

July 2017

uOttawa

Office of Research Ethics and Integrity

[INTERNAL GUIDELINES AND PROCEDURES]

The guidelines and procedures described herein are based on the Tri-council Policy Statement (2014) regulations as well as the University of Ottawa policies. The information in this document may not be inclusive and may be modified to address context-specific situations.

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SECTION 1 – APPLICATION SUBMISSION AND REVIEW PROCESSES

Article 1.1: REB representation

There are two Research Ethics Boards (REB) at the University of Ottawa. Each one complies with the TCPS 2 requirements regarding composition. The Social Sciences and Humanities REB evaluates all research projects originating from the Telfer School of Management, and the Faculties of Arts, Education, Law and Social Sciences (except School of Psychology). The Health Sciences and Science REB evaluates projects originating from the Faculties of Engineering, Science, Health Sciences, the Institute of Population Health and the School of Psychology. Research projects affiliated to the Faculty of Medicine are evaluated by their respective hospital's REB. *[Last approved on August 23rd, 2013]*

Article 1.2: Dates of submission for new standard applications

Standard applications must be submitted for research projects involving direct contact with human participants, if they have not been previously approved by another Canadian REB. Standard applications for initial review (that do not meet the criteria for Secondary Use of Data, Course Outline or Expedited review) are to be submitted to the Ethics Office on the first business day of the month and will be evaluated by the REB that same month. Within three days following the submission deadline, an acknowledgement of receipt will be sent to the researchers. Note that the REB does not review ethics files in July, including both initial reviews (new submissions, expedited reviews) and ongoing reviews (requests for modifications). *[Last approved on July 6th, 2017]*

Article 1.3: Timelines for submitting feedback to researchers

The REB's comments and feedback are compiled and sent to the researchers via email within the following timelines, which begin following the email of acknowledgment sent by the Ethics Office *[Last approved on March 24th, 2017]*:

- Full board review: 6 weeks or more
- Minimal risk review: 4 to 6 weeks
- Expedited review: 2 to 3 weeks
- Secondary use of data review: 2 to 3 weeks
- Course outline review: 2 to 3 weeks
- Administrative review: 1 week
- Modification requests: 2 to 3 weeks

Article 1.4: Deadline for researchers to respond to the REB feedback

Researchers have six months to respond to the REB feedback. If, after six months, a response has not been received, the ethics file will be closed. *[Last approved on November 26th, 2012]*

Article 1.5: REB decisions

Following the submission of an application for ethics approval and its evaluation by the REB, one of the following decisions may be issued [*Last approved on July 14th, 2014*]:

- a. *Approved*: The project is approved and an ethics certificate is emailed to the researcher. Recruitment and data collection may begin as outlined in the application.
- b. *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. Once the ethics certificate is issued and sent to the researcher, recruitment and data collection may begin as outlined in the application. If multiple approvals are needed, once approval is obtained for one site and submitted to the Ethics Office, a certificate of partial ethics approval will be issued so that recruitment and data collection may begin at that specific site.
- c. *Revisions required*: The project requires some clarifications/revisions. The REB will provide the researcher with written feedback outlining its concerns. Ethics approval will be granted and an ethics certificate issued once the feedback has been satisfactorily addressed.
- d. *Resubmission required*: There are major ethical concerns or the file is deemed incomplete by the REB. The project cannot be approved as submitted and a complete resubmission of the file is required. The REB will provide the researcher with a summary of the concerns, along with an invitation to meet with the REB, its Chair and/or a Protocol Officer to discuss the concerns. Following this meeting, a complete revised ethics application (including appendices) must be submitted for evaluation by the REB.
- e. *Refused*: Ethics approval of the project is refused following a full board review. The REB will provide the researcher with the reasons for the refusal.

Article 1.6: Ethics Certificates, Annual Reports and Final Reports

Upon granting full or partial approval, an ethics certificate (PDF version) is issued via email. At this time, recruitment and data collection may begin as outlined in the application. Generally speaking, ethics approval applies for one year. An Annual Status Report must be submitted for ongoing projects, and renewals also apply for one year. A maximum of four renewals may be granted for one same project for a total of five consecutive years, starting on the initial date of approval. Note that any modification to the project must first be approved by the appropriate REB before the changes can be implemented. [*Last approved on June 17th, 2014*]

Article 1.7: Process for files having reached the five-year renewal limit

For projects which have received the maximum number of renewals, a new standard ethics application must be submitted for REB review if the project is still ongoing. All standard submission procedures and deadlines apply to this application. When resubmitting an application in this context, researchers should include a cover letter outlining the current status of the project and clearly indicate in the updated application form which parts of the project have already been completed and which are still ongoing.

