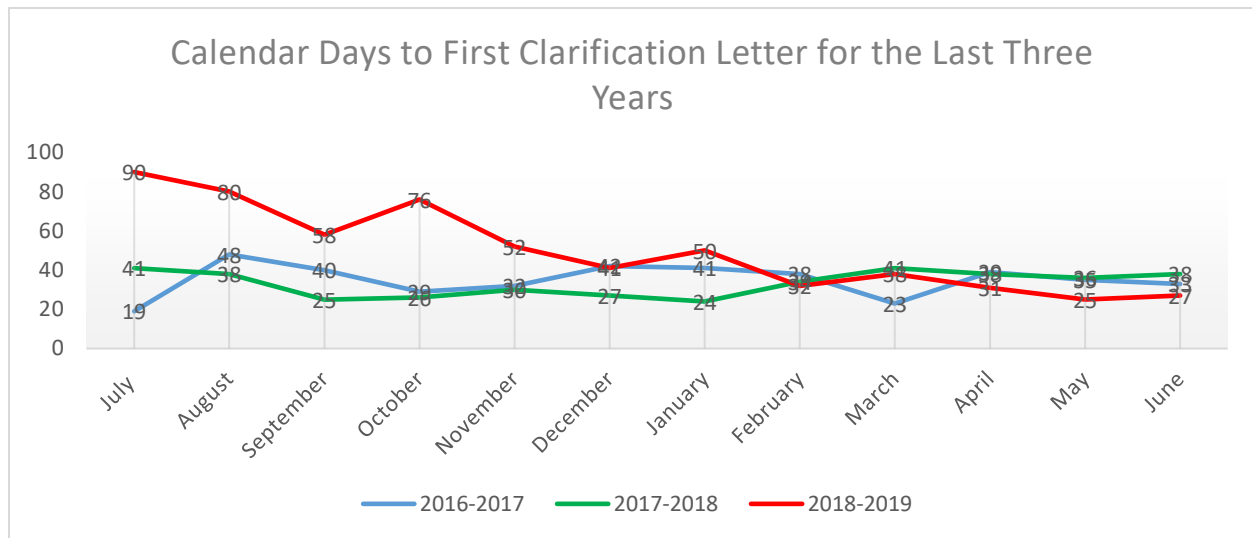
Figure 9.

Calendar Days to First Clarification Letter for the Last Three Years

Table 8.

Calendar Days to First Clarification Letter for the Last Three Years			
Month	2016-2017	2017-2018	2018-2019
July	19	41	90
August	48	38	80
September	40	25	58
October	29	26	76
November	32	30	52
December	42	27	41
January	41	24	50
February	38	34	32
March	23	41	38
April	39	38	31
May	35	36	25
June	33	38	27

11.7 REB Timelines: Submission to Approval

The initial REB approval includes the average number of days the application was under review with the REB from the date the application was accepted for review, to the date the application received ethics approval. The data captured in Figure 10 and Table 9 do not include the number of days the application was in the researcher's possession during the clarification response stage. The REB approval time reported in Figure 10 and Table 9 only include the time the application was under review by the REB.

Due to the limited availability of REB reviewers and absence of REB leadership in the summer, REB applications submitted from July 2018 to January 2019 were subject to unprecedentedly long review times from submission to approval. This period of under resourcing ultimately created a backlog of

submissions for the first six months of the fiscal year. Initial approval timelines improved in April (39 days), May (38 days) and June (31 days) compared to the previous two years due to expanded membership of the Board, strong leadership from the REB Chair and REB Vice-Chair, revisions to the reviewer model and other process efficiencies.
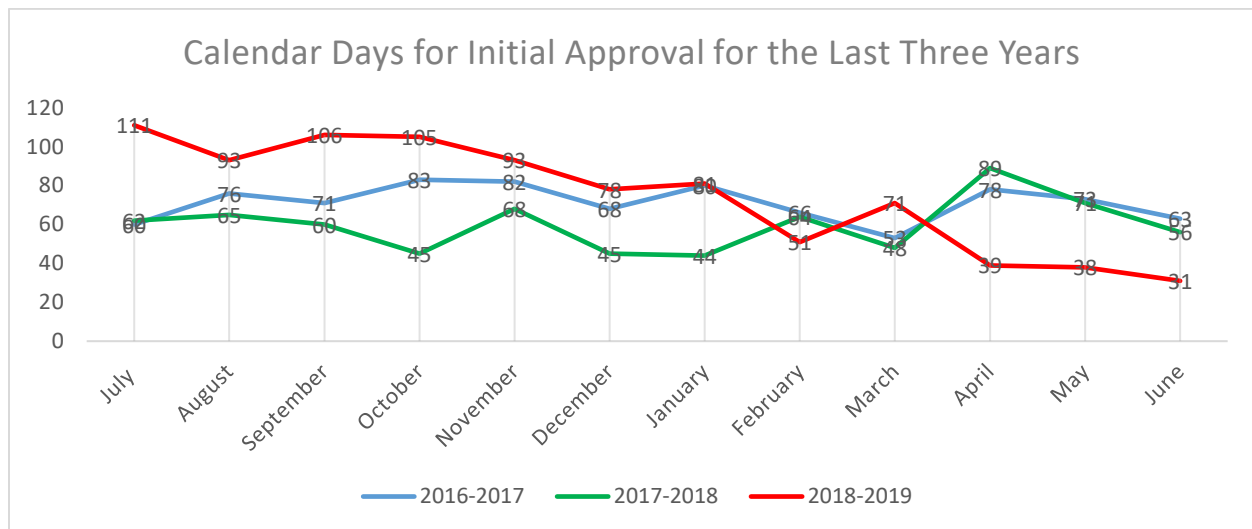
Figure 10.

