

University of Guelph

Research Ethics Boards

ANNUAL REPORT FOR FISCAL YEAR MAY 1, 2017 TO APRIL 30, 2018

Executive Summary

The President has established the University of Guelph Research Ethics Boards (REBs) according to Article 6.2 of the [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans](#) and has enacted the [University Policy on Research Involving Human Participants](#) which states that “all research involving human participants conducted on its premises or by its faculty, students, and other members of the University community, should be carried out in a manner consistent with certain fundamental principles.” In order to implement this policy, the REBs must review and interpret the most recent existing legislation and guidelines such as the [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, \(TCPS\)](#), [Good Clinical Practices: Consolidated Guidelines \(GCP\) E6](#), the [Food and Drug Act](#), and the [Personal Information Protection and Electronic Documents Act \(PIPEDA\)](#), among others. The REBs must keep abreast of developments in the field of ethics research and must respond to the post-audit requirements of the Tri-Council. The REBs must interpret guidelines in consideration of all University policy.

This report covers the period from May 1, 2017 to April 30, 2018.

Research Ethics Boards

The membership of the REB is constituted according to [Article 6.4 of the TCPS2](#). The distribution of members with relevant expertise in research content and methodology is determined by the relative frequency of submission from each College or Department. Thus the College of Social and Applied Human Sciences has three representatives, one from each of three departments – Sociology and Anthropology, Psychology, and Family Relations and Applied Nutrition – as these departments account for a large number of annual submissions.

In addition to regular members, alternate members are appointed who can replace a regular member unable to attend a meeting or unable to perform delegated reviews for a period of time.

Advisors or *ad hoc* members of the REB are appointed for their specific expertise which is required occasionally, but not often enough to warrant including them as a regular member [Article 6.5, TCPS2].

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Research Ethics Boards

Research Ethics Board – General (REB-G)

Meetings of the REB-G were held on the first Wednesday of May, June, July, August, September, October, November, December, January, February, and March with meetings typically lasting 2 to 3 hours. Since there were no submissions to review, the meeting for April was cancelled. [[Article 6.10, TCPS2](#)]

The membership of the REB-G is constituted according to [Article 6.4 of the TCPS2](#).

	College	Representing	Representative(s)	Alternate
Relevant Expertise in Research Content and Methodology	CSAHS	SOAN	Thomas McIlwraith (Assoc. Chair)	Sharada Srinivasan (to January 2018) Carolyn Yule (from February 2018)
		FRAN	John Dwyer (to September 2017) Jess Haines (from September 2017)	Tuuli Kukkonen
		Psychology	Stephen Lewis (Chair) Lana Trick (to November 2017) Deborah Powell (from July 2017) Saba Sadar - DRC	Ben Giguere (to December 2017) Patrick Barclay (from January 2018)
	OAC		John FitzGibbon (to March 2018)	Michael Rogers
	COA		Sally Hickson (to October 2017)	
	CBE		Jagoda Kalinga Elizabeth Kurucz	
Knowledge in Ethics				Karen Houle
Knowledge in the Law			Nathan Martin (to September 2017) Jennifer Trommelen-Jones (from October 2017)	Randy Ragan
Community Member		External	Diane Farr Christine Simpson	
		Graduate Student	Chris Quinn-Nilas	Jessica Boulé (from September 2017)
Advisors		Indigenous	Kimberly Anderson Anita Tucker (from September 2017)	
		Statistics	Julie Horrocks	
		IT Security	Gerrit Bos	
Non-Voting Member		Director, Ethics Office	Sandy Auld	

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Research Ethics Board – Natural, Physical and Engineering Sciences (REB-NPES)

Meetings of the REB-NPES were held on the third Wednesday of May, June, August, September, October, November, January, February, and March with meetings typically lasting 2 to 3 hours. Since there were no submissions to review, the meetings for July and December were cancelled. [\[Article 6.10, TCPS2\]](#)

	College	Representing	Representative	Alternate
Relevant Expertise in Research Content and Methodology	CBS		David Dyck Lori Vallis (Chair)	Leah Bent Phillip Millar John Srbely (Assoc. Chair) Amanda Wright (to January 2018) David Wright John Zettel
	OVC		Glen Pyle	Andy Papadopoulos
	CPES	Engineering	Stefano Gregori	Andrew Hamilton-Wright (from November 2017)
	CPES		Manjusri Misra	Deborah Stacey (to September 2017)
		Alternative Health	Kieran Cooley	
		Medical	Dorothy Bakker (to September 2017) Erin Weersink (from September 2017)	Nicole Petrov
Knowledge in Ethics			Karen Wendling	Andrew Bailey
Knowledge in the Law			Stephanie Sutherland	Randy Ragan
Community Member		External	Janice Kopinak Ron Webb	Robert Clayborne
		Graduate Student	Danyelle Liddle	Anthony Incognito
Advisors		Indigenous	Kimberly Anderson Anita Tucker (from September 2017)	
		Statistics	Julie Horrocks	
		IT Security	Gerrit Bos	
Non-Voting Member		Ethics Office, Director	Sandy Auld	

Comments from the Chairs

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Chair of the REB-General: Stephen Lewis

The following outlines the nature of work engaged in by the REB-General over the past year. Commensurate with its primary role, the REB-General continued its efforts in careful and rigorous review of research proposals involving human participants. Such efforts are essential to ensuring that research protocols conform to the standards articulated by TCPS2 and the safety and wellbeing of participants. In keeping with efforts to streamline the review process and the process undertaken by researchers to complete REB-related forms, the REB-General (in conjunction with the work of the Director and NPES-REB) revised and disseminated new forms for use by researchers at the university. These are housed online, via the REB portion of UoG's Research website. Indeed, this section of the website was updated and reorganized to offer researchers a series of new resources to guide their completion of REB protocols. Coupled with this, a series of updated Frequently Asked Questions as well as Standard Operating Procedures were developed and posted on the REB portion of UoG's Research website. Additional resources were developed and shared on the website to address various questions that may emerge for researchers (e.g., a corpus of mental health resources for student participants). Finally, the REB has continued improving its educational outreach through a regular dialogue series as well as continued communication between the REB and researchers.

Chair of the REB-Natural, Physical, and Engineering Sciences: Lori Vallis

Dr. Vallis commenced the Chair position of the NPES-REB board in May 2016. At that time the University was getting ready to launch a new online submission process, Research Link. Information and training sessions were conducted and the launch of the new system occurred in December 2016. Within the first 6-8 months it was clear that the new system was ineffective. Unfortunately, the failure of this platform resulted in considerable resources needing to be devoted to transferring ongoing REB protocols back to the 'old' review and submission process; this was complete approximately 1 year following the original launch of Research Link.

