



Ethical Research with Human Participants

Office of Research Ethics

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Learning Objectives

1. Recognize when ethics clearance is necessary
2. Identify the core principals of ethical research design
3. Identify resources for preparing a research ethics application
4. Recognize what behaviours constitute a RCR breach

When do researchers need ethics clearance?

- While affiliated with the University of Waterloo - any research that collects data from human participants requires ethics clearance.
- Data may include: bio-metric data, biological materials (blood, urine, saliva), responses to any qualitative or quantitative questions (interviews, surveys, focus groups etc.)
- Data that was collected for a different research purpose or for a non-research purpose (i.e., secondary data analysis)
- Working with another institution and they receive ethics clearance (You still need ethics clearance from UW).

Research (TCPS2, Article 2.1)

- “an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation”
- “a determination that research is the intended purpose of the undertaking is key for differentiating activities that require ethics review by an REB and those that do not”

The goal of research is to produce knowledge that is generalizable outside of uWaterloo

What types of activities fall into the Research Category

- Research funded by Tri-Councils (i.e., NSERC, CIHR, SSHRC) or other sponsor grants
- Contract or industrial research
- Fourth year theses, Masters theses, PhD dissertations
- Post-doctoral research projects
- Applied research/research related to a consulting assignment
- Secondary data analysis

RESEARCH

[Home](#)
[Research excellence](#) >

[About research](#) >

[Find and manage funding](#) >

[Forms](#) >

[Research ethics](#) v

[Research integrity](#) >

[Research with animals](#)
[Research with human participants](#)
[Research using tissue or bodily fluids](#)
[Research Ethics and Integrity Advisory Committee](#)
[Technology transfer and commercialization](#) >

INFORMATION FOR

[Your gateway to research](#) >

[Industry](#)
[Non-profit/public sector](#)
[Research](#) » [Research ethics](#) »

Research with human participants

Members of the University of Waterloo community must ensure the safety and welfare of participants are adequately protected and their research complies with the:

- [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans \(TCPS2\)](#), [TCPS2 Interpretations](#), and [revisions to TCPS2 \(pdf\)](#)
- [University of Waterloo Statement on Human Research \(PDF\)](#)
- [Office of Research Ethics guidelines and policies](#)
- [Guidelines of various governmental and professional organizations](#).

Please use the Waterloo Ethics Process to the right to guide you by clicking on the step in the process where you need more information.

IS ETHICS REVIEW NEEDED?
IS THIS RESEARCH?

QUESTIONS ABOUT
ETHICS APPROVAL?

WATERLOO ETHICS PROCESS

Pre-submission
and Training ☒

 Q & A

Application
Process 

 Review
Committees

Renewals 

 Modifications

Report
problems 

 Close a
study

Need 

Evolution in Protections

- Nuremberg Code, 1949
- Belmont Report, 1979
- Declaration of Helsinki, 1964, 2008 (most recent revision)
- Canada: Tri-Council Policy Statement (1998)
Tri-Council Policy Statement 2 (2014)

Post-Nuremberg

Even after implementation of the Nuremberg Code there are many examples of unethical research conduct:

Tuskegee Syphilis Study, 1932-1972

Willowbrook School Study, 1957-1963

Jewish Chronic Disease Hospital Study, 1963

Milgram Obedience Study, early 1960s

Tearoom Trade Study, mid 1970s

Uganda HIV/AIDs Study "More Tuskegee" 1994 - 1998

CIA experimentation on Guantanamo Bay Inmates, 2015

TCPS 2014 (2nd edition): Core Principles

- Respect for human dignity has been intrinsic to TCPS since its inception
- Expressed in three core principles:
 - Respect for Persons
 - Concern for Welfare
 - Justice

TCPS, 2nd edition, 2014

Principle 1: Respect for Persons

- Participants have the right to give *informed* consent to participate in any research study – process must be clear

TCPS, 2nd edition, 2014

Principle 2: Concern for Welfare

- Minimize exposure to unnecessary risks
- Consider physical, mental, economic risks
- Groups can also be impacted by research and findings

TCPS, 2nd edition, 2014

Principle 3: Justice

- Obligation to treat people fairly and equitably
- No group should be unduly burdened by risks or denied benefits of knowledge generated by the research
- Inclusion should be based on scope and objectives of study and not on easy access or manipulation
- Exclusion should not be based on factors unrelated to research (e.g., age, gender)
- Consider vulnerability in context of the study

Ethical Issues

- Focus Groups
- Surveys
- Interviews

Proportionate Ethics Review

Minimal Risk is...

