

Ethics Matters @ Waterloo

An information bulletin published by the Human Research,
Clinical Research, and Animal Care Committees

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Second edition of Ethics Matters @ Waterloo

It is our pleasure to once again present the Ethics Matters @ Waterloo newsletter. Please share this newsletter with members of your research team. We appreciate your feedback. Comments or suggestions can be sent to ohrac@uwaterloo.ca. Visit our [archived newsletters](#).

A message from the Research Ethics Committees

Changes to key personnel during the last year include:

- Dr. Richard Eibach has been appointed as the Vice-Chair of the Human Research Ethics Committee (HREC) with Dr. Jonathan Fugelsang as Chair.
- Dr. Richard Staines has been appointed as the Vice-Chair of the Clinical Research Ethics Committee (CREC) with Dr. Andrea Edginton as Chair.
- Dr. Brian Dixon has been appointed as Chair of the Animal Care Committee (ACC), effective September 2013 taking over from Dr. Russell Tupling who stepped down due to other commitments. We send all of our best wishes to Russ and thank him for the significant contributions he has made and his commitment to animal research at Waterloo.
- Dr. Joe Quadrilatero has been appointed as Vice-Chair of the ACC.

Our warmest congratulations go out to Dr. Andrea Edginton, CREC Chair, for recently receiving tenure!

Research Ethics and Integrity Advisory

[Compliments to the ORE](#)

We're recruiting!

The [Human Research Ethics Committee](#) (HREC) and the [Clinical Research Ethics Committee](#) (CREC) will be recruiting members for the 2014-2015 year.

Members use their expertise to review research ethics applications that have been identified as greater than minimal risk or otherwise require greater scrutiny.

If you are interested in learning about whether this may be an option for you, please contact [Maureen Nummelin](#) by email or call 519-888-4567, ext. 36005.



New website to better serve you!

Our website has been updated! The [Office of Research Ethics](#) (ORE) site is now consistent with the look and feel of all University of Waterloo websites.

A unique feature we have embedded in our site is a process flowchart to quickly and efficiently guide users to the sections they need.

Be sure to check out the Q&A

Committee (REIAC)

The Research Ethics Committees would like to move away from an Office of Research Ethics (ORE) driven model of policy and procedure development to one which fully involves and engages researchers and other stakeholders across the institution. The Associate Deans, Research have endorsed this recommendation and are supportive of this initiative.

A key responsibility of REIAC will be to identify emerging lines of research in each of the faculty areas. By doing so it is hoped that we can better anticipate and investigate the ethical implications associated with these types of research well before an application is submitted for ethics review. This anticipatory approach will likely speed up turn-around times for researchers since the ORE (and the research ethics committees) will not be required to react to problems and new compliance requirements. Operating in a reactive mode can, at times, create delays for researchers since guideline or policy development may need to occur before ethics clearance can be given.

REIAC will meet one or two times per year and their role is to advise the ORE on policy development and new guidelines to support research in the faculties. By involving faculty more actively in guideline development, we will find ways to meet compliance obligations using more effective and efficient processes.

Watch the [ORE website](#) for more details on REIAC in the coming months.

We continue to look forward to working together with Waterloo researchers to help you meet all of your compliance obligations.

TCPS2 tutorial is having a positive impact

In 2013 all Waterloo researchers planning to conduct research with human participants were required to complete the [TCPS2 tutorial](#) before submitting a research ethics application for review.

To date, 3,710 Waterloo associates have completed the tutorial:

- 334 faculty,
- 51 post-doctoral students,
- 891 graduate students,
- 2,254 undergraduate students,
- 180 others which includes staff, research assistants, and Research Ethics Committee (REC) members.

Did you know?

- Since making this a requirement, the REC members

and pre-submission and training sections of our site. These pages hold a wealth of information such as links to guidelines, policies, and documents that will greatly help you to consider ethical issues that may arise in the design and conduct of your research.

Send your feedback and suggestions on how to make our site better to ohrac@uwaterloo.ca.