Recently efforts have been devoted to projects with the aim of improving/updating information critical for researchers in their NPES-REB application submissions. This has included the improving communication with researchers via a new website design and user interface. For example, links to Frequently Asked Questions (FAQs) are now

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prominent on the website. Information contained in these links have been reviewed, revised and rewritten, if required and are now readily available to researchers and trainees. Similarly, links to templates and information regarding how to structure participant Information and Consent forms have been posted in addition to NPES-REB approved Standard Operating Procedures (SOPs). The regarding the latter, each posted SOP has been reviewed, revised and brought the NPES-REB board for discussion and approval over the course of this redesign phase.

Future projects and initiatives for the NPES-REB board include streamlining the review of experimental protocols involving participants in course based research endeavours. There has been some success in this avenue; the Ethics Office worked with the appropriate faculty/administrators in the Engineering Department and recently (Summer 2018) a submission for course based research related to the Engineering 4x project courses was submitted for NPES-REB review. Another project we hope to devote time and effort to is the transfer of compliance or non-compliance issues (e.g. not submitting Annual Renewal forms) into the mandate of the Research Integrity group within the Office of Research; the Research Integrity group are better positioned to deal with these issues, e.g. punitive responses if required. This move would free up staff/administrative time and resources and would allow for efforts to be focused on not only the REB application review process, but also would permit more time to work with researchers and trainees on complex REB application submissions that may require liaison with Contracts, International Development groups within the Office of Research (e.g. Clinical trials; industry sponsored research). This would facilitate new research initiatives and position the University of Guelph for optimizing collaborative efforts with research teams across campus, across Ontario, across Canada and Internationally.

Policy and Planning Committee

An overarching committee coordinates the two REBs. Called the Policy and Planning Committee, its membership consists of the Chair of the REB-G, the Chair of the REB-NPES, and the Director of Research Ethics. This committee has the following mandate:

- To develop University policy governing research involving human participants
- To develop guidelines governing the interpretation and implementation of the TCPS2
- To develop procedures to ensure the efficient review of research involving human participants
- To write an annual report to be submitted to the President, detailing the activities of both REBs

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- To discuss current issues and determine a coordinated response
- To plan educational outreach for the University community
- To plan educational opportunities for REB members and administrative staff

The committee meets at least once each semester. The Director, Research Ethics serves as the secretary to this committee, and the minutes of the meetings are made available to the Managing Director, Research Services.

The committee met in July of 2015.

Distribution of Protocols by Department or School

The following table outlines the distribution of submissions by College and by Department over the last 10 years. Data are not available for the 2016/17 academic year.

College	Department or School										
		07/08	08/09	09/10	10/11	11/12	12/13	13/14	14/15	15/16	17/18
COA	History	8	5	5	6	12	4	7	5	9	8
	Philosophy	3	0	1	1	2	1	0	0	0	0
	SETS	15	4	6	9	9	4	1	3	4	10
	SOFAM	6	1	6	0	5	6	2	1	4	1
	SOLAL	1	2	0	2	0	1	5	3	3	2
CBE	Management	2	7	12	16	13	24	18	13	16	29
	Economics and Finance	2	0	2	6	1	1	1	0	2	0
	MCS	27	17	17	30	28	26	29	27	13	22
	HTM	13	22	8	14	12	8	21	8	15	23
	Executive Programs	2	2	1	0	0	0	0	0	0	0
	Dean's Office	0	0	0	1	0	0	0	0	0	0
CSAHS	FRAN	51	20	33	57	43	40	43	37	27	58
	Geography	15	7	7	6	12	18	16	12	18	19
	Psychology	85	79	73	85	114	103	93	83	85	85
	Political Science	11	13	19	8	15	20	9	9	21	21

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	Sociology & Anthropology	28	24	24	38	28	27	27	28	16	32
OAC	Dean's Office	0	0	0	0	0	0	0	1	0	0
	Collège d'Alfred	0	0	0	0	0	0	3	1	0	0
	Kemptville College	3	1	0	1	1	0	1	2	0	0
	Ridgetown College	0	0	0	1	0	0	0	0	0	1
	Botany	0	0	0	0	0	0	0	1	0	0
	FARE	15	9	13	5	4	8	8	5	4	7
	Animal Biosciences (previously Animal & Poultry Science)	4	3	3	4	5	3	4	1	7	9
	Food Science	2	4	8	10	9	19	14	11	11	16
	Land Resource Science	0	1	0	0	0	0	0	0	0	0
	Plant Agriculture	0	1	1	1	1	3	1	4	1	2
	SEDRD	30	21	25	32	31	34	35	27	27	26
	Environmental Sciences	0	1	0	2	0	1	2	5	1	2
OVC	Dean's Office	0	0	1	0	1	2	2	0	4	1
	Biomedical Sciences	0	3	8	6	6	2	4	3	5	0
	Clinical Studies	6	4	4	2	4	4	3	4	7	12
	Pathobiology	2	0	2	7	1	3	3	5	4	7
	Population Medicine	10	11	22	33	33	25	36	51	29	32
	Equine Guelph						2	1	0	1	0
CBS	Integrative Biology	1	2	3	4	3	1	3	2	2	1
	MCB	0	3	4	3	2	1	2	2	3	10
	HHNS	28	29	18	37	34	31	36	42	46	57
	Zoology	0	0	0	0	2	2	0	0	0	1
	Chemistry	0	1	0	1	3	2	0	0	1	1
CPES	CIS	8	14	9	10	0	7	6	4	4	2
	Mathematics & Statistics	1	0	1	2	1	5	1	1	3	5
	Physics	0	0	0	0	1	0	0	1	0	3
	Engineering	18	8	9	11	5	11	15	11	15	18
Other	Centre for Toxicology	1	0	0	1	0	0	0	0	0	0
	Centre for Public Health and Zoonoses	n/a	2	1	3	1	1	2	1	1	1
	External Organizations	16	12	8	0	0	1	0	0	1	0
	Library	3	2	10	6	8	4	2	1	4	4
	Guelph-Humber	2	3	1	0	2	1	4	6	3	2
	Office of Registrarial Services						1	0	1	0	0

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	Open Learning and Educational Support	0	1	0	0	1	2	2	3	7	4
	Centre for Families Work and Well-Being	2	0	2	5	0	0	0	0	0	0
	Student Health Services	n/a	1	0	0	0	1	2	1	1	1
	Student Life	0	0	0	0	0	1	4	1	1	0
	Student Housing Services	0	0	0	0	0	0	0	0	2	0
	Career Services	0	0	0	0	0	0	0	0	1	0
	Health & Performance Centre	0	0	0	1	0	0	0	0	0	1
	Community Engaged Scholarship Institute	n/a	n/a	n/a	1	3	2	5	4	1	5
	Office of Research	3	1	0	0	1	2	2	0	0	1
	Lab Services – Research Coordination								1	0	0
	Centre for International Programs								1	0	0
	Institutional Analysis and Research										2
	Staff	2	0	0	1	2	0	0	0	0	0
TOTALS		426	341	367	469	459	465	475	442	430	544

