

# Ethics Clearance for Research Involving Humans

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Chair

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# Tri-Council Policy Statement 2 (2010)

## *Ethical Conduct for Research Involving Humans*

Available at: [www.pre.ethics.gc.ca](http://www.pre.ethics.gc.ca)

- Canadian Institutes of Health Research
- Natural Sciences and Engineering Research Council of Canada
- Social Sciences and Humanities Research Council of Canada

TCPS2

TRI-COUNCIL POLICY STATEMENT

## Ethical Conduct for Research Involving Humans

2010

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Natural Sciences and Engineering Research Council of Canada  
Social Sciences and Humanities Research Council of Canada

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Note: For the most recent information on amendments, please consult the official online version of the TCPS at [www.pre.ethics.gc.ca](http://www.pre.ethics.gc.ca).

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# Tri-Council Policy Statement 2: Core Principles

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- Respect for Persons
- Concern for Welfare
- Justice

# Tri-Council Policy Statement 2: Core Principles

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## 1. Respect for Persons

1. Recognizes the intrinsic value of human beings and the respect and consideration they are due
2. Respect autonomy of participants and protect those with developing, impaired or diminished autonomy
3. Defer to person's judgment about participation and ensure they are free to choose without interference
4. Seek free, informed and ongoing consent

## 2. Concern for Welfare

## 3. Justice

# Tri-Council Policy Statement 2: Core Principles

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1. Respect for Persons
2. Concern for Welfare
  1. Welfare of a person is the quality of that person's life in all its aspects
  2. Protect welfare of participants by providing sufficient information so they can assess risks and benefits to participation
  3. Ensure participants are not exposed to unnecessary risks
  4. Minimize risks/create most favourable balance of benefits to risks
  5. Consider potential tension between welfare of individual participants and groups
3. Justice

# Tri-Council Policy Statement 2: Core Principles

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1. Respect for Persons
2. Concern for Welfare
3. Justice
  1. Treat people fairly: with equal concern and respect
  2. Treat people equitably: distributing the benefits and burdens of research so that no sector is unduly burdened or denied benefits
  3. Does not always mean treating people in the same way – differences are sometimes justified (vulnerability, power issues)
  4. Recruitment should be aligned with research question

# Tri-Council Policy Statement

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- Ethics review is required for ALL research involving human subjects (including oneself) in order to protect both the participants AND the researcher
- ALL proposed research that involves greater than minimal risk is subject to scholarly review as well as ethics review
- Research is defined as an undertaking intended to extend knowledge through disciplined inquiry or systematic investigation

# Considerations in Ethics Review

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- Potential benefits

- Risks

  - Magnitude or seriousness of the harm

  - Probability of occurrence of the harm

- Minimal risk

  - Magnitude and probability of risk are no more than those encountered by participants in aspects of everyday life relating to the proposed research

- Balancing risks and benefits

  - Benefits must outweigh the risks

- A proportionate approach to ethics review

  - Level of review is determined by the level of risk

    - Minimal risk typically receives delegated review at GREB

    - Greater risk, vulnerable groups likely receives full review

# The role of the General Research Ethics Board (GREB)

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- To implement the Tri-Council Policy Statement
- To determine institutional procedures
- To review all recommendations from unit Research Ethics Boards
- To carry out full reviews
- To handle disputes

# The role of the Education Research Ethics Board (EREB)

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- A service committee for faculty, students & staff at the Faculty of Education
- To provide guidelines for research submissions
- To inform people about protocols
- To give one-on-one advice
- To make recommendations to GREB about level of review for ultimate clearance
- EREB meets monthly to review files – the submission deadlines are found on the Grad Studies website.

## EREB Membership 2011-2012

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- Derek Berg
- C J Dalton
- Richard Reeve
- LeRoy Whitehead
- Lesly Wade-Woolley (Chair)
- Supported by Erin Wicklam

# As a general rule...

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- All graduate students will have to complete ethics applications if they are dealing with human participants, even if they are using secondary data with identifiers removed
- All graduate students must complete the online ethics training module

# Course On Research Ethics (CORE)

## SGS 804

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- Previously called Course in Human Research Participant Protection (CHRPP)
- Web-based tutorial to help impart the principles governing research with human participants
  - Describe guiding principles of research ethics
  - Recognize ethics violations
  - Evaluate strategies for creating ethical research designs
- Takes 4-8 hours and will appear on your transcript
- Print the certificate at the end – you will need it!!!
- If you have already done CHRPP you are exempt from the CORE requirement

# The Ethics Review Process: Beginning

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1. Develop a research proposal and **have your thesis committee approve the proposal**. For a thesis, ethics clearance should be sought in the same time period as the colloquium or thesis proposal defense.
2. **Ensure that your thesis/project proposal has been accepted by your committee before submitting an ethics application**
3. Make a complete ethics submission:  
On-line (ROMEEO)

