University of Ontario Institute of Technology (Ontario Tech)
Research Ethics Board (REB)
Annual Report
July 1, 2019 to June 30, 2020

Contents

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, 2019, to June 30, 2020 fiscal year.

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 2018, Article 6.2) 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, and operates within, the core ethical principles of the TCPS2: Respect for Persons, Concern for Welfare, and Justice.

3. REB Responsibilities

The primary mandate of the REB is to ensure all research involving human participants conducted within the University's jurisdiction and/or under the auspices of the University meets the ethical principles of the TCPS2. This 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.

4. REB Membership

The REB members are essential to the successful operations of the Board. Appointments of general members are for three-year terms and are renewable for one additional term. Initially, appointments range from two to three years to allow for continuity of membership during transition periods when term appointments end. Appointments for the Chair and Vice-Chair are for two years, renewable for one additional term.

During the 2019-2020 fiscal year, the Ontario Tech REB experienced stable membership and minimal turnover with the assistance of the President's Office and faculty Deans in recruiting new members to replenish vacancies. Through a collaborative effort, the REB successfully recruited members from the following faculties:
- Health Sciences (2)
- Social Sciences and Humanities (2)
- Education (2)
- Business and Information Technology (1)

Based on the current submission trends, the REB received the highest number of submissions from the Faculty of Social Sciences and Humanities (FSSH), Faculty of Health Sciences (FHS) and the Faculty of Business and Information Technology (FBIT). For this reason, the REB recruited three new faculty members from the FSSH and FHS to reflect the volume of submissions from these faculties and to ensure that the Board had the requisite knowledge in specific research areas. Overall, the REB strives to have at least two members from the remaining faculties; however, due to an early resignation, the REB lost a member from FBIT. Another community member resigned before their term ended due to competing priorities.

Table 1 lists the membership throughout the fiscal year. Below are definitions of the membership status as of June 30, 2020:
- "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 in alphabetical order

Name	Role	Appointed	Faculty	Status
Joeann Argue	Community Member	April 1, 2019	n/a	Currently appointed
Rob Balogh	General Member	July 1, 2019	Health Sciences	Currently appointed

Name	Role	Appointed	Faculty	Status
Jeremy Bradbury	General Member	September 13, 2018	Science	Currently appointed
Ginny Brunton	General Member	November 8, 2019	Health 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
Aziz Douai	General Member	July 1, 2019	Social Sciences and Humanities	Currently appointed
Joe Eastwood	General Member	April 18, 2018	Social Sciences and Humanities	On sabbatical
Ying (Annie) Jiang	General Member	August 1, 2019	Business and Information Technology	Currently appointed
Tanya Karam-Zanders	General Member	October 4, 2019	Social Sciences and Humanities	Currently appointed
Tina Li	Community Legal Member	November 21, 2018	n/a	Currently appointed
Jennifer McKeller	General Member	August 27, 2018	Energy Systems and Nuclear Science	On sabbatical
Ruth Milman	REB Chair	September 12, 2018	Engineering and Applied Science	Currently appointed
Efrosini Papaconstantinou	General Member	August 27, 2018	Health Sciences	Currently appointed
Jen Rinaldi	General Member	October 1, 2017	Social Sciences and Humanities	Currently appointed
Robyn Ruttenberg Rozen	General Member	July 16, 2019	Education	Currently appointed
Donna Smeeton	General Member	July 3, 2019	Health Sciences	Currently appointed
Wendy Stanyon	General Member	July 4, 2017	Health Sciences	On sabbatical
Diane Tepylo	General Member	July 5, 2019	Education	Currently appointed
Paul Yielder	REB Vice-Chair	September 12,	Health Sciences	Currently

Name	Role	Appointed	Faculty	Status
		2018		appointed
Joan Young	Community Member	March 31, 2019	n/a	Currently appointed
Loutfouz Zaman	General Member	September 17, 2018	Business and Information Technology	Resigned
Kim Zetazate	Community Member	July 27, 2018	n/a	Resigned
Janice Moseley	Ex-Officio Non-voting	n/a	Office of Research Services	Current
Emma Markoff	Ex-Officio Non-voting	n/a	Office of Research Services	Current

5. REB Meetings

The REB meets monthly throughout the fiscal year to review all research proposals involving human participants that require a full board review. The REB meetings provide professional development and training to the REB members and enable discussions of any pertinent REB matters that require the attention of the full board. Quorum was maintained during all meeting decisions, and conflicts of interest were disclosed and mitigated prior to the meetings.

The REB meetings are normally held on the third Wednesday of each month from 11:00 am to 1:00 pm, alternating between North Campus and Downtown Campus locations. Meetings in December 2019 and February 2020 were held on the second Wednesday of the month due to reading week and the University closure

There was a **high level of engagement** from the REB members, where the average meeting attendance rate was **77%**.

at the end of the year, while the October 2019 meeting was held on the fourth Wednesday of the month. For the last 3 years, the REB offered hybrid in-person and virtual meetings to enhance accessibility and promote flexibility with meeting attendance. There was a high level of engagement from the REB members, where the average meeting attendance rate was 77%. Since March 2020, the REB has met virtually as a result of the COVID-19 pandemic.