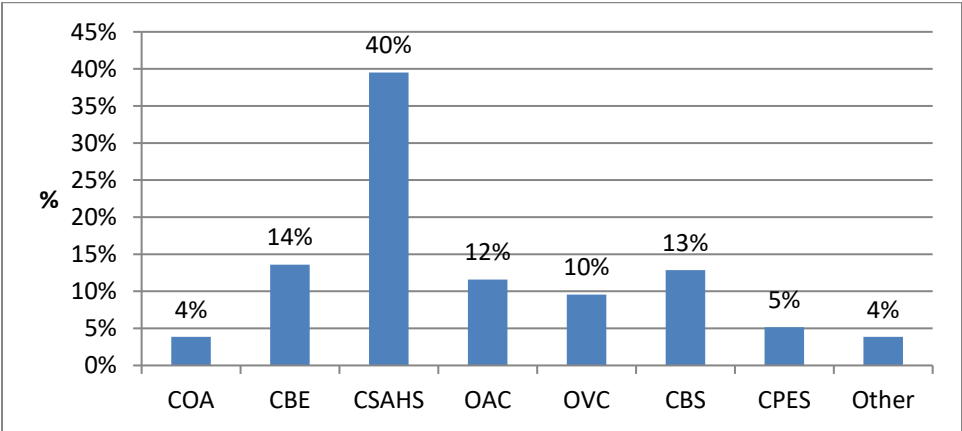
Distribution of Protocols across College by number of submissions

College	College Totals									
	07/08	08/09	09/10	10/11	11/12	12/13	13/14	14/15	15/16	17/18
COA	33	12	18	18	28	16	15	12	20	21
CBE	46	48	40	66	54	59	70	48	46	74
CSAHS	190	143	156	186	212	208	188	169	167	215
OAC	54	40	50	54	51	67	66	58	51	63
OVC	18	18	37	48	45	38	49	63	50	52
CBS	29	34	25	42	41	35	41	53	52	70
CPES	27	24	19	26	10	26	24	17	22	28

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Other	29	22	32	19	18	16	23	22	22	21
TOTALS	426	341	377	469	459	465	475	442	430	544

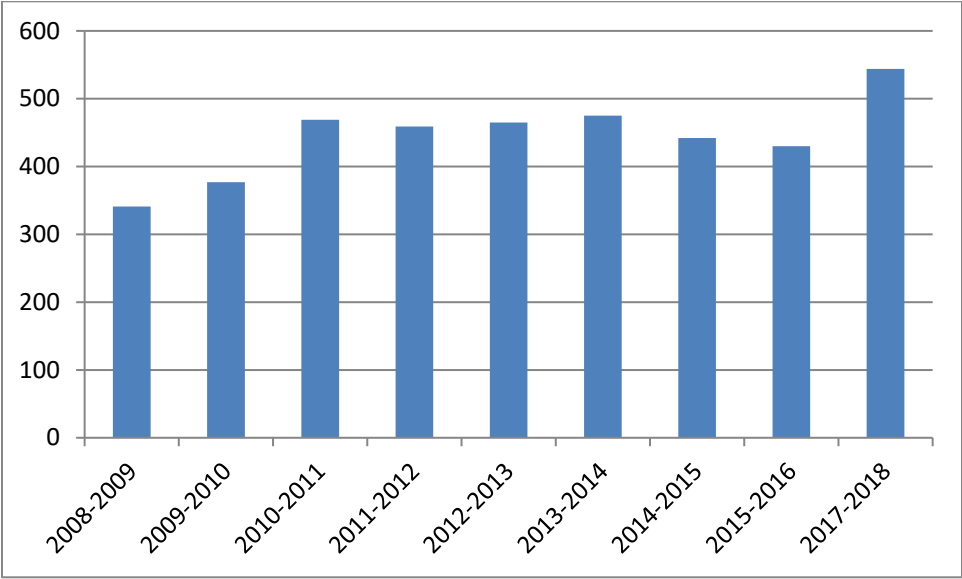
Distribution of Protocols across College by percentage



Total number of protocols submitted by year

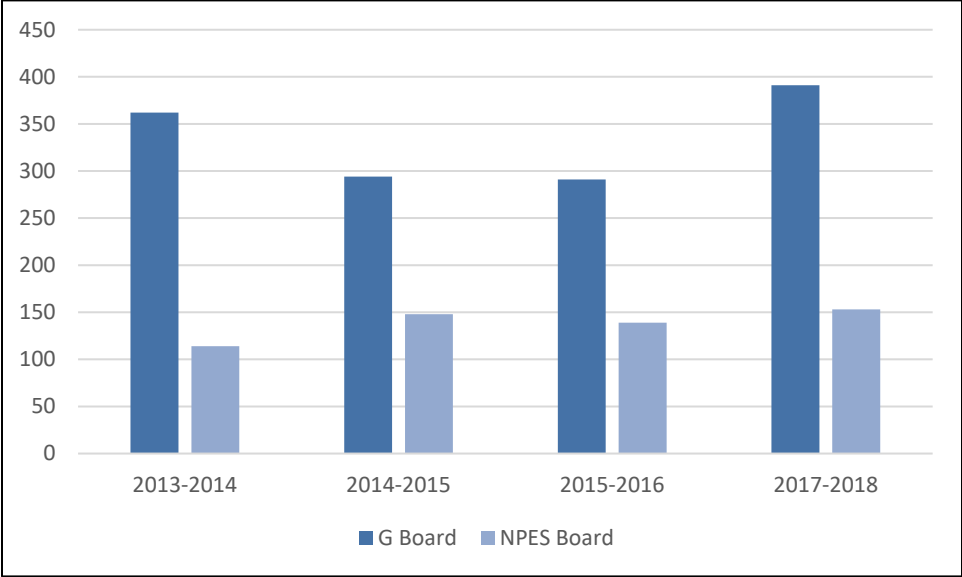
In total, 544 protocols were submitted for review in the year 2017-2018, up from 430 protocols submitted in 2015-2016, which represents a 26.5% increase. The numbers represent a nearly 60% increase over a 10 year period.

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Total number of protocols submitted by board

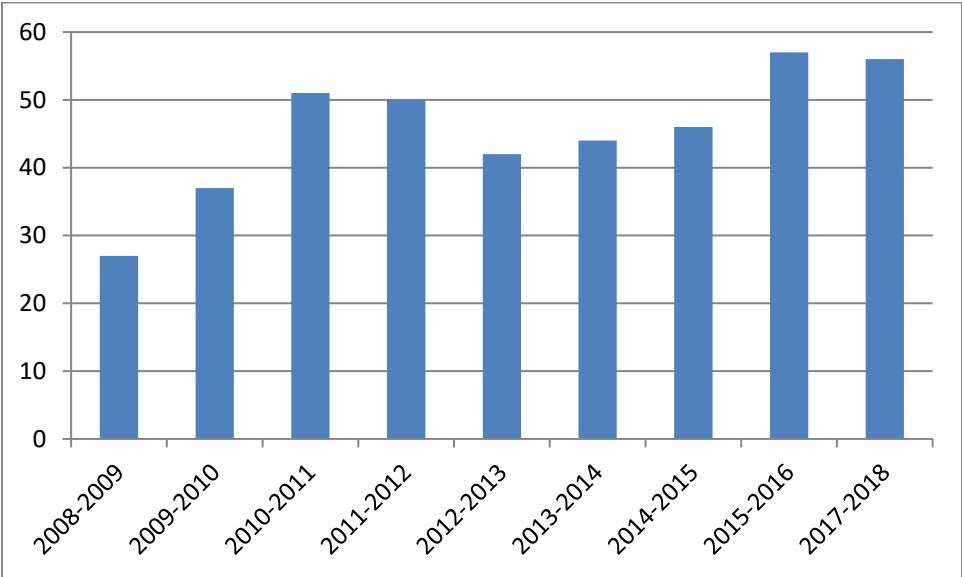
Of the protocols submitted, 391 were to the REB-G board and 153 were to the REB-NPES board.