....research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by the participant in those aspects of his or her everyday life that relate to the research.
(TCPS, 2014)

UWaterloo Proportionate Ethics Review

Two Ethics Review Levels

Full Research Ethics Board (REB) review

- Required for greater than minimal risk research
- Monthly meetings, with deadlines

Delegated REB review

- Delegation of authority from REB for ethics review of minimal risk research
- No deadlines

If you ever need to apply for ethics clearance yourself:

- Application process, step by step
- Samples and templates: Recruitment, Information and consent, feedback and other supporting materials

RESEARCH

[Home](#)
[Research excellence](#) >

[About research](#) >

[Find and manage funding](#) >

[Forms](#) >

[Research ethics](#) ✓

[Research integrity](#) >

[Research with animals](#)
[Research with human participants](#)
[Research using tissue or bodily fluids](#)
[Research Ethics and Integrity Advisory Committee](#)
[Technology transfer and commercialization](#) >

INFORMATION FOR

[Your gateway to research](#) >

[Industry](#)
[Non-profit/public sector](#)

Research » Research ethics » Research with human participants »

Application Process

7 steps for submitting an application

1. Prepare your application by reading the following:

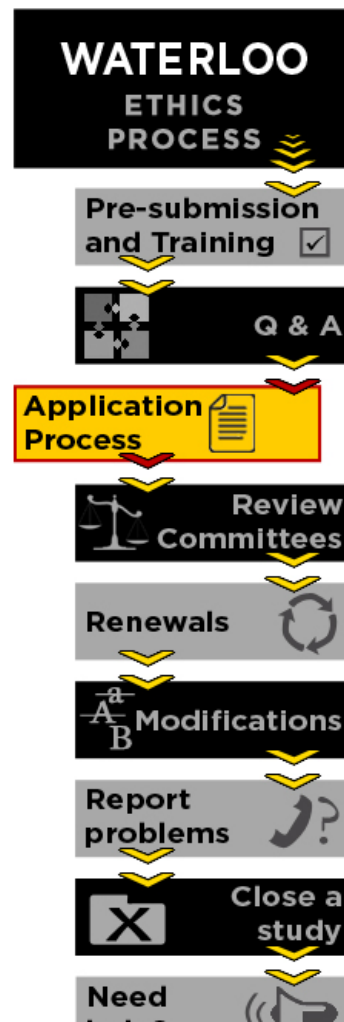
- [Who needs to complete an application form](#)
- [Video: how to apply for research ethics clearance](#)
- [Top 10 problems that can delay your ethics application](#)
- [Training requirements](#) and [Guidelines and policies](#)

2. Review the requirements for ethics review with:

- [Conestoga College](#)
- [Grand River, St. Mary's, or Cambridge Memorial Hospital](#)
- [Western University](#)
- [Wilfrid Laurier University](#)

3. Sign-in to complete the online application form

- Access to the sign-in page from off-campus is only available through the [Virtual Private Network \(VPN\)](#).
- VPN is also available for [non-uWaterloo applicants](#).
- [Sign-in](#) to complete the online application form.



RESEARCH

Home

Research excellence >

About research >

Find and manage funding >

Forms >

Research ethics ▾

Research integrity >

Research with animals

Research with human participants

Research using tissue or bodily fluids

Research Ethics and Integrity Advisory Committee

Research ethics system login ▾

Research ethics system training

Technology transfer and commercialization >

INFORMATION FOR

Faculty >

Research » Research ethics »

Research Ethics System login

The Research Ethics System is the University's online system that supports the development, review, and clearance of research ethics applications.