The REB met on:
1. July 17, 2019,
2. August 21, 2019,
3. September 18, 2019,
4. October 23, 2019,

5. November 20, 2019,
6. December 11, 2019,
7. January 22, 2020,
8. February 12, 2020,
9. March 18, 2020,
10. April 15, 2020,
11. May 12, 2020, and
12. June 17, 2020.

6. REB Administration and Operations

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

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, policies and applicable regulation. In addition, the Research Ethics Officer oversees several administrative responsibilities such as 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.

Over the last two years, the Research Ethics Officer portfolio has expanded to include policy development and implementation, process improvement, Board member recruitment and retention, education initiatives and oversight of the Research Ethics Assistant.   In December 2018, a Research Ethics Assistant was hired for a two-year limited term contract to provide administrative support and relief for the Research Ethics Officer, REB and other compliance committees. This support was in the form of pre- and post REB meeting organization and preparations (including planning and oversight of REB meetings when required), as well as managing office tasks such as filing compliance committee documents for the REB and ACC in paper and electronic files.

The Research Business Analyst provides business solutions and technical support to all functional units within ORS. The Research Business Analyst provides monthly statistical reports on several applications such as new submissions, modification requests, yearly renewals and closures for all compliance committees with ORS. 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.

Electronic System

The IRIS Research Portal (referred to as "IRIS") was launched in November 2016 and has been used exclusively for the submission of REB applications and managing 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.

7. REB Updates

Tri-Council Policy Statement 2, 2018, TCPS2 (2018)
In June 2019, Canada's Secretariat on Responsible Conduct of Research released the Tri-Council Policy Statement 2, 2018, TCPS2 (2018), which replaced TCPS2 (2014) as the official research ethics policy of the federal research agencies (CIHR, NSERC, SSHRC).

As the REB transitioned to the new TCPS2, researchers were encouraged to continue accessing the current CORE tutorials. The Secretariat is working on developing a new CORE tutorial to incorporate the changes referenced in TCPS2 (2018). Once available, all researchers will undergo training for the new TCPS2 2018.

Standard Operating Procedures (SOP)

Over the course of the fiscal year, the REB developed, approved and implemented the following Standard Operating Procedures (SOPs).

1. **REB SOP 211: REB Operations Suspension and Termination of Research Involving Human Subjects for Administrative Non-Compliance**
   This SOP describes the procedures for responding to suspension or termination of research involving human subjects for administrative noncompliance. As per article 6.14 of the Tri-Council Policy Statement (TCPS 2) and the REB's SOP 207, continuing ethics review consisting of an annual report (Renewal Request) or end-of-study report (Project Completion Notification) must be reported to the REB prior to study expiry. Failure to submit yearly reports prior to the expiry date will result in administrative non-compliance. Consequences of administrative non-compliance include suspension or termination of REB approval and freezing access to research funds for funded projects.

2. **REB SOP 212: Process for Reconsideration or Appeal of Decisions of the REB**
   This SOP describes the procedures for a reconsideration and appeal process for unfavorable decisions rendered by REB on proposals involving human participants or human biological material. This procedure has been set out in accordance with Article 6.17 Reconsideration and Appeals from the TCPS2 2018.

3. **REB SOP 213: REB Review Procedures and Research Conduct During Publicly Declared Emergencies**
   This SOP describes the modified research ethics review procedures and practices during a Publicly Declared Emergency. During a Publicly Declared Emergency, the REB membership and staffing levels may be reduced. This will result in delayed or postponed research ethics reviews for non-essential studies involving human participants or human biological materials until membership and staffing levels return to full complement. This SOP is to supplement the University's Emergency Preparedness Plan. This procedure has been set out in accordance with Article 6.20 of the TCPS2 2018 (Research Ethics Review during Publicly Declared Emergencies).

4. **REB SOP 214: Pre-Approval Review Process**
   This SOP describes the REB pre-approval process. This process will allow Principal Investigators to seek approval for a standard research procedure that can be applied across similar studies.

5. **SOP BOR 302: Coordinated Initial and Ongoing Review Process for Lakeridge Health and Ontario Tech University**
   This SOP describes the initial and ongoing review process for research studies involving human participants that have been accepted for ethical review through the Lakeridge Health (LH) and Ontario Tech University Board of Record (BOR) review process. The BOR review process will streamline ethics review between LH and the University so that an ethics submission is only required at one institution. Under the LH-University BOR review process, a BOR designation is assigned to either the LH or the University REB.

8. Research Reciprocal Agreements

Ontario Tech and Durham College

On September 9, 2019, Ontario Tech and Durham College (DC) renewed their agreement for Reciprocal Research Ethics Review for another two years. This agreement will streamline ethics review between DC and Ontario Tech so that an ethics submission is only required at one institution. Under the DC-OT BOR coordinated review process, a BOR will be responsible for the ethics review, approval and ongoing review of the study.

