Université d'Ottawa • University of Ottawa

Ethics Approval of Research Involving Human Participants

Office of Research Ethics and Integrity

http://www.research.uottawa.ca/ethics/index.html

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OVERVIEW

1. Research ethics
2. Ethics review process
3. General ethics application
4. Secondary use of data ethics application
5. Exemptions of ethics review

1. RESEARCH ETHICS

Scope of Research Ethics Review

- All activities defined as "research" involving "human participants" require ethics review, where: (TCPS2, Article 2.1)
  - "Research" = An undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation
  - "Human participants" = Individuals whose data, or responses to interventions, stimuli or questions by the researcher, are relevant to answering the research question

TRI-COUNCIL POLICY STATEMENT (TCPS2)

- Full title: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, (2018)
- A joint policy of: CIHR, NSERC, and SSHRC
- Provides minimal requirements and guidelines for research conducted with human participants
- Acts as the mandatory reference guide for REBs at uOttawa

RESEARCH ETHICS BOARDS @ UOTTAWA

- REB assesses the ethical acceptability of a research project through consideration of the foreseeable risks, the potential benefits and the ethical implications of the project (see Article 2.9)
- Two committees on main campus
  - Social Sciences and Humanities REB
  - Health Sciences and Science REB

2. Ethics Review Process

Levels of Review

- Minimal risk review
- Full REB review
- Expedited review
  - Multicentre research (if approved by another Canadian REB)
  - Secondary use of data
  - Modifications
  - Annual report / Renewal of ethics approval

Minimal Risk: Exclusions

- Minimal risk research → If the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in their everyday life
  - Populations in situation of vulnerability (i.e., individuals with cognitive or intellectual impairments)
  - Possibility of coercion
  - Use of deception

Overview of the Levels of Review by the REB

Research Projects	Criteria	Deadlines	Time Required
Full REB review	Default procedure for all research projects involving human participants	First working day of month No review in July	4-6 weeks (from the day acknowledgement of receipt is sent)
Minimal Risk	Risks must not be higher than those lived in every day life (see website for restrictions)	First working day of month No review in July	4-6 weeks (from the day acknowledgement of receipt is sent)
Expedited Review	• Project already approved through expedited review by another TCPS 2 compliant REB • Minor revisions to a previously approved project • Projects using non-public secondary data	No submission deadline No review in July	3-4 weeks (from the day acknowledgement of receipt is sent)

***No new submissions in July*

Filling out the Form

- Please answer all questions using a full sentence
- Provide complete information
- Avoid technical jargon (if used, explain your terms)
- Check your documents! If errors hinder proper understanding of content, documents will be sent back for corrections

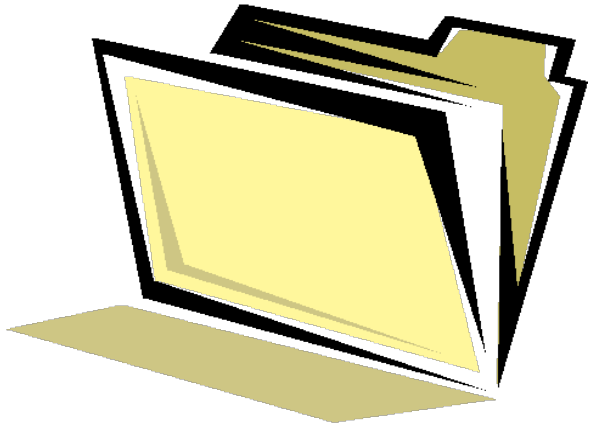
Documents to Submit

Mandatory:

- Recruitment text (i.e., posters, scripts, etc.)
- Consent document(s) (consent form, debriefing form, etc.)
- Research tools (interview guide, questionnaire, etc.)
- Thesis approval (from thesis committee or supervisor)

Process – REB Review

- File is received through eReviews system
- Verification of content and level of risk
- File review by evaluators
- Feedback sent to researchers via eReviews system



Categories of Ethics Approvals

- Refused

- Resubmission required

- Revisions required (minor modifications or clarifications must be made to the research project)

- Additional permissions/approvals required (All ethical issues are addressed but additional permissions or approval(s) must be submitted to the Ethics Office before the ethics certificate is issued)

- Approval (ethics approval granted - the project may begin)

Feedback & Approval

- You must respond to the feedback within six months
- When you respond:
  - Respond in the application form to each point raised by the REB
  - Submit a revised version of all the documents that must be modified and highlight these changes
- Once your file is in order, an ethics certificate (PDF version) will be sent through eReviews and you will be able to start the project
- Grant yourself enough time (2 months or more)

Important Information

NO RETROACTIVE APPROVALS!!!