This resubmission procedure does not apply for projects for which the primary REB review was done at another TCPS2-compliant institution and for projects based on Secondary Use of Data. *[Last approved on January 27th, 2015]*

Article 1.8: Final reports for closing an ethics file

When there is no more contact with research participants or to close an ethics file, a Final Report must be submitted to the Ethics Office in order to comply with regulations outlined in the TCPS 2 (Article 6.14). *[Last approved on July 14th, 2014]*

Article 1.9: Eligibility for ethics review for student research projects

In order to submit an ethics application, University of Ottawa students must be registered at the time of submission and have a full-time University of Ottawa Faculty member as the main project supervisor. *[Last approved on July 10th, 2014]*

Article 1.10: Approvals of student projects prior to ethics submission

Students must have submitted their thesis proposal and received approval from their thesis committee (as a form of peer review) prior to submitting their ethics applications to the REB. This ensures that the methodology of a project has been reviewed and approved by the thesis committee, and enables the REB to review the ethical components (which are highly dependent on the approved/chosen methodologies).

Note: This policy was implemented to reduce the number of requests for modifications that were being submitted to the Ethics Office, after thesis committees were requesting changes to the project proposal. Previously, the number of such requests for modifications created a greater workload and longer delays for both researchers and the REB. *[Last approved on October 2nd, 2013]*

In cases where there are no thesis committees or formal approval procedures, a letter signed by the project supervisor indicating that the proposed methodology has been reviewed and approved must be submitted along with the application form. This letter serves to replace the peer-review process of a thesis committee. Note that this applies to the following types of projects: Doctoral thesis, Master's thesis, Master's major research paper, fourth-year undergraduate projects, and independent student projects. *[Last approved on November 5th, 2012]*

Article 1.11: Adding a graduate student to an existing professor research project

In cases where a graduate student is to be added to an existing professor research project as part of their degree requirement, and where no component of the initial project is being changed as a result, a Request for modification form may be sufficient. However, if a new component is added to the project in order to fulfill the thesis requirements of the student, the student may be required to submit a full standard application. *[Last approved on February 4th, 2013]*

Article 1.12: Supervisor responsibility

Professors, in their role as project/thesis supervisors, are considered to be ultimately responsible for the conduct of the research and reporting obligations to the REB. The supervisor(s) must sign all ethics applications submitted (e.g., initial application, requests for modification, and Annual/Final Reports), as an indication that they have read and approved the information included therein. Supervisors will be copied on all communications regarding the project. *[Last approved on May 23rd, 2014]*

Article 1.13: Eligibility for expedited review

In line with Articles 6.12 and 8.1 of the TCPS 2, a project that is not above minimal risk and has been approved by a TCPS 2 compliant REB may be eligible for an expedited review at the University of Ottawa. However, eligibility for expedited review remains at the discretion of the REB and/or Ethics Office. Note that in cases where initial approval was obtained through a full board review by the other TCPS 2 compliant REB, a full board review is required at the University of Ottawa. *[Last approved on November 26th, 2012]*

Article 1.14: Eligibility for administrative review

When projects are conducted (including recruitment, data collection/analysis/storage) entirely at affiliated hospitals but a member of the research team is a University of Ottawa researcher (excluding from the Faculty of Medicine), applications must be submitted to the University of Ottawa for an administrative review (conducted by the Director of the Ethics Office) once full approval has been obtained from the hospital's REB. Projects may also be eligible for administrative review in cases where some data (excluding samples) are to be conserved on the University of Ottawa campus. For these types of review, the University of Ottawa will accept the documentation from the affiliated hospital REB as a project submission. Affiliated hospitals include: The Ottawa Hospital (TOH), the University of Ottawa Heart Institute (UOHI), the Ottawa Hospital Research Institute (OHRI), the Children's Hospital of Eastern Ontario (CHEO), The Royal and the Institute of Mental Health Research (IMHR), Hôpital Montfort and Institut de Recherche de l'Hôpital Montfort (IRHM) and Bruyère Continuing Care. *[Last approved on January 22nd, 2016]*

Article 1.15: Course Outline ethics applications

For courses requiring students to conduct small research projects within the context of the course, the instructor must obtain ethics approval before the projects begin. Research projects for course outlines must not be above minimal risk. Instructors should contact the Ethics Office if they are uncertain about the risk level of these projects. *[Last approved on January 14, 2013]*

Article 1.16: Ethics review for directed reading/studies

When students are conducting a research project as part of a directed reading or studies course, a full standard application must be completed and submitted, given that course outline applications are not sufficiently detailed for such projects. These applications are eligible for expedited review and must not be above minimal risk. *[Last approved on January 16th, 2015]*

Article 1.17: Type of review for projects involving children

Projects that involve children may be reviewed as minimal risk or undergo a full board review depending on the nature of the research. Regardless of the age group, a proportionate approach to assessing the ethical acceptability of the research, at either level of review, involves consideration of the foreseeable risks, the potential benefits and the ethical implications of the research. *[Last approved on April 23rd, 2013]*