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Total Full Board Reviews by Year

Fifty-six (56) of the protocols reviewed (10%) were brought to the full board for consideration (21 REB-G protocols and 35 REB-NPES protocols). This number is consistent with peer institutions with a strong social science emphasis.



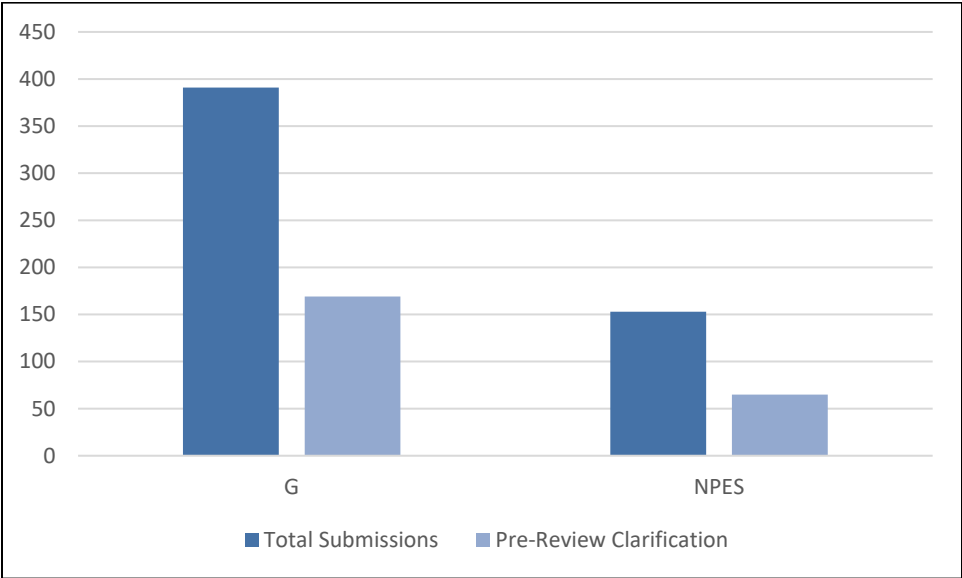
Twenty-eight (28) protocols were withdrawn from the process and two (2) were declined. Protocols would be declined or withdrawn when the research activities were not deemed to be covered by the TCPS2, the researcher decided not to proceed, or there was no response from the researcher within 3 months of receiving the feedback from the REB (researchers are notified prior to closure).

Pre-Review Clarification

Ethics office staff review submissions for documents requiring clarification prior to sending them to REB for review. This process helps ensure a clear and complete package will be provided to REB reviewers, and speeds the review process. This step was added to the ethics review process in late 2016. Of 391 protocols which were

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submitted to the REB-G, 169 under went pre-review clarification (43%). Of the 153 which were submitted to the REB-NPES, 65 under went pre-review clarification (42%).

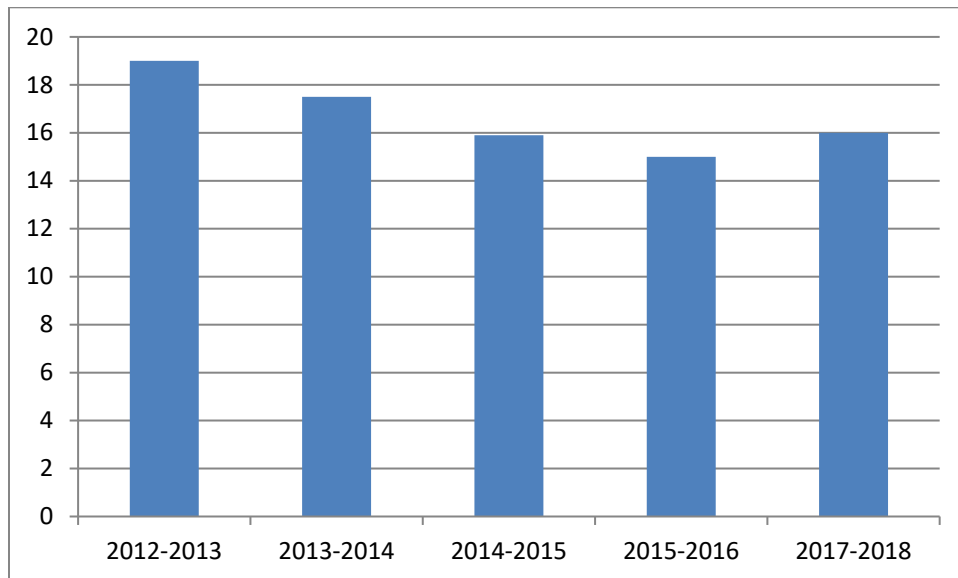


Days between submission and official response

For projects eligible for delegated review, the REB strives to ensure an initial response back to the researcher 14 days after submission. For those projects which require pre-review for clarification, this would be 15 days after the finalized submission is provided to the ethics office.

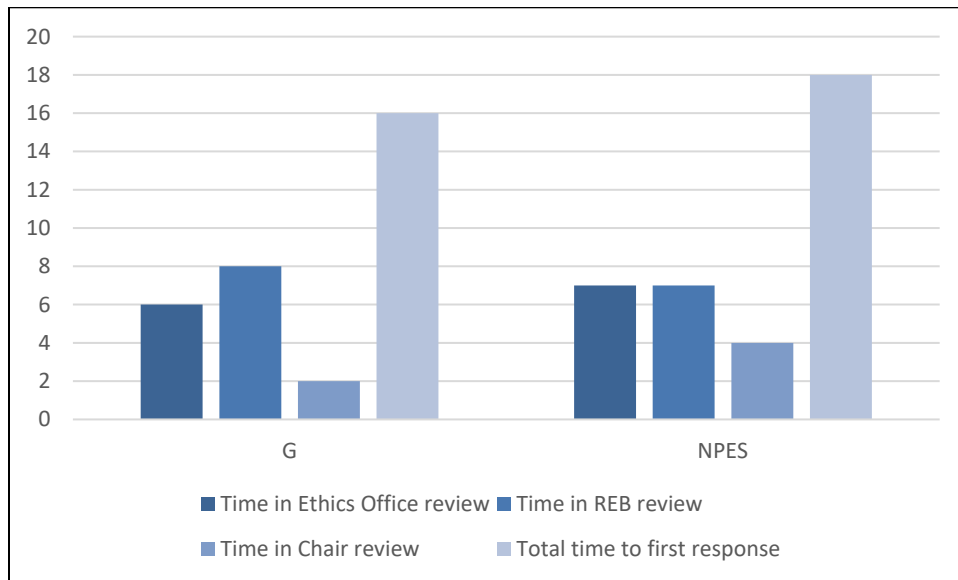
In this fiscal year, the average time between submission and official response was 16 days. This represents a slight increase in review time since the last fiscal period, which can be attributed to the ResearchLink shutdown. Removing data from protocols submitted during the ResearchLink shutdown period lowers the response rate to 15 days, consistent with the 2015-2016 period.