You must obtain ethics approval before beginning your recruitment and data collection

- Approvals are valid for one year
- Submit an annual report to extend approval or a final report to close the file
- Submit 'Request for Modification' form for approval of modifications to the project (before implementing changes)

HIGHLY RECOMMENDED

Meetings with Protocol Officers

Protocol Officers are available to meet with researchers to provide feedback on applications prior to submission

- After Thesis Committee Approval
- Fill in the application form on eReviews at least 48 hrs prior to meeting
- Schedule at least one week before submission deadline

3. General Ethics Application for a Research Project

Section 1: Project Description

- Section 1.1: Describe your research project (include clearly defined purpose, objective, and/or questions)
- Section 1.2: Situate the project in relation to the literature (i.e., what has been done, what do we know, links to present project, pertinence of research purposes, theoretical or conceptual framework)
- Section 1.3: Present an overview of the project in a general manner (briefly explain the methodology: what?, when?, with who?, how many?, etc - no need to discuss the recruitment and consent processes)

Section 2: Recruitment of Participants

- Section 2.1: Describe population from which sample will be recruited (i.e., gender, language, age, years of experience, organization, type of position, etc.) and ensure that all inclusion/exclusion criteria are included in all recruitment texts
- Section 2.6: Permissions

  You need to commit yourself to obtaining all required permisions before starting your research

  - Hospitals: Most institutions have their own ethics review process
  - Schools: Mandatory permission from school boards is required (or written confirmation that it isn't)
  - Organizations, associations or groups: If conducting critical research and permission is refused, inform participants in the consent form

Section 2: Recruitment of Participants

- Section 2.7: Local ethics approval: For research conducted outside Canada, local ethics approval should be obtained if there is a REB or other responsible review body or bodies at the research site. If there is no REB or review body, the researcher should describe the steps taken to have the information (Article 8.3).
- Section 2.10: Describe in detail the recruitment process: How will participants be identified?, How will participants be invited (telephone, in-person, via email)?, How will you obtain their contact information - All types of recruitment texts must be submitted (telephone script, letter of invitation, poster, etc)

SECTION 2: RECRUITMENT OF PARTICIPANTS

3.9 Describe how participants will be recruited. Please note that if participating organizations are being asked to distribute a recruitment invitation to potential participants, the researcher's contact information must appear on the recruitment invitation so that potential participants can contact the researcher directly.

Please append copies of all recruitment posters, advertisements, telephone scripts, letters of information, etc. that will be used for recruitment purposes.

> Recruitment will be done through the personal networks of the two researchers in the two communities and through a process of snowball sampling.

- Section 2.10: Please explain in more detail how recruitment will be conducted.
- Please explain how contacts from personal networks will be approached, how they will be identified, how the researchers will ensure that there is no coercion, etc.
- Please explain how snowball sampling will unfold, including who is the initial contact, how will other participants be invited to participate, etc.

SECTION 3: PARTICIPATION

- Section 3.1: Describe in detail the participation:
  - What will participants be asked to do? How many times? For how long?
  - All data collection instruments must be appended
  - While we are not evaluating the methodology of the project, we need to consider the ethical implications for the participants (e.g., Is what is being asked of participants feasible and/or appropriate?)

SECTION 3: PARTICIPATION (CONT'D)

- Section 3.6: Use of audio-recording (if yes, include in consent form). If participants are given the choice, such options/check boxes/initials must be provided in the consent form)
- Section 3.7: Use of video-recording (i.e., analysis purposes, future presentations, etc). If yes, include in consent form. (If preference is given, such options/check boxes/initials must be provided.)
- Section 3.8: If compensation is provided, and a participant chooses to withdraw from the study, they are entitled to receive compensation. (Compensation details must be included in the consent form.)

Section 4: Assessment of Risks

- Sections 4.1:
  - Risks described in application form must be consistent with those listed in the consent form
  - Explain how you will minimize potential risks
  - External resources may be required (if necessary - depends on context)
- Sections 4.3:
  - What is your experience with this topic and/or population? How will it help you manage potential situations?

SECTION 5: PRIVACY

- Section 5.1:
  - Direct and/or indirect identifying information that will be obtained during data collection as well as during recruitment and consent process.
  - Protection of anonymity.
  - Situations in which anonymity and/or confidentiality are not or cannot be protected (choice of participant, focus group discussion, etc.).