Waterloo's centralized process for research misconduct allegations

In December 2011, the federal Tri-agencies launched a new guideline which mandated a centralized process for investigating allegations of research misconduct for any university wishing to receive Tri-agency funds. This Tri-agency guideline, the [Tri-agency Framework: Responsible Conduct of Research](#), requires all universities to have a single, centralized reporting and investigation process for all research misconduct allegations.

Prior to July 2013, the reporting and investigational processes for research misconduct at Waterloo were more decentralized. Prior to July 2013, allegations and investigations of research misconduct were handled through the faculties themselves or through the affiliated and federated colleges and universities.

Effective July 2013, all allegations of research misconduct should be reported to the office of the Vice President University

and delegated reviewers have reported they are reviewing stronger applications with fewer rounds of revisions.

- Several professors and course instructors have told us that they have made the tutorial a requirement for their classes.
- The tutorial provides a beneficial training experience for students as they move forward in their university careers to conduct their own research projects or theses.
- The tutorial is a great learning experience with interactive features and numerous multi-disciplinary examples.

Here is a quote from a Waterloo graduate student who recently completed the tutorial:

"The TCPS2 tutorial is, in one word, "great". In another way, now I really have an overview of the fundamental reasons why a review by any REC is indispensable before conducting research which involves people (even if the researchers are in doubt), not only for the researchers sake, but also from the perspective of ensuring human respect and values."

Meet the people behind the scenes

Want some advice before you begin? Have a question about your application, or an issue regarding research integrity or ethics? There are some new faces in the Office of Research Ethics. Get acquainted, or re-acquainted, and learn how we can help!

Effective August 2013, [Maureen Nummelin](#), PhD, was named Chief Ethics Officer for the University of Waterloo. This new title reflects Maureen's role in serving as point person for the University in all matters related to ethics compliance obligations and research integrity. Maureen also serves as the Vice-President, Professional Development for the [Canadian Association of Research Ethics Boards](#).



Maureen can help you with:

- External advocacy on ethics or research integrity issues
- Comments or suggestions regarding ORE or Central Animal Facility operations
- General institutional ethics or integrity policy and institutional compliance obligation inquiries involving any aspect of human or animal research.
- International requirements for research involving human participants or animals.

Research. Refer to the [FAQ document](#) on the ORE website for more information. All allegations should be reported using the Waterloo complaint form described in the FAQ document.



Harmonized ethics review between Waterloo and WLU now in effect ...

- **one application form,**
- **one set of review comments,**
- **one clearance certificate!**

Waterloo has recently signed an agreement with Wilfrid Laurier University for simultaneous review of collaborative research. What this means is that the Research Ethics Committees at the University of Waterloo and the Research Ethics Board (REB) at Wilfrid Laurier University (WLU) have established an alternative review model for research involving investigators from both institutions.

The objective of this coordinated review process is to streamline the ethical review process for Waterloo and WLU researchers by providing a single point of contact at their home institution. The coordination of

- Research misconduct allegations.
- Human or animal research emergencies, protocol deviations, incidental findings and adverse events.
- Reviews for all regulated clinical trial research where Waterloo is the sponsor.
- General management issues or requirements involving the Central Animal Facility.

[Julie Joza](#), MPH, is the Senior Manager in the Office of Research Ethics. Julie has more than 15 years of experience working in research both at Waterloo and in the community. She has been in the Office of Research office for six years and is the secretariat and primary delegated reviewer for the [Clinical Research Ethics Committee](#) (CREC) and secretariat for the newly established [Research Ethics and Integrity Advisory Committee](#). Julie is the point of contact for researchers from the faculties of Applied Health Sciences, Engineering, Mathematics and Science.



Julie is responsible for:

- Developing Waterloo ethics guidelines and policies.
- ORE communication activities including our website and newsletter.
- Coordinated review arrangements with other institutions.
- Advising researchers on compliance obligations relating to requirements for health related research, clinical trials, medical devices and drug/pharmaceutical and natural health product trials.
- Liaising with the Waterloo region school boards.