Ontario Tech and Lakeridge Health

On June 7, 2020, the Ontario Tech and Lakeridge Health (LH) Board of Record agreement was finalized. The Board of Record (BOR) review process will streamline ethics review between LH and the University so that an ethics submission is only required at one institution.

9. Training, Education and Presentations

University community

The Research Ethics Officer provided training, education and presentations to the University community throughout the year. These events are detailed below:

- October 7, 2019: Criminology PhD Professional Seminar
- November 6, 2019: Grad Pro-skill Workshop on The 5 W's and the H of Research Ethics.
- November 26, 2019: CSCI 5010G: Computer Science Research Topics & Methods.
- January 8, 2020: Faculty of Health Sciences event on New Year; New Ideas Research at Lakeridge Health. Breakout session on "Nuts & Bolts of Collaborative Research".
- January 23, 2020: HLSC 5115G - Community Health of Vulnerable Populations.
- March 2, 2020: Research Methods in Education for the Faculty of Education's Master of Education program.
- February 11, 2020: Faculty of Social Sciences and Humanities graduate student professional seminar.
- Ongoing: New CAREB education eModule on Vulnerable Circumstances. The eModule is accessible for all University, staff, faculty and students.

Senior Leadership and REB Executive

The Chair and the Vice-Chair met (in-person and/or online) with University senior leadership to discuss research ethics issues, trends and updates on the following days:

- April 14, 2020: REB Chair and Vice-Chair presented to the Dean's Council
- April 27, 2020: REB Chair presented to the Faculty of Education on "REB Pointers for FEd".

- June 2020: REB Chair and Vice-Chair presented to the Return to On-Campus Research Task Force on "Research Conduct During Covid-19".

REB Members and Staff

The REB Chair and members attended the following professional development presentations:

- July 17, 2019: External presentation on Privacy from a Health Information Custodian's perspective
- February 6, 2020: Issues in Health Law & Biomedical Ethics presentation by an external presenter.
- May 27, 2020: Webinar on "Resuming laboratory testing with human participants" led by the Physiological Society.
- June 26, 2020: Webinar on Canadian Association of Research Ethics Board (CAREB) on "Addressing REB Review Challenges for Onsite Research in the Time of COVID-19".

10.   REB Activities
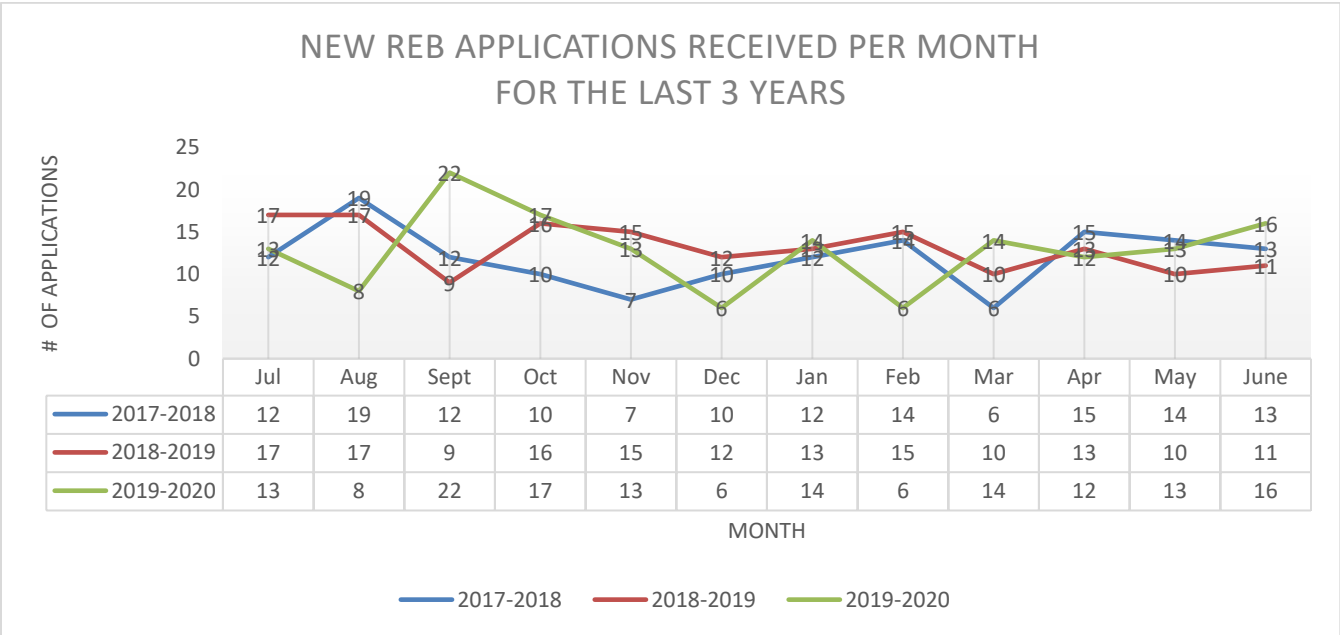
Initial (new) REB submissions

The REB received one-hundred and fifty-four (154) new submissions (referred to as "initial submissions") throughout the year. Initial submission types include Capstone, Faculty Course-Based, Faculty Research, Graduate Research, Post-Doc Research, Quality Assurance/Program Evaluation, Undergraduate Research and other research projects. There was a **-2.5%** decrease in initial submissions in 2019-2020 when compared to the previous year, a **+9.7%** increase in 2018-2019 when compared to the previous year and a **+4.3%** increase in 2017-2018 when compared to the previous year (see Table 2, Figure 1).