SECTION 6: CONSERVATION OF DATA

- Section 6.2:
  - Who will have access to the data?

  If research assistants, interpreters, translators or transcribers are involved they should sign a confidentiality agreement if they do not sign the application form.

- Sections 6.4 to 6.8:
  - How will the data be securely stored during the study and during the conservation period?

Section 7: Obtaining Informed Consent

- Section 7.1: Explain how and when consent will be obtained (participants will be able to ask questions before signing the consent form)
- Section 7.2: If written consent will not be obtained, explain how verbal consent will be documented (e.g., audio-recorded, field notes) and confirm that participants will receive either a copy of the consent form
- Consent form templates are available on the Office of Research Ethics and Integrity website. You are strongly advised to use or consult it.

No third-party or witness section on consent form

Consent Form (*template*)

If printed, the consent form must be on University of Ottawa letterhead.

Note: *the consent form provided below is merely a template; the researcher should adapt the form to accurately reflect her/his research project and remove italicized text in the final version.*

Title of the study:.....

Name of researcher* *(and of supervisor*, as the case may be)*, along with his affiliation *(Department, Faculty, Institute)* and coordinates *(namely, telephone numbers and email addresses)*.

** Note: There may be more than one researcher; the singular and the masculine gender have been used to simplify the text.*

Invitation to Participate: I am invited to participate in the abovementioned research study conducted by *(name(s) of researcher(s), or of student researcher(s) and supervisor(s), as the case may be). (If the project is funded, indicate the funding source)*.

Purpose of the Study: The purpose of the study is to *(clearly indicate the aim of the study, its purpose and objectives, in a language that participants are able to comprehend using a grade 8 reading level)*.

Participation: My participation will consist essentially of *(example: attending sessions)(give the number of sessions and length of time of each session/intervention)* during which *(description of tasks that the participants will have to perform). (The sessions)* have been scheduled for *(place, date and time of each session)*. I will also be asked to *(examples: complete questionnaires, participate in interviews or focus groups, etc.; be very specific and include the duration of each activity)*.

Risks: My participation in this study will entail that *(example: I volunteer very personal information,* and this may cause me to feel *(describe potential risks or inconveniences, whether emotional, psychological, physical, social, economic or other)*. I have received assurance from the researcher that every effort will be made to minimize these risks *(describe what measures are taken to minimize such risks)*.

Benefits: My participation in this study will *(explain how the participation will benefit the participant, society and/or how it will contribute to the advancement of knowledge)*.

Confidentiality and anonymity: I have received assurance from the researcher that the information I will share will remain strictly confidential. I understand that the contents will be used only for *(purposes for which the collected data will be used)* and that my confidentiality will be protected *(explain how the confidentiality will be protected). (If yours is a study where the protection of confidentiality may be breached because of a legal obligation, please indicate this in the consent form and explain the reason). (In cases where data collection is done via email / Internet, and particularly where the topic is personal or involves risk, please include the following sentence (or a similar one, as it applies to your project)* "In order to minimize

4. Secondary Use of Data

Secondary Use of Data Research

- The application is adapted for research using data originally collected for purposes other than the current research project
- Examples:
  - Datasets that are collected for specific research or statistical purposes, but then re-used to answer other research questions
  - Information initially collected for program evaluation
  - Health care records, school or criminal records, statistics registries or unemployment records, all of which are originally created or collected for therapeutic, educational or administrative purposes, but which may be sought later for use in research

5. Exemptions of Ethics Review

RESEARCH EXEMPT FROM REB REVIEW

Article 2.2: Research that relies exclusively on publicly available information:

a. The information is legally accessible to the public and appropriately protected by law; or

b. The information is publicly accessible and there is no reasonable expectation of privacy

- Examples: National Library documents, interview which has appeared on TV, Statistics Canada data, published documents, etc

Research Exempt from REB Review

- Article 2.3: Research involving the observation of people in public places where:
  a. It does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups
  b. Individuals or groups targeted for observation have no reasonable expectation of privacy
  c. Any dissemination of research results does not allow identification of specific individuals
- Limitations for online based observations (e.g., social media)

Useful Links

- Office of Research Ethics and Integrity
  http://www.research.uottawa.ca/ethics/index.html
- Ethics application forms
  http://research.uottawa.ca/ethics/submission-and-review
- Tri-Council Policy Statement
  http://www.pre.ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html
- FGPS - Preparing a Thesis or a Research Paper: A Guide for Graduate Students and Supervisors
  http://www.grad.uottawa.ca/Default.aspx?tabid=1381