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Once the application has been submitted and undergoes pre-review clarification, if applicable, it is sent to one of the two boards for REB review. Feedback from the REB review is approved by the REB Chairs and an official response (feedback) from the REB is sent to the Principal Investigator.

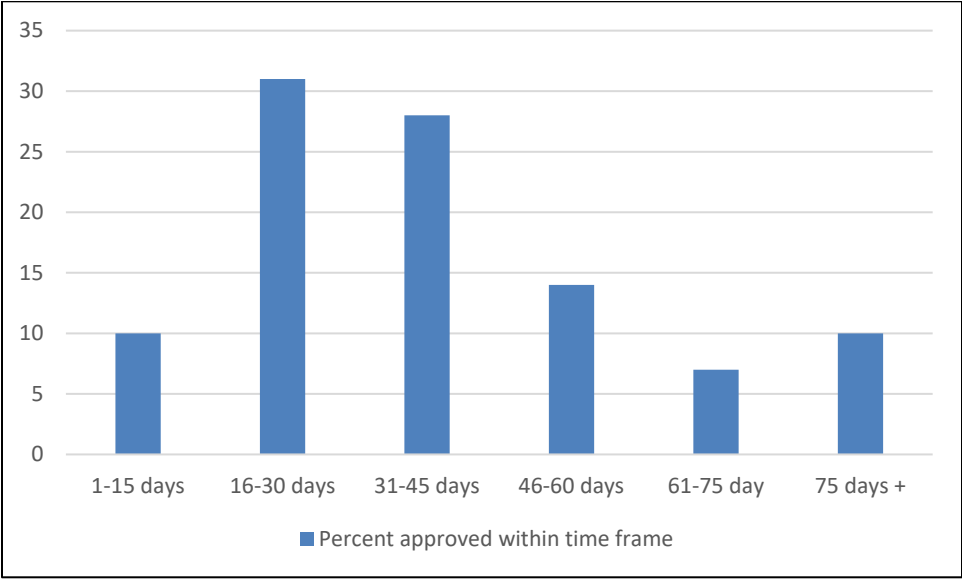
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Time between submission and approval - by percentage

Once the research team has been sent an official response, they are invited to submit modifications. The process of reviewing modifications to arrive at an acceptable application may involve a number of rounds of communication between the Ethics Office, the REB, and the research team. Once all of the REB concerns have been addressed an approval certificate is issued. The following chart indicates the number of protocols - by percentage - which are cleared in a specified number of days. Seventy percent (70%) of submissions are approved within 45 days. Only ten percent (10%) of submissions take over 75 days to receive approval.

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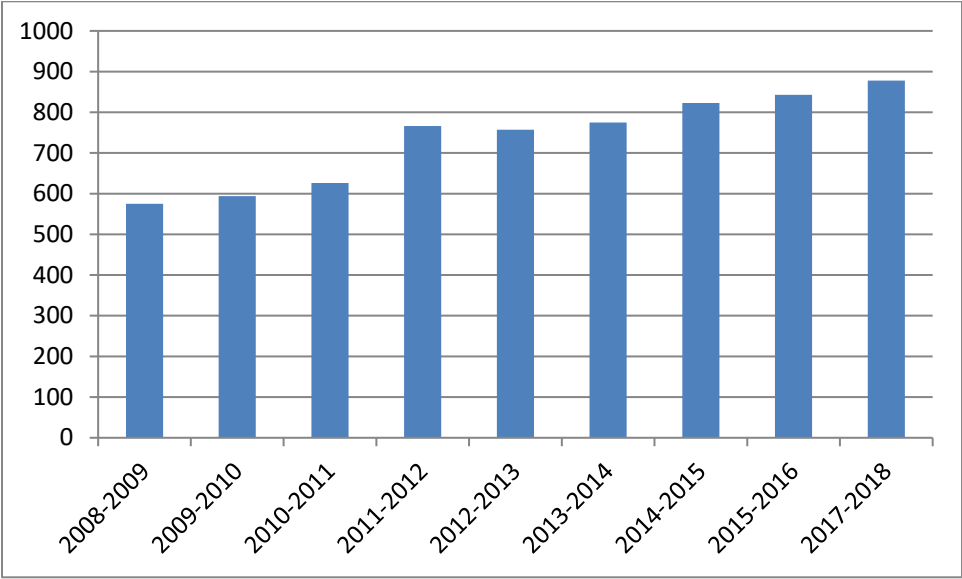
Total Active Files by Year

Active applications for which work is still in progress are retained for up to five years after which a new submission must be made. Annual Renewal forms are required for each file in order to remain compliant with the minimum requirement for continuing ethics review under the TCPS2 [Article 6.14]. The number of active files is arrived at by adding the number of new submissions to the number of renewals within the calendar year.

The number of active protocols as of April 30, 2018 was 878 representing a 52% increase over a 9 year period. A protocol is deemed inactive once the researcher is no longer interacting with human participants and an Annual Renewal form is received from the Principal Investigator closing the file.

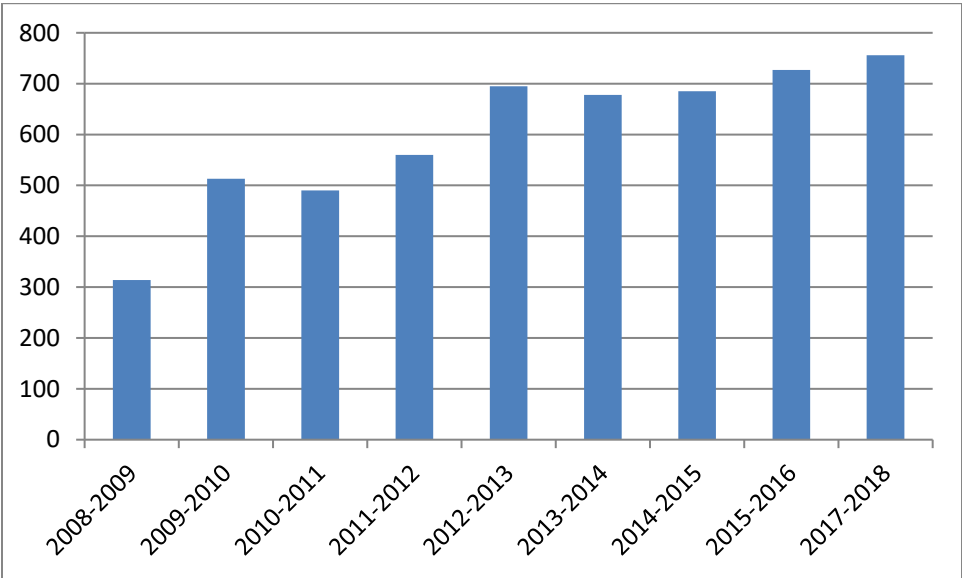
The increasing numbers of active files and annual reports represents an increase in administrative demand on the Ethics Office.