Table 2

Fiscal year	Total applications received
2016-2017	**138**
2017-2018	**144 [+4.3%]** ⬆
2018-2019	**158 [+9.7%]** ⬆
2019-2020	**154 [-2.5%]** ⬇

In 2019-2020, the REB observed peak submission periods in September (n=22) and August (n=17). This is a change as peak submission periods historically started in July and lasted until November in the previous fiscal years. The REB's peak submission period occurs when reviewers are not always available. For example, over the summer months, REB reviewer availability is limited due to planned absences. In addition, reviewer availability in September coincides with the startup of the fall semester which tends to be a busy time for faculty members. As such, the REB advises and encourages researchers to submit applications during non-peak periods or to submit applications early during peak times in order to avoid project start-up delays.

Figure 1

NEW REB APPLICATIONS RECEIVED PER MONTH FOR THE LAST 3 YEARS

	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	June
2017-2018	12	19	12	10	7	10	12	14	6	15	14	13
2018-2019	17	17	9	16	15	12	13	15	10	13	10	11
2019-2020	13	8	22	17	13	6	14	6	14	12	13	16

Initial REB Submissions by Research Type

In 2019-2020, the top three initial (new) submissions came from faculty research **(48.1%)**, graduate research **(30.5%)** and other submissions **(7.8%)**. From March to June, the REB received a number of faculty research COVID-19 related projects in response to the pandemic. This resulted in a **+48%** increase in faculty research compared to the previous year. In addition, a **-27.7%** decrease in graduate research was observed and a **-25%** decrease in other research projects. See Table 3.

Table 3

Research Type	2016-2017 [n (%)]	2017-2018 [n (%)]	2018-2019 [n (%)]	2019-2020 [n (%)]
Capstone	3 (2.2)	4 (2.8)	9 (5.7)	9 (5.8)
Faculty Course-Based	5 (3.6)	5 (3.5)	2 (1.3)	2 (1.3)
Faculty Research	50 (36.2)	55 (38.2)	50 (31.7)	**74 (48.1)**
Graduate Research	51 (37.0)	46 (32.0)	65 (41.1)	**47 (30.5)**
Other	17 (12.3)	21 (14.6)	16 (10.1)	**12 (7.8)**
Post doc	5 (3.6)	5 (3.5)	6 (3.8)	0
Quality Assurance/Program Evaluation	4 (2.9)	5 (3.5)	8 (5.1)	4 (2.6)
Undergraduate Research	3 (2.2)	3 (2.1)	2 (1.3)	3 (1.9)
Pre-Approval Process	0	0	0	3 (1.9)
Total	**138**	**144**	**158**	**154**