LOG IN TO THE
RESEARCH ETHICS SYSTEM

Log into the system using your WatIAM credentials. If you are not a UWaterloo member, please contact researchethics@uwaterloo.ca to request access.

Please use current versions of Chrome, Firefox, Safari, and Microsoft Edge when using the system.

Records from the previous system

Active records in the previous system have been migrated to the new Research Ethics System and mapped to the Principal Investigator (PI)/Faculty Supervisor's WatIAM account. Student investigators, or other member of the research team, may not see the application when logging in. Please work with your PI to be added to an application. The PI will need to open the application, select amend, and add you to the People section. The PI must also select "full access" if you will be creating amendments in the system. For further instructions, please review the training guide for [locating records from the previous system](#).

Questions

Contact
researchethics@uwaterloo.ca

Training

View upcoming [drop-in sessions](#)
View the [Research Ethics System training guide](#)

The process in a nutshell

1. Make time for ethics clearance in your research planning (4-6 weeks for a minimal risk study after all materials submitted).
2. Visit our website: <https://uwaterloo.ca/research/office-research-ethics/research-human-participants>
3. Ensure you've completed the required training. –TCPS2
4. Fill out an online application.
5. Ask your supervisor (i.e., the Principal Investigator) to log in and submit the application.
6. Respond to any requests for revision or clarifications through the system

RESEARCH

[Home](#)
[Research excellence](#) >

[About research](#) >

[Find and manage funding](#) >

[Forms](#) >

[Research ethics](#) >

[Research integrity](#) >

[Research with animals](#)
[Research with human participants](#)
[Research using tissue or bodily fluids](#)
[Research Ethics and Integrity Advisory Committee](#)
[Technology transfer and commercialization](#) >

INFORMATION FOR

[Your gateway to research](#) >

[Industry](#)
[Non-profit/public sector](#)

Research » Research ethics » Research with human participants » Application Process »

Samples and other supporting materials

You can select from the available samples and revise them to suit the specifics of your project.

[Recruitment materials](#)

[Information-consent letters and forms](#)

[Feedback and appreciation letters and documents](#)

[Other supporting materials](#) such as:

- Confidentiality agreement or declaration of non-disclosure
- Clinical trial agreement
- Health status form
- Data sharing agreement

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ETHICS
PROCESS**

**Pre-submission
and Training** ☒

Q & A

**Application
Process**

**Review
Committees**

Renewals

Modifications

**Report
problems**

**Close a
study**

**Need
help?**

Recruitment

- All materials must undergo ethics review (i.e., telephone, email, paper, poster, flyers, scripts)
- Provide ORE with how, when, where, and who you are recruiting
- Use language that:
 - Conveys the voluntariness of participating in the study
 - Participants will be able to understand
- Financial or other incentives cannot be so large or attractive to cause participants to take risks they would otherwise not take

Information and Consent forms: Why do we use these?

- Inform a potential participant about a research study

Consent forms are used to:

- document a participant's agreement to take part in the study, and
- obtain permission to use quotations or take video-recordings or photos
- Sample information-consent letters and forms
- Guide to the informed consent process
- Checklist for creating an information letter and consent form (PDF)
- Waterloo e-letterhead

Informed Consent Process

Exceptions to written consent:

- Research poses less than minimal risk
- Is not the norm in certain communities, cultures or countries
- Might adversely affect welfare of participants
- Not practical due to study design, such as:
 - Ethnography, observational research
 - Mail back questionnaires
 - Online/web-based studies

Consent to Participate

With full knowledge of all foregoing, I agree, of my own free will, to participate in this study.

☐

I agree to participate.

☐

I do not wish to participate (please close your web browser now).