SECTION 2 – GENERAL ETHICS GUIDELINES

Article 2.1: Requirements for conducting draws as compensation

If compensation is offered to participants in the form of a draw, specific information must be included in the consent form as required by Ontario law. A template is available for researchers to consult in order to ensure that all requirements are included (<http://research.uottawa.ca/ethics/guidelines/draws>). *[Last approved on February 1st, 2012]*

Article 2.2: Age requirements for participating in draws

There is no age limit/requirement to be eligible for participation in draws in Ontario. All participants, regardless of age, must provide informed consent prior to their involvement in the project, at which time, their consent makes them eligible to the draw, if they so choose to participate in it. *[Last approved on April 30th, 2012]*

Article 2.3: Research projects conducted in class

The REB recognizes that research projects conducted in class can have pedagogical value to students, when these are in line with the course objectives and content. In such instances, the researchers requesting to use class time to collect their data must demonstrate that participation in their research projects contributes to student learning and/or academic goals. Additional important considerations when conducting in-class research revolve around ensuring free and informed consent of students, as well as minimizing the risk of coercion and the possibility of deception.

When professors seek to conduct their research as part of their course curriculum with their own students, additional considerations include but are not limited to: outlining the research components in the course syllabus, obtaining consent from students in a way that eliminates perceived coercion and only accessing data once grades are finalized. *[Last approved on July 9th, 2012]*

Article 2.4: Using student email addresses for recruitment purposes

For privacy reasons, researchers should not have access to students' email addresses (i.e., professors should not divulge students' personal email addresses), nor should academic listservs be used as a means to recruit students. In such instances, other alternatives (i.e., in-class presentations, post-class flyer distribution, etc.) should be considered. Note that should academic listservs be used, a letter of permission from the Dean must be submitted in order for this recruitment strategy to be considered by the REB. Researchers wanting to recruit students from the Faculty of Medicine must obtain approval from the Vice-Dean, Undergraduate Medical Education. *[Last approved on September 17th, 2012]*

Article 2.5: Need for parental consent

In order for persons to be able to freely consent to participate in research, they must have the capacity to understand the purpose, as well as the risks and benefits of the project. The need for obtaining parental consent is therefore not solely determined by a child's age but rather by the context of each project.

Factors to be considered include, but are not limited to: the characteristics and age of the participants, the nature of the research, the research setting (e.g., schools), the level of risk and provincial legislation related to legal age of consent. *[Last approved on February 21st, 2013]*

Article 2.6: Postsecondary students and capacity to consent

Postsecondary education students (including those under 18) are considered to hold the capacity to give informed consent, and therefore parental consent does not need to be obtained for this group. *[Last approved on July 10th, 2014]*

Article 2.7: Minimum requirements for recruitment documents

At a minimum, the following items must be included in all types of recruitment documents: (a) name of Principal Investigator, (b) contact information of research team member, including an institutional email address, (c) theme/topic of the research project, (d) overview of participation details, and (e) inclusion and selection criteria. Note that at the discretion of the REB, additional information may be requested. *[Last approved on June 3rd, 2014]*

Article 2.8: Use of "uottawa.ca" email addresses

For University of Ottawa-affiliated researchers, all email communication with participants should be conducted through the researcher's "uottawa.ca" email address. This email address should also be provided on all documents distributed and/or accessible to potential participants, including recruitment and consent documents. *[Last approved on June 3rd, 2014]*

Article 2.9: Research via the Integrated System for Participation in Research (ISPR)

The School of Psychology has developed and created an Integrated System for Participation in Research for students in their School as well as other units. The ISPR was created to expose students to different topics and different types of research methodology, including laboratory research, and to facilitate contact between students and researchers. In order to obtain points, students can participate in research activities or choose an alternative activity (e.g., viewing a film). Guidelines for using the ISPR system can be found on the School's website at: <http://socialsciences.uottawa.ca/psy/ispr-researcher-info>.

Recruitment: In their ethics applications, researchers using ISPR must include the text that will appear to inform students about their research (i.e. the study description).

