

# Ethics Matters@Waterloo

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

July 2013

**WATERLOO  
RESEARCH**

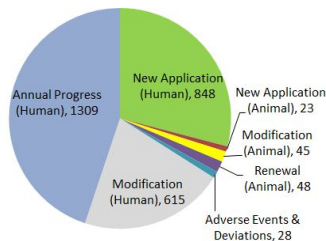
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## Website refresh

Our website is undergoing a refresh. Watch its progress on the [Office of Research Ethics \(ORE\)](#) site.



In 2012, 2916 research ethics applications and event forms were submitted. Of all new applications, 3% were reviewed by a committee.

## First edition of Ethics Matters@Waterloo

It is our pleasure to present, Ethics Matters@Waterloo, the first research ethics newsletter. Please share this newsletter with members of your research teams. We appreciate your feedback. Comments or suggestions can be sent to [ohrac@uwaterloo.ca](mailto:ohrac@uwaterloo.ca)

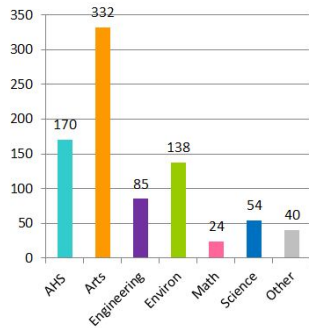
## A message from the ethics committees

It's been a very busy year! Here are a few highlights:

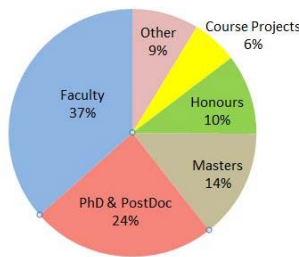
- 2,916 files were reviewed in 2012, up from 2,181 in 2006 (a 34% increase).
- Requests for ethics clearance of modifications have increased substantially - 72% since 2006.
- Since 2006, 97% of new applications (on average) have been reviewed through a delegation process and 3% go to full committee.
- New applications reviewed in 2011 - 2012 represented \$6.6 million in annual animal research funding and \$16.5 million in annual human research funding.
- The complexity of research ethics applications has increased since 2006 to include clinical trials, multi-site sponsored research involving new technologies and new privacy and consent issues. The increased complexity may be due to innovative procedures and equipment and an increase in multi-jurisdictional applications.

Changes to key personnel during the last year include:

- Dr. Maureen Nummelin was appointed Director, ORE, in June 2012, replacing Dr. Susan Sykes.
- Dr. Jonathan Fugelsang succeeded Dr. Richard Staines as Chair of the Human Research Ethics Committee (HREC) in November 2012. Membership on the Clinical Research Ethics Committee (CREC) expanded to include Dr. Richard Staines to represent kinesiology in November 2012
- Dr. Russell Tupling succeeded Dr. Niels Bols in January 2012 as Chair of the Animal Care Committee (ACC).



Over a third of new human ethics applications in 2012 were from the Faculty or Arts, predominantly from the department of Psychology. AHS was second with 170 followed by Environment with 138.



61% of new human applications in 2012 were for faculty, PhD or postdoctoral projects.

## Research Ethics Committees

### *Human Research Ethics Committee (HREC)*

The Human Research Ethics Committee (HREC) reviews applications that involve sensitive or invasive procedures and/or populations that could be considered vulnerable or potentially vulnerable in relation to the research question.

The committee consists of representatives across four faculties including Arts, AHS, Environment, and

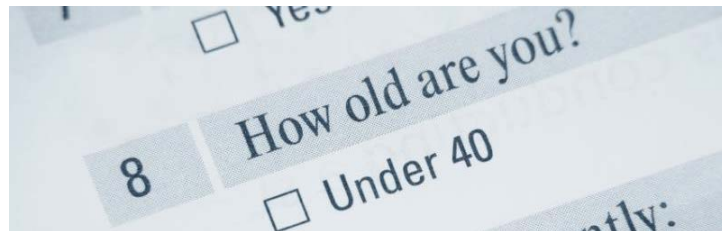
- Dr. Andrea Edginton, will succeed Dr. John Flanagan as Chair of CREC, effective September 2013. Dr. Flanagan was the inaugural Chair of CREC and played a key role in its start up activities. We thank him for his significant contributions and unflinching commitment to ethical research.

The responsibility of these three committees, together with the ORE, is to ensure any research conducted by university faculty, students, and staff involving humans and/or animals complies with an ever-changing roster of national and international [guidelines and statutes](#). This compliance oversight is required to ensure that Waterloo researchers continue to receive tri-council funding and ensure that all research on humans and animals is conducted according to the highest ethical standards.

In 2013, the three committees and the ORE will continue to work toward:

- streamlining processes
- clarifying compliance obligations
- ensuring that ethical review is focused on areas of real risk
- improving researchers' familiarity with the [Responsible Conduct of Research](#) obligations, and
- developing a method to allow for broader and more proactive input into ethics review policy and guideline development.

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



## What's New?

Several new initiatives have been launched to continue the university's ongoing efforts to streamline the ethical review process and address common concerns heard from researchers. They include:

### **Reduced paper**

Researchers no longer need to submit two copies (or up to 16 for committee review) of their ethics application. Effective July 2012, one signed hard copy will suffice.

### **Reduced review cycle time**

The ORE continues to develop guidelines to help researchers better interpret various agency, legislative, and governmental

Mathematics. Their expertise includes qualitative research, statistics, clinical psychology, law, and medicine. There are two community representatives and two student representatives as well as ORE representation.