Types of REB Submissions

The REB and REB administration review a number of initial applications, which include delegated, full board, multi-jurisdictional, secondary use of data, REB exemptions and pre-approval applications. The pre-approval application is a new application that was launched in May 2020. 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 June 30, 2020, **three-hundred and sixty-seven (367)** active studies were recorded within the REB database**,** which is a **+47.3%** increase in active studies compared to the previous year (n=249). 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 in the form of change requests, yearly reports, and unanticipated problem/adverse event reports.
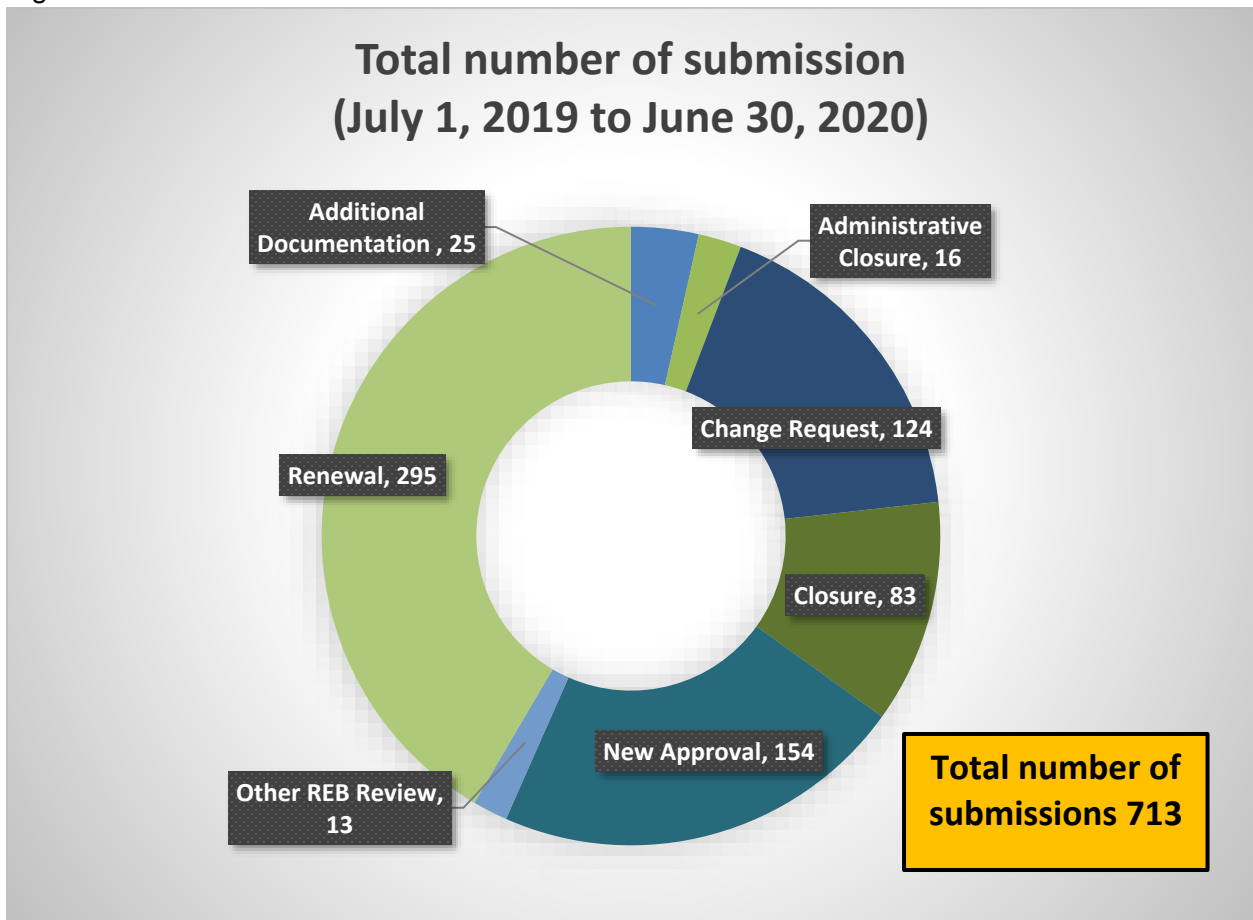
> As of June 30, 2020, **three-hundred and sixty-seven (367)** active studies were recorded within the REB database**,** which is a **+47.3%** increase in active studies compared to the previous year (n=249)

The REB received various submission types throughout the year that required review and approval. In 2019-2020, the REB received **713 submissions** in IRIS seeking review and approval (see Figure 2). This is a **+16.1%** increase in total submissions since the previous year (n=614).   These submissions included initial applications, and several post-approval events consisting of:
- change requests for study modifications of previously approved proposals;
- 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.

The top three submissions are renewals (41.4%), initial submissions (21.6%) and change requests (17.4%).

Figure 2

Total number of submission
(July 1, 2019 to June 30, 2020)

Additional Documentation , 25
Administrative Closure, 16
Change Request, 124
Renewal, 295
Closure, 83
New Approval, 154
Other REB Review, 13
Total number of submissions 713

Initial (new) Submissions by Faculty

The faculties of Social Sciences and Humanities and Health Sciences continue to be in the top two spots for frequent submitters of initial (new) applications to the REB for the last four years, with 49 applications from FSSH and 42 applications from FHS. The faculty of Business and Information Technology (FBIT) is the third most frequent submitter for the last three years with 29 applications (see Table 4).

Table 4

Initial (new) Applications Per Faculty				
Faculty	**2016-2017 [n (%)]**	**2017-2018 [n (%)]**	**2018-2019 [n (%)]**	**2019-2020 [n (%)]**
FESNS	0 (0)	1 (0.7)	2 (1.3)	**0 (0)**
FEAS	1 (0.8)	3 (2.1)	2 (1.3)	**1 (0.6)**
FSCI	4 (3.1)	9 (6.3)	6 (3.8)	**11 (7.1)**
Staff	1 (0.8)	3 (2.1)	6 (3.8)	**0 (0)**
External PI	11 (8.6)	7 (4.9)	8 (5.1)	**3 (1.9)**
FED	16 (12.5)	9 (6.3)	11 (7.0)	**19 (12.3)**
FBIT	12 (9.4)	9 (6.3)	18 (11.4)	**29 (18.8)**
FHS	43 (33.6)	52 (36.1)	46 (29.1)	**42 (27.3)**
FSSH	40 (31.3)	51 (35.4)	59 (37.3)	**49 (31.8)**
Total	**128**	**144**	**158**	**154**