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Number of Annual Renewals

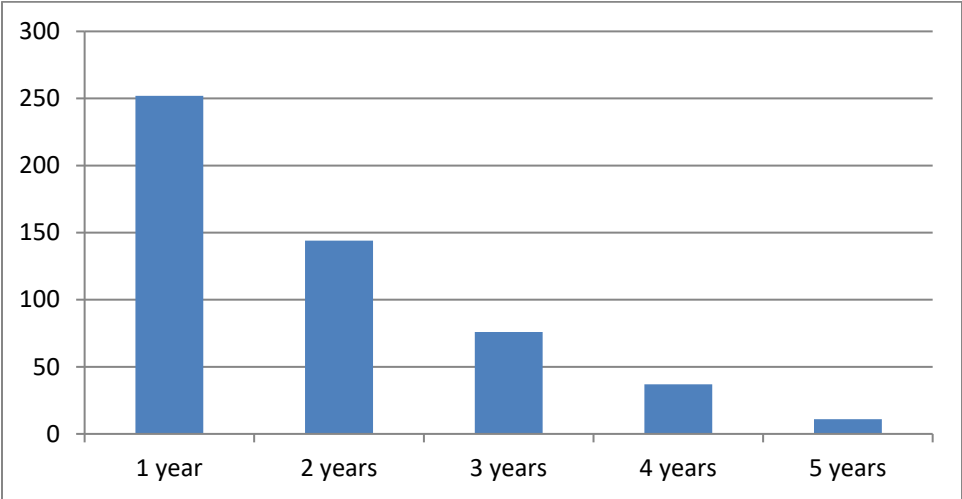
Of the 756 annual renewal forms that were received in 2017-2018, 236 protocols were closed and 520 protocols were renewed for an additional year



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Number of Protocols Renewed by Year

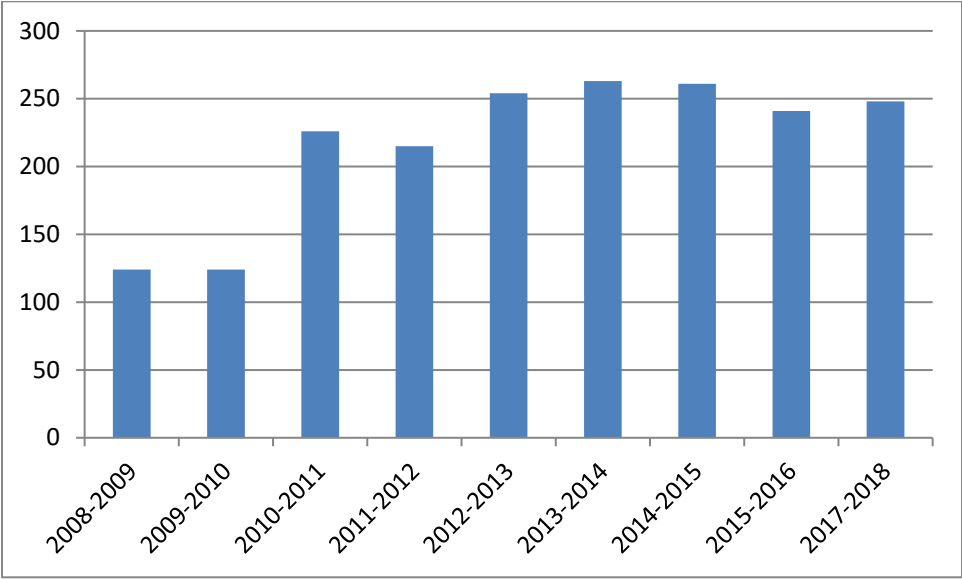
Protocols may be renewed up to five years. In 2017-2018 over 76% of renewals were for protocols which were renewed for an additional year or two. Only 2% of all protocols reached the 5 year renewal limit. If research is continuing beyond 5 years, researchers are invited to submit a new ethics application.



Number of amendment requests

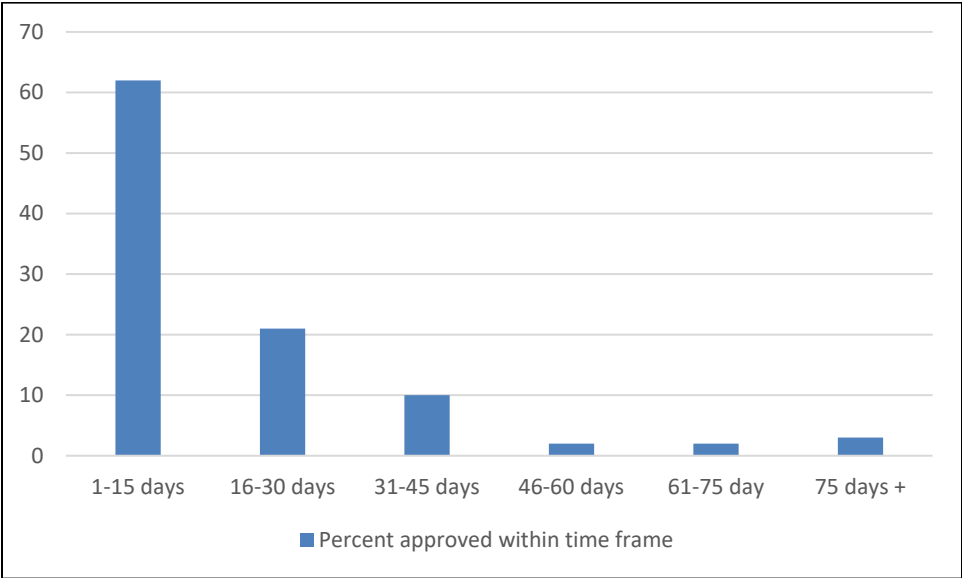
Once an application has been approved, any change to the protocol must be reported by the research team as an amendment request. Amendments can be simple, requiring only administrative review, or complex, requiring full board review of the application. In 2017-2018, there were 248 requests for approval of amendments. Of these amendment requests, 178 were submitted to the REB-G and 70 were submitted to the REB-NPES. Four protocols were reviewed at full board, all at the REB-G.

