

Research Ethics Board

June 2020

To start ... let's define our terms

Research

A disciplined inquiry or investigation with the goal of gaining or extending knowledge.

Ethics

*Principles or values used to define acceptable conduct.
Ethical guidelines help distinguish between good and bad and right or wrong.*

Research Ethics

Applying sound moral principles when conducting scientific inquiry.

What is an REB?

- A panel that evaluates research proposals involving human participants
- Deliberations & decisions are confidential
- REB members have a range of experience and expertise (data collection, research, science, technology, legal knowledge, ethics guidelines)
- Primary duty: to ensure human participants in a research study are protected and respected
- REB members function as advocates on behalf of human participants in a proposed study

The REB at Loyalist

- Functions independently from the College
- Receives no financial compensation
- Faculty and staff of the College; at least one community member (all are volunteers)
- Formed in 2015; meets monthly
- St. Lawrence College REB evaluated Loyalist applications before 2015
- Loyalist faculty member Dr. Karen Holder sat on the St. Lawrence REB

Who is on Loyalist's REB?

- A minimum of five members (faculty & staff)
- Two community members not affiliated with the College
- A chair (or co-chairs)
- Members must be Canadian citizens or permanent residents
- A list of REB members is posted at:

<https://loyalistappliedresearch.com/centres-and-services/research-ethics-boards/>

Mandate of Loyalist REB

- Ensure research involving human participants meets standards detailed in the Tri-Council* Policy Statement on Ethical Conduct for Research Involving Human Participants

https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html

**Tri-Council is: Canadian Institutes of Health Research; Natural Sciences and Engineering Research Council of Canada; Social Sciences and Humanities Research Council of Canada*

Tri-Council Policy Statement (TCPS 2)

- Policy Statement: Ethical Conduct of Research Involving Human Participants (1998, 2010, 2014)
- REB members must complete TCPS2 on-line training certification
- Website:
<http://tcps2core.ca/welcome>
- Three principles define value of human dignity:
 - ✓ Respect for persons
 - ✓ Concern for welfare of participants
 - ✓ Justice and Fairness

TCPS2

TCPS 2: CORE
Welcome

Panel on Research Ethics
www.pre.ethics.gc.ca

More Information¹
Rollover Glossary²
External Link³
Internal Link⁴ >

TCPS 2: CORE — Tutorial

The online tutorial TCPS 2: CORE (Course on Research Ethics) is an introduction to the 2nd edition of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2)*. It consists of eight modules focusing on the guidance in TCPS 2 that is applicable to all research regardless of discipline or methodology.

The purpose of TCPS 2: CORE is to provide an introduction to TCPS 2, primarily for researchers and, secondarily, for **REB²** members.

If this is your first time accessing TCPS 2: CORE, we suggest you click on the "CORE User Guide" for some tips on navigating the modules. There are also some other useful links below. Or you may go directly to the program by clicking the Log In button at right.

- > CORE User Guide
- > FAQ
- > Acknowledgements
- > Terms of Use
- > Glossary
- > Copyright
- > Help/Contact Us
- > Institutional Access

LOGIN TO CORE / CREATE ACCOUNT

Best viewed at a screen resolution of 1280 x 720 pixels.

Home Glossary FAQ Help/Contact Us Acknowledgements Dashboard Account Details Logout

Government of Canada / Gouvernement du Canada

Canada

100% 12:13 PM 5/12/2014

What projects require REB approval?

Research on human subjects, including:

- ✓ Human tissues or biological fluids
- ✓ Human remains or cadavers
- ✓ Embryos or fetuses

Projects that require REB approval

Studies involving human research

- ✓ Conducted by College faculty, staff or students
- ✓ Conducted on College premises
- ✓ Involves use of resources/facilities at the College

Projects that require REB approval

- Student- and course-based research involving human participants
- Researchers outside the College who wish to conduct research using any member of the College community or College resources
- No data collection may begin until a researcher has submitted an application to the REB and it has been approved by the REB

Projects NOT requiring REB approval

- Evaluations part of regular college business
(Student tests/exams, employee performance review)
- Quality assurance studies/surveys
(Key Performance Indicators; student performance rates)
- Usage/service surveys
(e.g. a library or cafeteria survey on usage/feedback)
- Data collected for college decision-making
(Program reviews, student course evaluations)
- Use of secondary data from public sources

Applying for REB approval

- Step 1: Complete TCPS 2 online tutorial
<http://tcps2core.ca/welcome>
- Fill out appropriate application form
 - Loyalist application (if study is at Loyalist only)
 - Or multi-site application if conducting research at more than one college
- Include all consent forms, information letters, questionnaires and supporting documents with application

Application process

- If you have questions, contact:
Cher Powers
Applied Research & Innovation Department
(613) 969-1913, ext. 2108
cpowers@loyalistcollege.com
- Or contact Cher to make appointment to meet REB for a Q&A at a scheduled monthly meeting

Application Process

Important reminders about application process:

- Staff will answer basic questions about an application
- Staff role is not to edit, proof-read, analyze or evaluate the quality of your application or your research methodology
- Submit your application to staff
- The REB strives to review and respond to applications within two weeks (not in July and August)
- Multi-site REB reviews – for a study at more than one college – typically take longer for approval

REB evaluation process

Types of review

1. Delegated review: if study is deemed minimal risk, REB chair and one member review
2. Full-board review: if study is deemed of higher risk, a quorum of REB members review/discuss at monthly meeting

Criteria REB use to assess applications

- ✓ Level of risk to participants
- ✓ Informed consent
- ✓ Precautions/considerations for vulnerable populations
- ✓ Safeguards: privacy and confidentiality
- ✓ Potential conflict of interest

Level of risk to participants

- Physical risks
- Psychological and/or emotional risks
- Social risks (including economic)

Minimal risk: anticipated risk to participants would be no greater than those encountered in ordinary daily life

(Examples: non-identifiable questionnaires, interviews, surveys; lab studies using previously collected samples; non-invasive procedures)

- Study deemed more than minimal risk must offer methods to mitigate risk and consider the risk benefit to participants

Informed Consent

Researchers must fully & clearly inform participants:

- About the purpose and nature of the research
- About potential risk(s) and benefit(s) to participants
- Their participation is entirely voluntary
- They may withdraw at any time, without providing a reason, without penalty
- That if they are not able to give informed consent, they are not eligible to participate

Informed Consent

Important reminders:

- Consent forms must be clear and easy to understand
- Participants should *actively* choose whether or not to participate
- A lack of response (i.e. a statement such as: “Your consent to participate will be assumed unless you indicate otherwise to the researchers”) does not qualify as informed consent
- Written consent is not required in all circumstances. For example, it may be acceptable to require participants click a box in an online survey or provide verbal consent

Privacy and Confidentiality

- Informed Consent forms must tell participants how their privacy and confidentiality will be assured
- Privacy of participants must be maintained *during* the research stage and *afterwards* (data collection and disposal)
- Data storage: locked file cabinets, locked office
- Limited access: coding of data, security clearance
- Technological safeguards: password protected, encryption, biometrics
- Data sent to the United States, or uploaded to U.S.-based servers (e.g. Survey Monkey), are open to access by U.S. regulatory bodies. Researchers must inform participants of this fact.

Personal Health Information Protection Act

PHIPA Requirements

- Paper files with identifiable information must be kept in a locked cabinet in a locked office (e.g. not at home)
- Electronic files with identifiable information must be stored on a password-protected computer on a secure network (i.e. virus protection, file backup, firewall) or they must be encrypted.
- Electronic files with identifiable information may be stored on mobile devices (e.g. laptop, CD, USB, PDA), but no alternative method of storage; these files must be encrypted.
- Identifying and/or identifiable PHI cannot be transmitted by email unless it is encrypted

Coding

- Identifying and/or identifiable PHI must be protected by coding system
- The code (study ID and identifiable PHI) must be isolated from study data and stored in a secure manner

Vulnerable Populations

Vulnerable populations include people:

- Under age 18
- With intellectual difficulties or mental illness
- Receiving medical treatment; with on-going health issues; in medical emergencies; in long-term care
- In prison
- Who are elderly
- Aboriginal people
- People living in poverty
- Otherwise unable to consent

Conflict of Interest

- A conflict of interest may be real, potential or perceived
- Conflict of interest may involve the researcher, the institution and/or participants
- A conflict of interest may jeopardize integrity of research

Some examples:

- Power imbalance (boss/employee; teacher/student)
- Interpersonal relationship (e.g. between researcher and participant)
- Researcher has dual roles
- Financial gain or reward

Types of REB decisions

When the REB reviews your application, it will deliver one of the following decisions:

- Approved

(You may begin data collection)

- Recommended for Approval

(Questions from REB need to be addressed. You must submit revised application for review by REB chair & Applied Research & Innovation Department staff)

Types of REB decisions

- Pending Approval

(Significant issues/questions from REB to be addressed. Revised application must be resubmitted for review by REB.)

- Not approved

(Applicant may appeal decision. The REB at Durham College would be the appeal board for Loyalist College.)

Web link to Loyalist REB

<https://loyalistappliedresearch.com/centres-and-services/research-ethics-boards/>

REB Policies and Forms

- AOP 220: Integrity in Research and Scholarship (under review)
- Loyalist College REB application form
- Completion and Termination form
- Renewal and Amendment form
- Adverse Event form
- Acknowledgement of Course-Based Research with Human Participants form

Questions



Sources

- Sarah Matthews, Research Services Officer, Applied Research Office, St. Lawrence College, Kingston
- Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2018.

https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html

- *A Guide to the Personal Health Information Protection Act, December 2004*, by Ann Cavoukian, Ph.D., Information & Privacy Commissioner for Ontario.

<https://www.ipc.on.ca/resource/a-guide-to-the-personal-health-information-protection-act/>