Table 9.

Calendar Days for Initial Approval for the Last Three Years			
Month	2016-2017	2017-2018	2018-2019
July	60	62	111
August	76	65	93
September	71	60	106
October	83	45	105
November	82	68	93
December	68	45	78
January	80	44	81
February	66	64	51
March	53	48	71
April	78	89	39
May	73	71	38
June	63	56	31

Section 12: Achievements

A joint relationship between the REB and President's REB Task Force was established with the intention of streamlining the REB processes, facilitate with refining the research ethics framework and implement positive changes for REB users and REB members at the University. The joint process improvement and refinement initiatives include:

1. **New REB membership** – Through a University-wide call from the President's office, the REB successfully recruited a new Chair, Vice-Chair and several general REB members. In addition, the REB was successful in recruiting a legal member and several community members with expertise ranging in healthcare and Indigenous focussed research.

2. **REB delegated and full board review process** - In November 2018, the REB review process for all research involving humans was changed to a model from another comparable Canadian university. The new model involves a peer review approach to research ethics with frequent monitoring of the review milestones and progress to ensure timely reviews of ethically sound applications.

3. **Revisions and peer review of the draft Policy on Research Involving Human Participants and the REB Terms of Reference** – These documents have been peer reviewed by the REB, REB Task Force and two subject matter experts in research ethics. The next step will involve a review and approval through the Ontario Tech governance framework.

The work of the President's REB Task Force concluded in June 2019 and the REB will continue the refinement of initiatives established by the REB Task Force. As such, the REB developed and implemented the following initiatives:

1. **REB application revisions** – In June 2019, a draft of the REB main application was created and is currently undergoing a peer review process. The revised application will be pilot tested amongst select research groups and launched in the winter of 2019.

2. **New consent form templates** – In June 2019, a new revised consent form template was posted on the REB homepage for researchers to use as a guide when creating informed consent forms. By the winter of 2019, the REB will implement a standard practice where REB applications must use the consent form template when creating REB submissions. The content of the consent form is flexible enough to adapt to various study designs and multi-institutional collaborations.

3. **REB Reviewer Ethical Merit Assessment Form** – In June 2019, the REB reviewer form was posted on the REB homepage. REB reviewers use this form to structure and ground the review according to research ethics themes and principles of the Tri-Council Policy Statement 2 (TCPS2), institutional, provincial and federal regulatory requirements. This form is available to the researchers as a self-assessment tool to complete prior to REB submission to ensure that the application considers the research ethics themes identified on the form.

4. **IRIS pre-submission checklist** – In June 2019, a pre-submission checklist was posted on the REB homepage. Researchers are encouraged to use this pre-submission checklist to ensure that REB

applications are complete before submitting in IRIS. This can reduce the time required for the review process and minimize the return of REB applications with incomplete information or omissions.

5. **Quarterly REB communications** – To enhance communication and transparency between the REB and the University research community, the REB will send out quarterly communications through the weekly report and email notifications about new activities, initiatives, updates and peak submission periods.

6. **REB consultations** – Scheduled REB consultations have increased over the year resulting in well-constructed and thorough applications, which facilitated the review and timely approval of the applications. Researchers are encouraged to seek consultations with the REB to facilitate with future submissions.

Section 13: Challenges

In addition to long application review times, the REB also faced criticism from the University research community about its processes and operations. Major criticisms of the REB are the lack of transparency in processes and decision-making, and the lack of consistent standards. In the interest of improving the transparency of the REB processes and maintaining consistent standards, the REB administration developed a website to house SOPs, resources and self-assessment review tools for the University community. In addition, the REB committed to greater outreach and training opportunities with the research community especially for first-time REB users. REB consultations with the researchers support decision-making transparency through collaborative discussions.

Another challenge in research ethics involves an increase in the complexity of research projects that require additional regulatory reviews and approval, as well as specialized knowledge. The REB must keep abreast of research trends and changes in order to be adequately resourced and prepared to conduct reviews of complex research studies. As such, it is important that the research community seeks advice from the REB and REB administration well in advance of an application submission to ensure the REB has the requisite knowledge to conduct an ethics review and to identify upfront other regulatory or institutional approvals that are independent of the REB, if any.