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Days between submission and approval of amendments - by percentage

The REB attempts to address requests for amendments within two weeks. The graph below shows that 62% of change requests are approved within 15 days.



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Compliance Reports

A compliance report is created by the Ethics Office whenever there is information received of a possible breach of the ethics protocol or policy. Wherever possible, the REB deals with the situation through an educational approach up to and including a letter to the Principal Investigator and, if appropriate, the student researcher involved. For compliance issues which require a further response, the issue is brought to the attention of the VP Research via the Managing Director, Research Services.

Numbers of compliance reports are unavailable for this time period.

Event Reports

Event reports are filed either by a researcher or by the ethics office whenever there is a report of some unexpected happening during the course of research which should be brought to the attention of the REB.

- Data on Event reports are unavailable at this time.

Guidelines and Procedures

- The Director continued the process of using a new common template which is [Accessibility for Ontarians with Disabilities Act](#) (AODA) compliant, to generate, redraft, and update all guidelines. Some will become Standard of Practice (SOP) documents and some will become Frequently Asked Questions (FAQs) which will be displayed on the Research Ethics website. The new SOPs will include a full suite of administrative SOPs. To date there are thirty-two FAQs in draft waiting to be edited and uploaded to the website. Close to One hundred (100) SOPs have been generated including forty-one (41) administrative SOPs, thirty-four (34) SOPs dealing with the running of the REB, and (27) SOPs outlining methods used by researchers. To date 23 have proceeded through the approval process and been uploaded to the website.
- The ethics website revision continues. The coming year will see the uploading of the new FAQs once the format is established through collaboration with the IT team in the OVPR. As soon as information is uploaded in the new format, the current listing of Guidelines will be removed.

ResearchLink

The University of Guelph implemented a research administration and information management system with the Human Ethics process being the first module to be built and launched. This system, known as ResearchLink was an attempt to automate and

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integrate research administration across the University. The ethics application process moved entirely online with a new branching, logic-based smart form instead of the current Word form in December of 2016. The goal was to enable the Research Ethics Office to provide better online help, easier storage and retrieval of research protocols, and better tracking of researchers' human ethics submissions and all accompanying documents.

The process of building this system is required a great deal of time from the Director, Research Ethics. In 2015-2016 there were 104 scheduled ResearchLink meetings including seven full days of onsite visits. These meetings only account for a small portion of the substantial workload that the development and implementation of ResearchLink has placed on the Office of Research and in particular the Director of Ethics.

In July 2017, the decision was taken to suspend the ResearchLink program and a few weeks later, the decision was taken that there would be no attempt to reactive the program. The ResearchLink platform launched in December 2016 was shut down.

During July 2017, the Director, Research Ethics downloaded all of the protocols from the ResearchLink system and rebuilt the tracking system as previously used by the ethics office. During August of 2017, communications went out to researchers who had an application in the process of review, and the process continued again, now outside the electronic system.

It took until January 2018 to download all of the data from ResearchLink and fully populate the Excel spreadsheets.

From December 2016 to January 2018 no reports could be run to determine annual renewal requirements and clearance of the backlog in requests took until June 2018. Since no report could be run from the system, no attempt was made to report delegated reviews, amendments, or annual renewals to the REB during this period of time.

Educational outreach

To REB Members:

Developing an active educational component is one of the key mandates of the REB according to the TCPS2. The discussion following Article 1.2 states that "Institutions should ensure that all REB members receive appropriate education and training in ethics review of research involving humans, to enable them to fulfil their duties. This includes providing training opportunities for all members in core principles and understanding of

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this Policy, basic ethics standards, applicable institutional policies, and legal or regulatory requirements. It includes an understanding of the role and mandate of REBs and responsibilities of REB members. Training should be tailored to the types and complexities of the research the REB reviews. This training should be offered both upon the appointment of new members, and periodically throughout a member's tenure."

The Director, Research Ethics engages each new REB member in a one-hour orientation meeting before they begin their tenure on the REB. All REB members are required to complete the [CORE Tutorial](#), and the Director continues to provide feedback regarding reviews, and answer questions. Alternate members are encouraged to attend meetings to develop an understanding of the ethics process.

This year saw the launch of the new [CITI courses](#). Courses offered free of charge to the University community include:

Course name	Certificate Expiry Date(years)	Purpose
Drugs for Clinical Trials Involving Human Subjects	5	Clinical Trials involving controlled substances.
Good Clinical Practice (GCP) (Basic)	3	Clinical Trials; Required by some research sponsors.
Good Clinical Practice (GCP) (Refresher)	3 Basic is required again after 2 Refresher courses	Clinical Trials; Required by some research sponsors.
Human Subjects Research (HSR) - Biomedical	5	Required for students to submit either CITI training or CORE training . Highly recommended for faculty submitting a Human Ethics Application.
Human Subjects Research (HSR) -	5	Required for students to submit either CITI training or CORE training .

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Social and Behavioural		Highly recommended for faculty submitting a Human Ethics Application.
Privacy (Information Privacy and Security)	5	Recommended for researchers submitting a Human Ethics Application.
Responsible Conduct of Research (RCR) - Life Science	No Expiry	Highly recommended for University of Guelph faculty, students and staff conducting research in life sciences. Suitable for inclusion into research methods course.
Responsible Conduct of Research (RCR) - Physical Science	No Expiry	Highly recommended for University of Guelph faculty, students and staff conducting research in physical sciences. Suitable for inclusion into research methods course.
Transportation of Dangerous Goods/International Air Transport Association (TDG/IATA)	2	Focuses on biohazard specific issues complementing training from the University of Guelph Environmental Health and Safety Office . Required for those shipping, transporting or receiving dangerous goods.

Students who must submit a training certificate now have the option of completing Human Subjects Research (HSR) - Biomedical and Privacy (Information Privacy and Security) OR Human Subjects Research (HSR) - Social and Behavioural and Privacy (Information Privacy and Security) in place of the CORE certificate.

In the past there have been requests for free access to Good Clinical Practice (GCP) (Basic) including the Refresher course, and these are now available to faculty and students who need to fulfill the requirements of Health Canada.

In the past, REB members were encouraged to attend meetings – both regional and national – of the [Canadian Association of Research Ethics Boards](#) and they were attended by the Director and staff of the Ethics Office. Due to reduced funding capabilities, attendance must now be limited to one administrative and one REB member attending each of the two conferences. Attending these meetings is essential

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to maintain current knowledge of the research ethics community. Members of the REB should be encouraged to take advantage of these educational opportunities, and funding should be provided for them to do so. Offering educational opportunities to REB members serves to enrich the expertise they bring to application review; promoting discussions within the university community provides a forum for researchers to express concerns and viewpoints regarding the review process.

To Researchers:

Positive educational outreach often dispels myths about the ethics review process and clarifies reporting, the relative roles of the University, granting agencies and government, as well as outlining the guidelines and legislation which form the basis of the REB's policy.