### ***Clinical Research Ethics Committee (CREC)***

This committee reviews applications involving drugs, natural health products, or medical devices, clinical trials, and/or procedures involving controlled acts (e.g., blood draws, ultrasound, etc.).

The CREC consists of representatives from two faculties - AHS and Science. Committee expertise includes medicine, law, ethics, and neuroscience. There is one community representative as well as ORE representation.

### ***Animal Care Committee (ACC)***

The ACC consists of representatives from AHS, Mathematics, and Science. Committee expertise includes a veterinarian, animal health technicians, a graduate student, and two community members as well as ORE representation.

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## **Responsible conduct of research training available**

Do you supervise graduate students with whom you collaborate on research projects? Do you want to be

requirements, as well as providing hyperlink explanations within the applications to reduce iterations. By helping researchers understand the ethical issues associated with various protocols, we expect the cycle time will be compressed. We continue to review feedback to ensure it focuses on ethical issues rather than editorial comments or minor items.

### **Guidelines to clarify requirements**

For many researchers, the ethical review process can feel like a "black box." However, there are fairly predictable issues which ethics review committees are mandated to look for depending on the type of human research. In an effort to improve transparency and speed up the ethics review process, the ORE/HREC/CREC have developed a series of guidelines in order to identify common ethical issues and provide possible solutions:

- [What Requires Ethical Review?](#) (Coming soon!)
- [How Do I Ensure Data Security and Confidentiality ?](#)
- [What Special Issues Exist When I Use Equipment to Collect Biomedical Data?](#)
- [What Do I Need to Consider When Establishing a Biobank or Biorepository?](#)
- [How Can I Use Crowdsourcing to Recruit Participants?](#)
- [Are There Special Considerations When Conducting Off Campus Research?](#)
- [What Are the Special Ethical Considerations When Reviewing Course or Honour's Projects?](#)
- [Can I Conduct Research in Classes Using Students as Participants?](#)
- [How can I Use Partial Disclosure and Deception in Research?](#)
- [How Can I Ensure I Comply With Ontario's Controlled Acts Legislation?](#)
- [What Research is Conducted Under the Auspices of Waterloo?](#)

### **Opportunity for harmonized review with WLU**

The ORE is working jointly with the REB at Wilfrid Laurier University on a pilot project for simultaneous review of collaborative research. Once complete, it's expected this agreement may be used as a model to negotiate agreements with other institutions.

### **Project Management Assistance for Clinical Trials**

To help streamline the time-consuming administrative project management issues that researchers face, a Multi-site Clinical Trial Agreement has been created that can be used for clinical trials when the University of Waterloo is the sponsor. As of July 2013, the CITI Canada standard operating procedures are available for biomedical and clinical researchers to incorporate directly into their protocols. These are [available to Waterloo researchers upon specific request](#). These generic SOPs cover common clinical trial requirements (e.g., data management) and have been approved "as is" by Health Canada.

able to demonstrate you've been "duly diligent" if a member of your research team is found to have committed research misconduct?

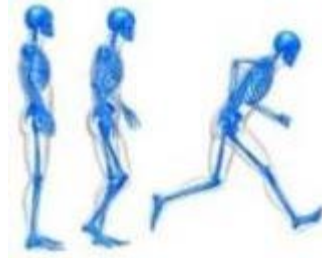
If so, you may wish to have members of your research team complete the new free, online [training](#) on "Responsible Conduct of Research." We think this training is particularly valuable for those who are new to research.

### Good Clinical Practice Training

Researchers required to complete Good Clinical Practice Training as part of clinical trial research are now able to do so through the university. Effective July 2013, CITI Canada provides this training so Waterloo researchers can demonstrate competency. [CITI Canada training](#) will be accessed through the [ORE website](#) and includes:

- Good Clinical Practice
- Responsible Conduct of Research (RCR)
- Biomedical Research Ethics
- Social and Behavioral Research
- Transportation of Dangerous Goods TDG/IATA

Information about how to register can be found on the [ORE website](#).



## Compliance reminders

- Have you taken [CORE \(the Course on Research Ethics\)](#)? The tutorial outlines the second edition of the Tri-Council Policy Statement on the Ethical Conduct for Research involving humans (TCPS2). This tutorial is a newer version than the tutorial released in 2010 and is mandatory for all University of Waterloo researchers.
- Researchers at all institutions who receive tri-agency funding will be required to implement the [Tri-Agency Framework: Responsible Conduct of Research](#). A Tri-agency online tutorial is expected in the fall, however, an online tutorial is currently available through [CITI Canada](#).
- If you're conducting clinical research, you'll need to be aware of (and should read about):
  - [Canada's Strategy for Patient-Oriented Research](#) which outlines a vision and 10-year plan to improve health outcomes of Canadians and enhance patient care through research.
  - [Good Clinical Practice](#), a set of standards implemented internationally and focused on the ethical and scientific quality of the design, conduct, recording, and reporting of clinical trials that involve

humans.

- o [Clinical Trials Ontario](#) is a new organization that has been established through the Ministry of Research and Innovation to provide a streamlined approach to conducting multi-centre clinical trials while ensuring the highest ethical standards for patient safety.

If you have feedback, comments, or topics for future issues, we would like to hear from you at [ohrac@uwaterloo.ca](mailto:ohrac@uwaterloo.ca).

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