# Required supplementary documents (1)

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- The following are required by EREB, plus the documents required by GREB
  - EREB checklist (**Read this thoroughly before you write your Letter of Information and Consent Form**) (hand in)
  - Confirmation of acceptance of thesis proposal from supervisor (signature on EREB checklist)
  - Confirmation supervisor has read and approved the ethics submission (signature on EREB checklist)
  - Two-page overview of research proposal (uploaded)
    - rationale, purpose, data collection methods, analysis, references (references may extend to a third page)

# ROMEEO

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- ROMEEO is the Queen's online ethics submission system
  - Probably, if you have **ever** been on contract at Queen's, you should try to login under Queen's Faculty and Staff
  - Log in with your Net ID or register for the first time
  - Make a new application

# Uploads

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- You will need to upload a set of documents
  - Forms (confidentiality agreement, photo release consent, etc.)
    - Available through our Grad Studies and Research webpage and also through Office of Research Services
  - Letter of Information and Consent Form
  - Recruitment Script
  - Sample interview schedule, survey items, etc.
  - CORE certificate
  - **2-page proposal**

## Completing the Initial Application

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- You can export the application file into Word to allow for offline editing and sharing with your supervisor before submission. You must return to ROMEO to make the changes to the actual application file.
- Once you submit the file for review by EREB, the system freezes your application and makes it “read-only” until the next stage of approval is complete
- Be sure that *ALL* the necessary documents have been uploaded – incomplete files **will not be reviewed** until the next month’s meeting.

# Remember!

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- You must submit the completed EREB checklist and all signatures to Erin Wicklam by 4.30 on the monthly deadline
- EREB will not review the file without the completed checklist and signatures

# The Ethics Review Process: Next steps

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- Your file will be read by three members of EREB, one will be the principal reader of your file
- Files are discussed by the entire committee – excluding the supervisor of a student who has submitted a file.
- A list of recommended revisions are compiled by the principal reader after the committee discussion and logged into ROMEIO.
- You will receive an email that there is a communication for you
- Log into ROMEIO and look at the Log tab – the report from the principal reader will be here, containing
  - Revisions
  - Likely recommendation to GREB

## The Ethics Review Process: Next steps

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- Make the revisions to the file – share the comments with your supervisor.
- In the Log Notes box, include a detailed memo that specifies how you addressed the suggested revisions or made any other changes to the file. If any revisions are left undone, explain why.
- Submit the revised version.
- The principal reader will review the file and either ask for further clarification or, more likely, will forward your file to GREB for final review and clearance.

# Three Types of EREB Recommendation

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1. Delegated review (for minimal risk proposals). Read by one member of GREB committee.
  - Most common
  - No time constraint for you
2. Full review (for more than minimal risk, for some international research, for research involving Aboriginal peoples). Read by full GREB committee and discussed at GREB meeting.
  - Attend to GREB meeting schedule and submission deadlines
3. Departmental level review for course requirements. Read and cleared by EREB committee.

# GREB Clearance

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- Gail Irving from GREB will be in contact with you to inform you that your proposal has been cleared OR to pass on the report from GREB asking for additional changes.
- You will receive a letter from GREB informing you that clearance has been given.
- **Then AND ONLY THEN can you begin to collect data.**
- If required, School Board or other applicable institutional ethics clearance must be obtained prior to or subsequent to this step.

## Example timeline (month view)

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- EREB deadline: October 26
- EREB meeting: November 4
- GREB deadline: November 23
- GREB meeting: December 7

# If you have questions . . . .

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- Refer to the document:

*A Guide to Obtaining Ethics Clearance for Research in Education*

Copies may be signed out from the library or from the Graduate Studies Office

- Ethics information, including forms and examples of Letters of Information and Consent Forms, can be sourced at the Graduate Studies and Bureau of Research website at:  
<http://educ.queensu.ca/research/ethics.html>

## Submission deadlines for EREB & GREB

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- For submission deadlines, go to the Research link and then to the Research Ethics Link.

[http://educ.queensu.ca/research/ethics/ereb-dates/  
index.shtml](http://educ.queensu.ca/research/ethics/ereb-dates/index.shtml)

Please note: Deadlines are firm!

## Help is available from . . . .

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- Your thesis or project supervisor
- The GREB & EREB web pages
- *A guide to Obtaining Ethics Clearance for Research in Education*
- Lesly Wade-Woolley - Chair (wadewool@queensu.ca)
- Any other member of EREB:
  - CJ Dalton (PhD candidate)
  - Derek Berg
  - Richard Reeve
  - LeRoy Whitehead

Questions?

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Good luck with your research!