A proposal to make the CORE tutorial mandatory for all faculty, staff, and students who submit an ethics application for review was put forward to the VP Research by the Director, Research Ethics with the support of, and at the direction of, both REBs. A full educational proposal was submitted. While the VP Research declined to make the CORE tutorial mandatory for all researchers at this time, it will become mandatory for students named on ethics submissions.

The Director, Research Ethics continues to support a move by University of Guelph to Collaborative Institutional Training Initiative (CITI) <https://www.citiprogram.org/> and access their training modules. There is more Canadian content in this initiative all the time – with in depth training in Good Clinical Practice, Human Subjects Research - Biomedical, Human Subjects Research - Social and Behavioural Focus, Responsible Conduct of Research, Transportation of Dangerous Goods/ International Air Transport Association (TDG/IATA), Health Canada Division 5. Also offered are Animal Care and Use, Biosafety and Biosecurity, Clinical Research Coordinator, Conflicts of Interest, Disaster Planning for Research Enterprise, Essentials of Research Administration, Good Laboratory Practice, Healthcare Ethics Committees, Information Privacy and Security, and IRB Administration.

Also available to CITI members are a full set of SOPs which cover a wide ranging number of topics, and access to professional mentorship. Funding was denied for this project.

The past year saw the continuation of an educational outreach to students and researchers by the Director, Research Ethics, on behalf of the REB. The Director plans to continue to offer presentations prepared for new audiences as well as continuing to

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presentation to department meetings, graduate methods courses, and undergraduate classes.

- Class presentations for graduate and undergraduate students help instructors manage class projects where students will be involving human participants in research activities. The number of class project forms submitted to cover course-based research involving humans has been slowly increasing. The Director will encourage faculty members to discuss projects they would like to encourage in their classrooms to see if they fall under the ethics guidelines, and how best to obtain approval in advance.
- Presentations in graduate research methodology classes on the process of obtaining ethics approval simplifies and speeds the process when they begin their graduate research projects and will be useful in their future careers.
- Workshops will be offered to new faculty at orientation programs. The ethics review process at the University of Guelph may differ from the process new faculty members learned at other universities – particularly if they come from a country other than Canada.
- The Director has attended department meetings to give a brief update on the application process and to obtain feedback from researchers regarding this process. Since ethics is a continuous dialogue, it is essential that the educational process function in both directions—from and to the REB. This service will continue to be offered since it was found to greatly improve communications between the Ethics Office and departments on campus—giving faculty the opportunity to state what works and what does not, and giving the Director the opportunity to clear up any misconceptions and learn how best to proceed in policy development.
- The Director continued to meet with faculty to discuss special interests, such as:
 - Bio/data banks
 - Research in the Executive Programs
 - SONA participant pool systems
 - Case based research
 - Quality assurance projects

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- Data security
 - Long term data storage
 - Stem cell research
 - Clinical trials
 - Microbiome research
- The Director provides a Brown Bag lunch drop-in weekly – enabling students and faculty to drop by and discuss a new project or get help with an application.
 - The Director, Research Ethics, encourages staff, faculty, and students to complete the CORE tutorial. Perhaps most importantly and more difficult to quantify, are the face-to-face or telephone meetings to discuss the ethical implications of research plans and opportunities, and to provide guidance to graduate and undergraduate students.

Listed in the table below are the individually scheduled outreach opportunities and formal presentations. Tracking of individual meetings is far from accurate and is likely much higher.

Training and education opportunities and corresponding participants

	2009-2010	2010-2011	2011-2012	2012-2013	2013-2014	2014-2015	2015-2016	2017-2018
Presentations	27	18	16	10	33	27	30	24
Number of participants	543	402	180	289	805	512	718	unknown
Individual Meetings	48	80	69	74	77	63	113	45
CORE Tutorial completion	N/A	N/A	488	441	545	716	951	1830

Educational Opportunities

Areas for further education of the university community might include:

- ResearchLink

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- interdisciplinary differences in interpretation of ethical guidelines
- qualitative versus quantitative research
- variations on informed consent
- randomized controlled trials/clinical trials
- internet research
- privacy legislation
- data security and storage

The Director, Research Ethics hopes to begin a Speaker's Series to engage University of Guelph speakers on these topics, or to bring experts from outside the community to discuss issues such as these.

The Director, Research Ethics participates in a local networking group of research ethics administrators from institutions which share the same focus as the University of Guelph. This has been very helpful in allowing the Ethics Office administrators to remain current and consistent with other institutions. The group currently meets annually, but there is active telephone communication and sharing of ideas within the group.

Goals of the REB

The goals of the REB in the coming year are to continue to explore the Canadian and international ethics communities, learning about existing and new legislation and guidelines to better serve our researchers and research participants. To this end, the Chairs have identified several areas that deserve more attention:

- Restore the data from the online system to the Excel tracking system used before ResearchLink
- The Director will continue to work towards reducing the turnaround time of ethics review while ensuring the quality of the reviews for projects which are increasing in complexity.
- The Director will continue to ensure that appropriate REB approvals are in place prior to the release of Tri-Council funds on a yearly basis.
- Increased educational outreach is essential to maintain lines of communication between the REB and the researchers. It is important that, as the administrative

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demand on the Director's time increases, the need for educational outreach and increased communication remain a priority. Much of the discord which arises in response to the ethics policies and requirements could be avoided by open and healthy lines of communication.

- Continue work on the project to establish the relevance of [Regulated Health Professions Act](#) for University of Guelph researchers, and if it is determined that it is applicable, to develop a roll out of compliance which will ensure smooth continuity for researchers and instructors.
- Continue work on the project to establish a central review committee at the University which can review quality assurance projects which do not fall under the scope of the TCPS2, regulate access to student personal information, and control access to the staff, students, and faculty of Guelph by researchers from outside the institution.
- Enhance the information available to researchers regarding how to draft consent forms and improve the review of consent forms to ensure that they are readable and convey the information required for informed consent as outlined in the TCPS2
- Develop a template for confidentiality agreements between research teams and research assistants, interpreters, translators, etc.
- Develop a template for media release agreements to be used when researchers collected photographs of humans for the purposes of research and publication.
- Continue to work with IT Security to ensure that the latest tools and information are provided to research teams to protect participant research data.
- Work with Psychology and Marketing and Consumer Studies to ensure that SONA software SOP is implemented.
- Continue to work towards AODA compliance on the Research Ethics website
- Continue to create a set of administrative SOPs and update all guidelines and SOPs using the new template. Establish an annual review schedule.
- Establish a REB evaluation tool to determine efficiency and effectiveness of the REB.

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- The Director, Research Ethics hopes to begin a Speaker's Series to engage University of Guelph speakers or to bring experts from outside the community, to discuss topics of general interest.

Conclusions

This report has summarized the work by the REBs and the Ethics Office during 2017-2018 fiscal year, and the goals for the coming year.

Thank you for your consideration of this report.