[Sacha Geer](#), PhD, is a Manager in the Office of Research Ethics. The newest face on the team, Sacha brings her experience as an educator and cultural anthropologist to the ORE and serves as secretariat and primary delegated reviewer for the [Human Research Ethics Committee](#) (HREC). Sacha is the point of contact for researchers from the faculties of Arts, Environment, and the university colleges.



Sacha is responsible for:

- Developing ethics and integrity training activities.
- Developing standard operating procedures (SOPs) relating to the HREC operations and facilitating HREC operations.
- Procedures related to the Delegated Ethics Review Committee (DERC) for Psychology.

[Joanna Eidse](#), BA, has been with the ORE for more than five years and is the Research Ethics Officer handling the administrative processes which facilitate ethics review for research

simultaneous review is expected to eliminate the need for consecutive review at both institutions and reduce the waiting time researchers experience obtaining ethics clearance for multi-site research. This process is also expected to aid researchers in handling comments made by one REB that then requires approval as a modification to another REB.

Research eligible for the Waterloo-WLU joint review process must be research deemed to be minimal risk as outlined by both institutions standard operating procedures and as defined by the TCPS2.

[Details about this new joint review process can be found on the ORE website.](#) During 2014, the ORE staff will be initiating discussions with other universities and research institutions to see if we can interest them in a similar type of coordinated review process.

If you will be conducting a study jointly with WLU investigators and have questions about the joint review process contact [Julie Joza](#) in the ORE who is our liaison with the REB at WLU.

5 things that typically cause review delays

1. Not all Waterloo investigators listed on the application have completed the TCPS2 tutorial.
2. Missing materials such as an appreciation/feedback letter or a copy of the

involving human participants. She is the voice of wisdom behind the ohrac@uwaterloo.ca email address and is the initial point of contact for most inquiries for human participant research.



Joanna can help you with questions regarding your ethics application, completion of the [TCPS2 tutorial](#), questions about whether your project will require ethics review, and administrative questions about modifications, revisions, annual progress reports and the status of your application.

[Cindy Futher](#) is the Animal Research Coordinator in the Office of Research Ethics. Cindy is the point person for the [Animal Care Committee](#) and submission of Animal Utilization Project Proposals (AUPP). Cindy can help you with questions about animal care training and enrollment, AUPPs, and Canadian Council on Animal Care (CCAC) standards and guidelines.



[Nancy Gibson](#) is the Central Animal Facility (CAF) Coordinator and Senior Animal Health Technician. Nancy can help you with questions about animal facility operations, technical service requests, care emergencies, per diem charges, and special equipment needs.



Office of Research Ethics by the numbers

Did you know the University of Waterloo is one of a few Canadian institutions with a dedicated staff specializing in delegated review of applications related to research with human participants?

In 2013, the ORE handled 865 new human research applications and 659 requests for modifications through delegated review and through our Human and Clinical Research Ethics Committees. An additional 1,311 applications were renewed.

This means we are in the top 5% for volume across Canada, according to a 2013 McMaster survey of 64 Canadian Research Ethics Boards (REB). By comparison, nearly 50% of all REBs in Canada handle fewer than 100 applications per year. In just 3 months, between November 2013 and February 2014, the ORE handled 305 applications!

Waterloo's turnaround time is usually less than 15 business days. We have heard from our researchers they have waited months for

standard operating procedure for equipment being used with participants.

3. Study purpose, rationale, and methodology has been written as a vague idea of what the objectives and desired processes will be, used a great deal of academic jargon, or was a cut and paste from other documents such as a grant or project proposal.

4. Recruitment and information-consent is a generic letter and not tailored to the needs of the participant population.

5. No explanation was provided that outlined additional permissions that have been or will need to be sought to conduct the research (i.e., there was a failure to investigate other jurisdiction's requirements and compliance obligations).

Does my data collection activity require ethics review?

The ORE has recently developed a guiding document and decision tree to try and help Waterloo staff, faculty, and students determine if the "data collection activity" they are planning to undertake requires ethics review.

Waterloo undertakes many surveys and other data collection activities in an attempt to learn from stakeholders if the institution, department, program, or service is doing a good job,

feedback from other Research Ethics Boards!