In 2019-2020, the FSSH experienced a **-16.9%** decrease in initial submissions from the previous year. The FHS also experienced an **-8.47%** decrease in initial submissions from the previous year. Meanwhile, the FBIT experienced a **+61.1%** increase in new submissions compared to the previous year.
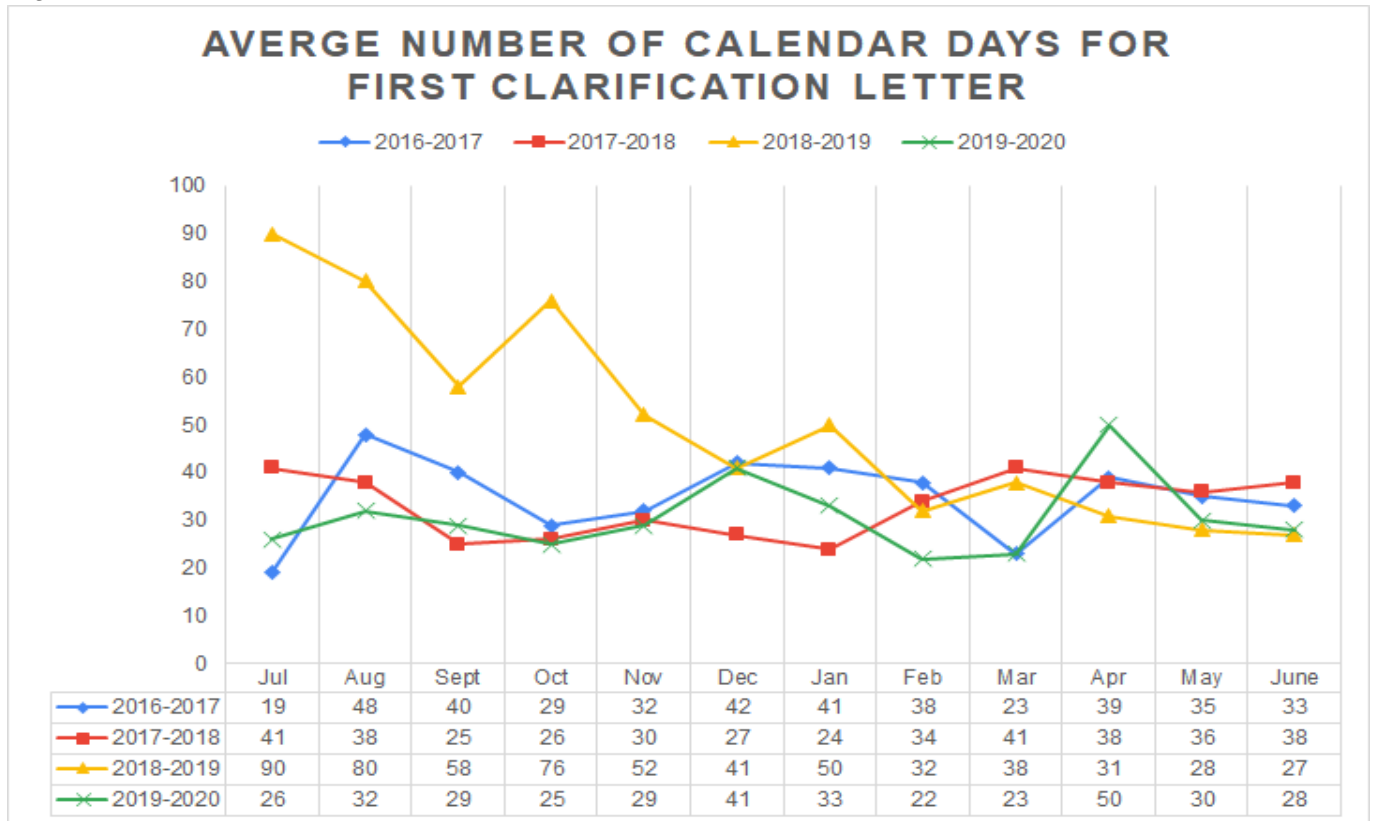
Type of Submissions by Faculty

The FSSH, FHS and FBIT take the top three spots in terms of frequent submitters to the REB for all submission types, which include additional documentation, closures, renewals, change requests and initial applications. Overall, FSSH submitted 37.0% of all submission types to the REB, FHS submitted 29.0% and FBIT submitted 12.1% (see Table 5).

Table 5.

Faculty	Additional Documentation	Administrative Closure	Adverse/ Unanticipated Event	Change Request	Closure	New Approval	Other REB Review	Renewal	TOTAL [n (%)]
FBIT		2		6	6	29		43	**86 (12.1)**
FED	3		1	12	12	19	2	41	**90 (12.6)**
FESNS				1				2	**3 (0.4)**
FEAS				1	1	1		3	**6 (0.8)**
FHS	6	2		35	26	42	3	93	**207 (29.0)**
FSCI	3			2	2	11		19	**37 (5.2)**
FSSH	13	9	2	67	30	49	8	86	**264 (37.0)**
External to OTU		2			6	3		4	**15 (2.1)**
Durham College								2	**2 (0.3)**
OTU Staff		1						2	**3 (0.4)**
Total	**25**	**16**	**3**	**124**	**83**	**154**	**13**	**295**	**713**

REB Timelines: First Clarification Letter

Figure 3.