Privacy, Anonymity and Confidentiality

Safeguarding Participants' Information

- De-identify data as soon as possible (e.g., remove personal identifiers like names, addresses etc.)
- Assign unique or encrypted identifiers (e.g., pseudonyms or ID codes)
- Store ID codes securely and separately from data
- Install authentication methods to access databases (e.g., user names, encryption, password protection)
- Maintain computers and files in secure settings (e.g., locked office at school or home)
- Storage on network vs. local drives
- Avoid use of laptops for storage of personal data

Researcher Safety

- The primary focus of the ethics review process is the protection of research participants
- But.... there may also be risks to researchers while conducting a study which require consideration and the necessary safeguards should be outlined and put in place
- Travelling overseas? Policy 33 requires that institutional approval is given in addition to ethics approval. Make sure you register with Waterloo International

Want to change your study after clearance? Submit an amendment

All proposed changes must be reviewed and approved.

- Modification of approved study protocols or materials.

This process is *not* negotiable. Neither is it time consuming. These requests are usually turned around within 5-15 business days

RESEARCH

Home	
Research excellence	>
About research	>
Find and manage funding	>
Forms	>
Research ethics	▼
Research integrity	>
Research with animals	
Research with human participants	
Research using tissue or bodily fluids	
Research Ethics and Integrity Advisory Committee	
Research ethics system login	>
Technology transfer and commercialization	>
INFORMATION FOR	
Faculty	>
Industry	
Non-profit/public sector	

[Research](#) » [Research ethics](#) » [Research with human participants](#) »

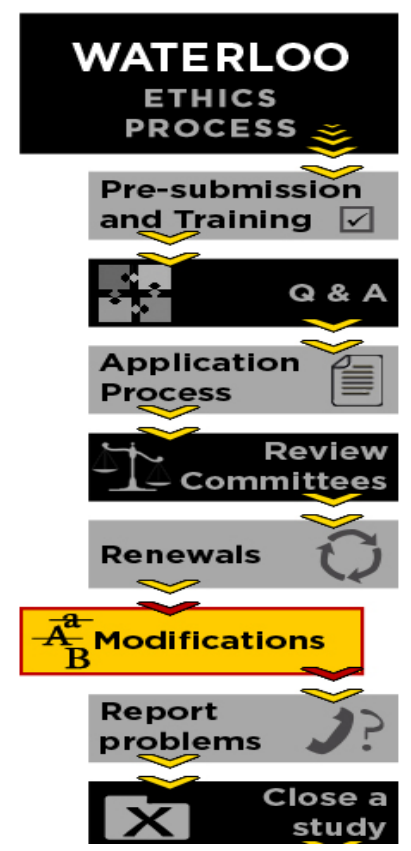
Modifications

As a condition of continued ethics clearance, researchers must conduct their research according to the details provided in their originally approved application.

Researchers are responsible for receiving ethics clearance for amendments to their study prior implementing the changes. For example, an increase in sample size, change to procedures or materials being used, or revisions to the information-consent letter.

Amendment applications to an ongoing study are to be submitted using the [research ethics system](#).

- **Expect the review to take 10 to 15 business days after being submitted.** See [understanding review times](#). These times may increase during peak periods such as in March, June, and November.
- **Only one modification request may be submitted at a time.** An outstanding modification request needs to receive ethics clearance before a subsequent modification request can be made.
- If the proposed modification cannot be included under the original project or if the modification is sufficiently substantive to require submission of a new application the researchers will be instructed to submit a new application.
- A study with a new purpose requires a new application.



What happens when problems arise after ethics clearance?

These must be reported to the Office of Research Ethics within 24 hours

- Adverse event (research must stop pending investigation).
- Protocol deviation
- Incidental or secondary findings (research may need to stop for participant)

RESEARCH

[Home](#)
[Research excellence](#) >

[About research](#) >

[Find and manage funding](#) >

[Forms](#) >

[Research ethics](#) >

[Research integrity](#) >

[Research with animals](#)
[Research with human participants](#)
[Research using tissue or bodily fluids](#)
[Research Ethics and Integrity Advisory Committee](#)
[Technology transfer and commercialization](#) >

INFORMATION FOR

[Your gateway to research](#) >

[Industry](#)
[Non-profit/public sector](#)
[Research](#) » [Research ethics](#) » [Research with human participants](#) »

Report problems

Researchers are required to report all unanticipated occurrences associated with their research, such as:

- [adverse events](#) that occurred with a research participant,
- [deviations](#) from the study protocol, or
- [incidental or secondary findings](#).