In 2013, our Animal Care Committee handled 33 new applications, managed 50 annual reviews and 46 requests for modifications to existing applications.

We are proud that our work helps to expedite and solidify the University of Waterloo's reputation as a leading research intensive university.

Federal anti-spam legislation to take effect this year

Canada's new federal [anti-spamming legislation](#) ("CASL") will be in effect on July, 1 2014.

This new legislation is designed to prohibit the sending of commercial electronic messages without consent. The legislation also bans the collection of personal information via access to computer systems, and prohibits the unauthorized compiling or supplying of lists of electronic addresses.

It is not clear the extent to which CASL applies to university activities. It is clear that universities are not fully exempt from the legislation, although some exemptions are provided related to fundraising activities for registered charities. Lawyers in the university sector remain unsure about the extent of our compliance obligation, and whether much of our ordinary messaging will be deemed commercial or not. In any case, and although individual damages for breach of the legislation might be small, General Counsel at the University of Waterloo has advised that a real threat of class action lawsuits exists for the University if we are not fully compliant. Best practice, therefore, suggests that we exercise due diligence in preparing and sending messages that have any aspects that could be considered "commercial."

Potentially, CASL will affect any "commercial message" sent via electronic means. These include "commercial messages" sent using e-mail, Facebook, Twitter, Reddit, etc. The legislation defines a "commercial message" as a message with the purpose of encouraging participation in a commercial activity including: an offer to purchase, sell, barter or lease a product; an offer to provide a business investment or gaming opportunity; advertising any of the above or promoting a person who does any of the above activities. General Counsel advises erring on the side of caution and recommends treating any offer of remuneration

addressing the needs of users or clients, and what could be done better.

When used exclusively for assessment, management, or improvement purposes the following data collection activities are typically not research and do not require ethics review, provided there is no element of research: a) quality assurance and improvement projects, b) performance reviews, or c) testing related to assessing performance of employees or students within normal educational or employment requirements. This position is consistent with [Article 2.5](#) in the TCPS2.

We have recently posted to our website a [guideline and decision tree](#) to aid you in answering this question.



Improving ethics and research integrity training and awareness

We are working to improve training and awareness about research ethics and research integrity obligations, and to provide better, more tailored opportunities for education.

Stay tuned! In the next few months we'll be looking for input on improving the already strong culture of research integrity conduct across the Waterloo campus.

In the meantime, if you have ideas or suggestions for

contained within an electronic message as a "commercial message."

Here are some tips to ensure your messages, such as recruitment emails, are fully compliant with this new anti-spamming legislation:

1. Be clear about whether or not what you are sending is a "commercial message." For example, even if the e-mail itself contains no commercial elements, the definition of a "commercial message" extends to content accessed through any hyperlinks, web site URL or other databases which are embedded within the e-mail message. If you are in doubt, contact the [Secretariat and Office of General Counsel](#).
2. The best course of action is to obtain express or implied consent from intended message recipients before you send them a "commercial message." Express consent can be "evergreen" and does not need to be renewed. Consider developing participant pools of potential participants who have provided consent to be contacted about particular topics as an easy way to ensure compliance.
3. The "commercial message" you send needs to contain specific information. For example, it should contain an easily accessed unsubscribe mechanism, information on who sent it and the person on whose behalf it was sent, plus contact information for both. This should be contained in all messages that might be construed as a commercial electronic message.
4. If the consent involves the installation of a computer program, the purpose, function and impact of this software must be clearly described in the consent documentation.
5. If you use another organization to distribute messages by asking them to send "commercial messages" on your behalf, these organizations should be instructed to send "commercial messages" only to those who have already provided consent to the organization.

For further information, please contact uw.generalcounsel@uwaterloo.ca.

- Learn [Fast Facts](#) about the law.
- Find links to the [Law and Regulations](#).
- Get information on [Oversight and Management](#) as well as [Enforcement](#), including who will enforce the law.
- Check out the [Frequently Asked Questions](#)

News from the Animal Care

webinars or training that could help you, or members of your research team, contact [Sacha Geer](#), and be sure to check out our [online training and education resources](#).