	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	June
2016-2017	19	48	40	29	32	42	41	38	23	39	35	33
2017-2018	41	38	25	26	30	27	24	34	41	38	36	38
2018-2019	90	80	58	76	52	41	50	32	38	31	28	27
2019-2020	26	32	29	25	29	41	33	22	23	50	30	28

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, as well as timing of submission during peak 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 a 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 for completeness, risk assessments of study procedures and vulnerability of 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.

Note: when a research project requires a full board review, it is typical that added time and added touchpoints will be required which can translate into a longer turnaround time to provide the clarification letter. To mitigate the risk of a higher turnaround time, the Chair or Vice-Chair and researcher will undertake preliminary discussions with the intent to provide advance information on areas of potential clarification.

The REB's turnaround times continue to improve throughout the year as seen in the downward trend in the average number of calendar days for the first clarification letter in Figure 3. During peak submission period from **July to November**, the REB turnaround time for the first clarification letter was **28.2 calendar days**. This is within the promised turnaround time for the first clarification letter. In December, the turnaround time was 41 calendar days which is higher than previous months. The University closure and planned absences contributed to the increase review time.

> During peak submission period from **July to November**, the REB turnaround time for the first clarification letter was **28.2 calendar days**. This is within the promised turnaround time for the first clarification letter.

At the beginning of 2020, the REB experienced an increase in REB applications due to the COVID-19 pandemic. From March to June, the REB received 10 new applications and 12 change requests related to COVID-19 that required immediate attention. Under the REB's Review Procedures and Research Conduct During Publicly Declared Emergencies, the REB prioritized reviews for essential research studies that were directly related to the pandemic because new information may become available and require timely action during emergencies. Due to prioritization of COVID-19 studies, the review turnaround time for a clarification letter averaged 50 calendar days for non-COVID19 related studies from when the application was accepted for review. This is outside of the promised time frame as workload was shifted to focus on the COVID-19 studies.

REB Timelines: Submission to Approval

Table 6

The REB approval time period includes the average number of calendar days the application was under review to the date the application received ethics approval. This timeframe does not include the number of days the application was in the researcher's possession during the clarification response stage.

The REB approval time continues to improve where a downward trend was observed in the average number of calendar days. In 2019-2020, the REB reduced their average approval time by almost half compared to the

Year	Average number of calendar days for REB approval time
2016-2017	71.1
2017-2018	59.75
2018-2019	74.8
2019-2020	43.7

previous year. In 2018-2019, in Table 6 the REB average approval time was approximately 2.5 months (74.8 days) which was exceptionally high due to the limited availability of REB reviewers and the absence of REB leadership in the summer. During this period, REB applications were subject to unprecedentedly long review and approval times due to the lack of resources which created a backlog of submissions.

11. COVID-19 Reviews

The COVID-19 pandemic has altered research conduct significantly and disrupted services within the REB. In March 2020, researchers were faced with converting in-person research into remote methods of recruitment and data collection due to an elevated risk of exposure to the virus and to abide by Public Health and government directives. During the initial stages of the pandemic, many studies were temporarily suspended if recruitment/data collection procedures could not be converted into remote methods.

Under the REB's SOP 213 (REB Review Procedures and Research Conduct During Publicly Declared Emergencies), the REB conducted priority rapid reviews for new studies and change requests directly related to the emergency. The research studies included:
- Frontline workers who have a high risk of exposure to COVID-19, given the nature of their profession, and individuals required to work to provide necessary services to protect the public and allow government mandated distancing and quarantine (e.g. health-care professionals, emergency responders, law enforcement, grocery store workers, environmental service workers, postal/delivery workers).
- Patient care and/or diagnostics.
- Equipment/devices related to personal protective equipment, and patient care/diagnostics.
- Supply-chain management.

In addition, any change requests that affected research participant's safety received priority review. The REB reviewed all other COVID-19-related studies not related to essential research areas after the essential COVID-19-related studies.

From March to June, 2020 the REB received **10 new COVID-19 related** research studies that were reviewed and approved in **10 calendar days**. This is **4 times faster** compared to non-COVID-19 related turnaround times and can mainly be attributed to the 'rapid review' approach which was limited to 1-2 days, maximum.

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As Government and University restrictions began to relax, the REB accepted submissions for research with in-person contact so long as the proper health and safety directives from Public Health and the University were followed and TCPS2's new ethical concerns involving research during a pandemic were addressed in the study.

12. Reconsideration and Access to Information Request

The REB received a reconsideration request for a REB decision on a study. The request was managed according to [REB SOP 212 (Process for Reconsideration or Appeal of Decisions of the REB)](#). In an effort to resolve the disagreement, an external REB with requisite knowledge and experience conducted an external review of the study which Ontario Tech accepted as the review. In addition, the University received its first access request for research records under the Freedom of Information and Protection of Privacy Act, R.S.O. 1990, c. F.31 (FIPPA). The University Access and Privacy Office coordinated the response to this request.