Scheduled REB consultations with students and faculty members will also address the REB reviewer challenges related to the quality of the REB submissions. Often, REB submissions contain information gaps, inconsistent information and do not adequately answer the questions in the REB application, which often delays the ethics review due to the number of questions that are asked post review and the back and forth communications with the PI. In addition, through the consultations, researchers are strongly encouraged to visit the REB website to use the templates, self-review assessment tool and pre-submission checklist to ensure completeness of their application prior to submission. In fact, the REB observed a positive effect on the quality of the REB applications when researchers scheduled consultation in advance of their submission and used the available resources on the REB website. The REB found these submissions to be well written, and to adequately address the requirements of the TCPS2.

Maintaining full Board membership is a chronic challenge for the REB as the Board is in constant need of new members to replenish vacancies due to terms ending and upcoming sabbaticals. University faculty members, who have competing teaching, research and other service priorities, conduct the core review functions of the REB. As a result, it is often difficult to find new members to serve on the Board. In addition, given the small size of Ontario Tech, especially of the faculties with relevant expertise to the REB, only a small pool of faculty members are available for recruitment to the REB. In order to ensure the continued success of the REB, there is a great need to increase the number of REB general members and leadership for appointment to the Board. It is the REB's hope that the President, Deans and ORS will continue to have an integral role in supporting and promoting the recruitment, and retention of current and future REB members.

The most significant challenge the REB experienced this fiscal year involved the shortage of REB members and leadership from July 1 to September 12, 2018. During this time, the REB members, REB administration, and research community suffered due to this shortage. The REB members were inundated with initial applications requiring a review at a time when the REB received the highest number of submissions, and the availability of members and leadership were limited and absent. The research community, in particular the students, suffered great losses with their project start-up time as review turnaround times were severely delayed.

As a result of this experience, the REB and REB administration will continue to monitor the membership to ensure the REB is at full complement at all times. In addition, the REB is suggesting to researchers that they should consider submitting their applications during non-peak submission periods to avoid the peak-submission rush. Last, the research community and REB must maintain open communication through frequent posting of updates on the REB website, all-user email communications and scheduled REB consultations to facilitate with planned REB submissions.

Section 14: Recommendations

The REB recommends quality assurance measures of operations, maintenance of general resources and succession planning as future priorities. In particular, the REB is making the following recommendations:

1. Researchers seek the advice of the Chair, Vice-Chair, or Research Ethics Officer during the clarification phase to gain more understanding on how to respond to the REB's clarification request. Seeking clarification on these issues can greatly expedite the clarification review phase.

2. Recertification with the TCPS2 should be considered mandatory. The Panel on Research Ethics (PRE) recently released a fourth edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2018). The PRE will roll out new training modules on the TCPS2 2018. Once available, all researchers should undergo recertification to ensure that individuals working with human participants have the most current information on research ethics.

3. Frequent monitoring of the REB membership to ensure vacancies due to terms ending and planned sabbaticals are covered. To support this need, the REB must collaboratively work with the President's Office, the deans and the Office of Research Services to identify prospective members and ensure succession planning of outgoing members.

4. Professional development for the REB members and REB administration to keep current with research ethics trends and complexities of research studies. In addition, professional development enables engagement opportunities with other REBs for sharing best practices and participating in discourse surrounding research ethics at the national level.

5. Allocate permanent resources for a full-time continuing Research Ethics Assistant who will continue to provide support to the REB members, researchers and Research Ethics Officer. As seen Table 5, three-hundred and sixty-four (364) post approval events, which includes applications for changes requests, renewal and closures, as well as, additional documentation from the researchers were received, reviewed and approved by the REB administration unit. Throughout the year, the REB receives a large number of submissions, which is not feasible for one Research Ethics support person to oversee on their own. For this reason, the REB recommends that the Research Ethics Assistant role becomes permanent to continue with the administrative responsibilities. This will enable the Research Ethics Officer to focus on operational, strategic, process improvement, and educational outreach initiatives to support the refinement activities that were set out in the President's REB Task Force.

Section 15: Future Initiatives

Future initiatives of the REB will continue to refine and consolidate best practices, to ensure a consistent, high quality, efficient and timely review process in addition to ongoing engagement with the research community. Future planned initiatives are:

1. **Protocols as appendix**
   - For studies involving a health outcome, REB submissions will require a protocol in addition to the REB application in order for the REB reviewer to fully understand the nature of the research project and to make an assessment on the project. The protocol shall be submitted as an appendix to the REB application.

2. **Pre-approvals for standing practices in research projects**
   - For research studies that conduct standard research procedures involving specialized equipment, recruitment of a unique population, and/or standard data collection procedures, a pre-approval application will allow researchers to seek approval for the standard research procedure that can be applied across similar studies. The application process will require the completion of a pre-approval application and a stand-alone document that will describe standard research practices. The pre-approval application will undergo a review by the REB. Once approved, researchers can append the approved process as an appendix to the REB application. This will eliminate redundancy of requesting for the same questions for previously approved research procedures in subsequent applications.

3. **REB website**
   - The REB website will serve as a primary information source for researchers that will house SOPs, policies, REB annual reports, consent form templates, reviewer checklists, position papers and important communications.

4. **Other Reciprocal Board of Record (BoR) agreements**
   - For multi-site research involving regional institutions with an established REB, the Ontario Tech REB will work with institutional representatives to develop a BoR agreement where research partnerships involving human participants are common.