Compensation/Incentives: Students recruited via the ISPR can earn up to four percent of their course grade based on a total of four participation points by participating in research studies, and/or by viewing films of research methods. **The number of points offered for participation must be indicated on the consent document.** Additional compensation (e.g., money, draws) is not allowed, given it isn't possible to provide an equivalent alternative for potential participants. In the case of multi-phase studies where a subsequent phase occurs outside the ISPR, the REB evaluates the appropriateness of the compensation

based on the relevant TCPS 2 guidelines (see TCPS 2, Chapter 3 – The Consent Process). *[Last approved January 21, 2016]*

Article 2.10: Compensation for withdrawal

If compensation is offered to participants, individuals who choose to withdraw from the study should still receive the compensation. This information should be included in the consent form. *[Last approved on July 10th, 2014]*

Article 2.11: Demographic questions on sex and gender as part of data collection instruments

In order to respect the dignity of all individuals when collecting data on sex and gender, the Ontario Human Rights Commission (OHRC) recommends that persons should be given the opportunity to self-identify their gender beyond the binary male/female options. For example, the option of a blank box or the option “You don’t have an option that applies to me. I identify as (please specify) _____” are considered most inclusive. The REB asks that researchers take this into consideration when designing their data collection instruments (e.g., a blank box or additional options vs. only male/female check boxes). For more information: <http://www.ohrc.on.ca/en/policy-preventing-discrimination-because-gender-identity-and-gender-expression> . *[Last approved on June 23rd, 2014]*

SECTION 3 – PERMISSIONS AND APPROVALS

Article 3.1: Conducting research in countries with travel advisories

The Office of Risk Management has set in place a procedure for approval of travel to countries with travel advisories in effect. It is suggested that researchers contact them in order to determine if any special procedures and/or permissions are required. *[Last approved on June 17th, 2014]*

Article 3.2: Determining need for international permissions and approvals

In line with Article 8.3 of the TCPS 2, given that permissions/approvals vary from one country to the next and from one international organization to the next, the REB typically suggests that researchers provide written confirmation (i.e., website link, policy document, or email correspondence) to determine if local ethical clearance from selected countries is necessary. If no written confirmations are available, researchers are asked to provide a written account of the measures that were taken to determine if research permits and/or permissions are required. *[Last approved on May 23rd, 2014]*

Article 3.3: Ethics approval for multisite projects

When conducting multi-site projects, researchers should verify with the other REBs as to the necessity of obtaining additional ethics approvals at these sites. If multiple approvals are needed, once approval is obtained for one site and submitted to the Ethics Office, partial ethics approval may be granted so that recruitment and data collection may begin at that specific site. Note that copies of all ethics approvals must be submitted and added to the uOttawa Ethics file before full ethics approval can be granted. *[Last approved on August 21st, 2012]*

Article 3.4: Invasive procedures and/or scientific equipment involving direct or indirect contact

When methodologies involve invasive procedures, researchers must contact the University of Ottawa's Office of Risk Management in order to determine if permissions are required for the protocol or the person performing the procedure. If permission is required, a copy must be submitted to the Ethics Office before final approval for the project can be granted. *[Last approved on May 22, 2009]*

SECTION 4 – ANONYMITY, CONFIDENTIALITY, AND PRIVACY

Article 4.1: Using American servers to host online surveys

Generally, the REB suggests that researchers conducting online surveys use a Canadian server rather than an American one, as this would prevent the data from being subject to the Patriot Act of the United States of America. If the survey is hosted through an American company, the data could be subject to the U.S. Patriot Act, which allows American authorities access to it. Researchers should consider whether the data collection method poses any risks to participants' confidentiality and any such risks must be explicitly stated in the consent document. *[Last approved on June 24th, 2011]*

Article 4.2: Confidentiality statement for use of Internet/email in a project

In cases where data collection is done via email/Internet, and particularly where the topic is personal or involves risk, the following statement (or a similar one, as it applies to the project) should be included in the consent form: "In order to minimize the risk of security breaches and to help ensure your confidentiality we recommend that you use standard safety measures such as using a secure connexion when completing the study and signing out of your account, closing your browser and locking your screen or device when you are no longer using it / when you have completed the study." *[Last approved on May 26th, 2014]*

SECTION 5 – DATA CONSERVATION

Article 5.1: Data conservation for student projects

As per the University of Ottawa's Faculty of Graduate and Postgraduate Studies guidelines, a copy of all original data should be securely stored on campus (e.g., supervisor's office) during the full conservation period. Typically, data should be conserved for a minimum of five years. (For more information: <http://www.grad.uottawa.ca/Default.aspx?tabid=1385>.) [Last approved on June 11th, 2013]

Article 5.2: Safeguarding of data during the conservation period

According to the TCSP 2 (Chapter 5), researchers shall assess privacy risks and threats to the security of information for all stages of the research life cycle, and implement appropriate measures to protect information. Security measures should take into account the nature, type and state of data: the data's form (e.g., paper or electronic records); content (e.g., presence of direct or indirect identifiers); mobility (e.g., kept in one location or subject to physical or electronic transport); and vulnerability to unauthorized access (e.g., use of encryption or password protection). Measures for safeguarding information apply both to original documents and copies of information. [Last approved on September 25th, 2012]

Article 5.3: Data conservation for Course Outline approvals

Data collected as part of a course must be conserved by the professor for one year following the submission of final grades for this course. [Last approved on February 11th, 2013]