Animal research training using myHRInfo and Desire to Learn

The ORE has been working with the Animal Care Committee to enhance our approach to providing animal research training. Although mandatory animal training has been a requirement at Waterloo since 2006, the ORE is now taking advantage of online learning environments to deliver theoretical material relevant to animal research.

The ORE currently offers nine courses using LEARN, with more to come. These online courses offer flexibility to researchers and are supplemented by hands-on clinical practice, as appropriate. If you have taken a similar course at another institution send this information to oreaupp@uwaterloo.ca and we will work with you to assess if this training meets Waterloo's requirements.

A major change which animal researchers will experience is that we have made all of the training courses, workshops, and orientation sessions that are offered to animal researchers available for self-enrollment using myHRInfo.

In addition to moving towards an enhanced use of myHRInfo to track training information and registration data, the ORE and ACC will also be expanding the types of training sessions and workshops that we currently offer to animal researchers and more clearly differentiating between theory

Committee

Canadian Council on Animal Care recent assessment visit results

All Canadian institutions involved in research, teaching, and/or testing activities with animals participate in the CCAC voluntary assessment program on a three year rotation.

On November 13, 2013 Waterloo participated in the one day [assessment](#) with positive verbal feedback from CCAC. Our official assessment feedback from CCAC received on March 7, 2014 stated the CCAC Assessment Director found Waterloo's "institutional animal care and use program to be of high quality, with strong support and investments from the senior administration and thoughtful work by all concerned."

Several commendations were cited:

1. That the animal care and use program members of the University of Waterloo be commended for their solid teamwork.
2. That the senior administration be commended for the strong support of the University of Waterloo animal care and use program, and for the extensive investments made, in particular in additional human resources and improvements to facilities.
3. That the Animal Care Committee chairs and members, including the Animal Research Ethics Coordinator, be commended for their hard work and dedication to animal welfare.
4. That the Director of the Office of Research Ethics be commended for her excellent work and leadership of the program, and that the Animal Health Technicians also be commended for their excellent work.
5. That the consulting veterinarians be commended for their active involvement and numerous contributions to the program.
6. That the researchers be commended for their contributions to sound standards of animal care and use.

In addition to these commendations, the University of Waterloo received two "regular recommendations". A response to these two CCAC recommendations is due by September 12, 2014 in order for the university to receive a renewal of its Good Animal Practice certificate.

Networks of Networks (N2)

Did you know Waterloo is a member of N2?

courses and skill courses.

Our website has a full [list of all courses and training](#) available.



Animal Standard Operating Procedures

All approved SOPs are currently available on SharePoint. Researchers are asked to email oreaupp@uwaterloo.ca for access.

The [Network of Networks](#) (N2) is a not-for-profit incorporated organization and an alliance of Canadian research networks and organizations working to enhance national clinical research capability and capacity.

There are several benefits of this membership including access to SOPs for human biomedical and clinical research.

A recent quote shared by a N2 member:

"During a recent Health Canada inspection at one of our member sites, the inspector provided some great feedback on the N2 SOPs. This is what the inspector said:

"I am very impressed with the SOPs, they are well written. The SOP addresses the important regulatory requirements without being restrictive".

The inspector was also happy to see that N2 has developed a quiz to go along with the SOP, for training purposes. The inspector commented several times during the day as to *"how well the N2 SOPs are written"*.

N2 SOPs are available to Waterloo researchers. See the ORE website for a [list of available N2 SOPs](#).

Compliments from Waterloo researchers

"Your prompt review a couple of months ago enabled the visit I've just completed with a remote community. When I was there I received compliments from our partners on the clarity and quality of the documentation, proof that the ORE carries out a necessary and valued job for the University, and which I now forward to yourself and your colleagues."

"Just a short note to thank you very much for this review. So far the company we need to impress is very impressed!"

If you have feedback, comments, or topics for future issues, we would like to hear from you at ohrac@uwaterloo.ca.

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