Adverse events

Any undesirable experience or response by a study participant is considered an adverse event. They may be emotional, psychological, or physiological in nature and include injury or a detrimental incident experienced by a research participant. These events are usually related to study participation or a result of the research procedures.

The Principal Investigator, or Faculty Supervisor in the case of student research, **must report the adverse event by e-mail the chief ethics officer, as soon as possible but no later than 24 hours following the event.** Submission of the [Adverse Event Reporting Form - Form 106 \(PDF\)](#) must follow within one (1) business day of the e-mail notification.

The Principal Investigator or Faculty Supervisor is expected to respond to the adverse event immediately and according to the description originally outlined in the safeguards section (Section E2) of the approved application (Form 101). If the study is a [clinical trial](#) refer to the serious adverse event reporting requirements.

The following are examples of adverse events that must be reported:

- Negative, physical, or allergic reactions to drugs administered in a study
- Physical consequences from dietary manipulations (e.g., fainting)
- Negative physical reactions in volunteers who have chronic diseases (e.g., heart conditions, diabetes)
- Unexpected accidents that occur during the course of a research project (e.g., a participant in an exercise study falling off an exercise bike or treadmill)
- Equipment failure during an experimental session should also be reported if it resulted in harm to a participant



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SEARCH

RESEARCH

[Home](#)[Research excellence](#)[About research](#)[Find and manage funding](#)[Forms](#)[Research ethics](#)[Research integrity](#)[Research with animals](#)[Research with human participants](#)[Research using tissue or bodily fluids](#)[Research Ethics and Integrity Advisory Committee](#)[Research ethics system login](#)[Technology transfer and commercialization](#)

INFORMATION FOR

[Faculty](#)[Industry](#)[Non-profit/public sector](#)[Research](#) » [Research ethics](#) » [Research with human participants](#) »

Need help?

Staff are available to address your questions regarding ethics clearance for research involving human participants.

We provide consultations, assistance, and support to researchers at all stages of the application and review process. We also develop and distribute educational materials, guidelines, procedural information, and sample documents related to research with human participants.

We can help in determining if your research is minimal risk and can be reviewed by a delegated reviewer or is greater than minimal risk requiring review by one of the two Research Ethics Committees.

Course instructors are encouraged to contact us to arrange a guest lecturer for a course or to give a presentation on a topic related to research ethics.

We can discuss with you the [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans](#) and how these guidelines apply to your proposed research or point you to other resources if needed.

Vanessa Buote

Research Ethics Advisor, ext. 30321

Joanna Eidse

Research Ethics Advisor, ext. 37163

WATERLOO ETHICS PROCESS

[Pre-submission and Training](#) ✓[Q & A](#)[Application Process](#)[Review Committees](#)[Renewals](#)[Modifications](#)[Report problems](#)[Close a study](#)

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Examples of Breaches to Responsible Conduct of Research (RCR) Framework

1. **Fabrication of data**
2. **Falsification of data**
3. **Plagiarism**
4. **Destruction of research records**
5. Redundant publications
6. **Invalid authorship**
7. Inadequate acknowledgment
8. **Mismanagement of conflict of interest**
9. Misrepresentation in an agency document
10. **Mismanagement of grants or awards**
11. **Breaches of agency policies of requirements/failure to obtain approvals**

(Tri-agency Framework: Responsible Conduct of Research, 2011)

Have a question about ethics?

1. Visit the Waterloo ORE website at <https://uwaterloo.ca/research/office-research-ethics>
2. Call or email and ask questions!
 - (519) 888-4567 ext. 35217 or ohrac@uwaterloo.ca
3. Schedule a meeting to discuss your project/study.

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Questions about a RCR breach?

Bruce Muirhead, Associate Vice President, external research
muirhead@uwaterloo.ca, ext. 32933

Questions about ethics?

Office of Research Ethics, ohrac@uwaterloo.ca