13. Challenges

In early March, the REB went through extraordinary efforts to quickly respond to the government and University directives on the COVID-19 pandemic. On March 16, 2020, the University activities came to a halt where any in-person activities on campus and all in-person research was suspended until further notice. The REB asked researchers to modify or eliminate direct person-to-person contact for ongoing studies into remote means of recruitment and data collection. Studies that did not have direct person-to-person contact were allowed to proceed. The REB developed a modified priority review process to conduct rapid reviews for studies with topics that are necessary and essential to prevent, reduce or mitigate serious harm resulting from the pandemic (e.g. patient care and/or diagnostics; equipment/devices related to personal protective equipment). In addition, the REB created a Frequently Asked Questions document, guidance documents and new SOP to guide researchers during this unprecedented time.

The REB did not experience any set-backs with pivoting to virtual meetings as the REB has offered hybrid meetings (in-person and virtual) for a number of years. The hybrid meeting format provided flexible options for members to engage in the meeting which enhanced membership attendance. However, REB members, being faculty members, experienced an

increased workload with pivoting their courses into online formats. The increased workload had impacts on their service obligations with the REB. Despite the increased workload and added challenges, the REB was able to adapt very quickly to the changes and maintain a high-performance level in fulfilling its core business and mandate.

14. Quality Improvement Efforts

The REB and REB administration introduced several process initiatives to facilitate the review process and provide support to the REB members and researchers.

Application Forms and Processes

On May 1, 2020, the REB launched a revised Application for Ethical Review (V.04) that is available in the IRIS Research Portal. The application was revised to align with current standard practices and regulations related to research involving human participants.

REB Consultations
In-person or remote consultations are available to all researchers and students who need help with their REB submissions. REB consultations include discussions on:
- How to submit to the REB.
- Human ethics advice.
- Interpreting the content of the REB application.
- Applicable legislation.
- Procedures and/or policies.
- Assessing the level of risk for your study and determining which REB application to use.

The REB Chair, Vice-Chair and Research Ethics Officer led 90 in-depth REB consultations with faculty members and students during the fiscal year.   Researchers are encouraged to seek a consultation before applying to the REB as consultations can facilitate and streamline the ethics review and approval process.

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New Board of Record Intake Form

A new Board of Record Intake form was created which must be completed when studies qualify for a Board of Record under SOPs 301 (BOR Review Process with Durham College and Ontario Tech) and 302 (BOR Review Process with Lakeridge Health and Ontario Tech). The Principal Investigator must complete this form when the Ontario Tech research ethics review is deferred to an external Board of Record.

New Pilot Pre-approval

The REB launched a pilot pre-approval process that allowed researchers to seek approval for a standard research procedure that can be applied across similar studies (e.g. in the case of multi-research studies that conduct standard research procedures involving specialized equipment, recruitment of a unique population, and/or standard data collection procedures). Once approved, researchers can append the process to subsequent REB applications. This will eliminate the need to answer the same questions about methods each time a new REB application is submitted.

The application process will require the completion of a pre-approval application and a stand-alone document (e.g. Standard Operating Procedure or protocol) that will describe in detail the standard research practices as outlined in [REB SOP 214 (Pre Approval Review Process)](#).

Mandatory use of Consent Form Template

Effective February 28, 2020, researchers are now required to use the REB's consent form template for future REB submissions for studies where the primary study participants involve the Ontario Tech population. The REB's revised consent form template serves as a guide to assist researchers to develop a consent form that meets the standards set out by the current guidelines, policies, regulations and research ethics best practices. This template can be tailored to fit the design of any study. In cases when simplified consent is necessary, researchers must follow the spirit of the REB's consent form template and the necessary consent form elements as outlined in the TCPS2.

New Consent Form Addendum

A new consent form addendum was created for research projects that required re-consent of study participants enrolled in an ongoing research study. This occurs when changes to the research project may have implications that are germane to their decision to continue research participation, or may be relevant to the particular circumstances of individual participants.

Document on Emerging Ethical Issues Related to Research Conduct During COVID-19

The REB provided researchers with guidance and requirements on how to conduct in-person research during the COVID-19 pandemic. The guidance document outlines the requirements for consent, re-consent and the REB application. In addition, guidance is provided on the new risks related to conducting in-person research during COVID-19, as well as risk mitigation strategies and important considerations.

15. Future Initiatives

The REB's future initiatives include:
- Refinements to the REB application in response to feedback from end users.
- Creation of data management plans in response to Tri-Agency's policy.
- Refinements to the REB's guidance on face-to-face in-person research.
- Explore different Chair and Vice-Chair models where the Vice-Chair would transition into the Chair role to support succession planning.
- Continue with research engagement efforts through consultations that will deliver customized research ethics advice on projects.