October 2018

# 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

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**Article 1.1: REB representation**

There are two Research Ethics Boards (REB) at the University of Ottawa., both of which comply 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, and Health Sciences, Medicine and the School of Psychology. *[Approved August 2013; Revised January 2018]*

**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 for projects that do not meet the criteria for Secondary Use of Data, Course Outline or Expedited review are to be submitted by the first business day of the month in order to 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). *[Approved June 2014; Revised July 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 *[Approved November 2012; Revised March 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
- Annual and Project Closure requests: 1 to 2 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. *[Approved November 2012]*

**Article 1.5: REB decisions**

Following the submission of a request for ethics approval and its evaluation by the REB, one of the following decisions may be issued *[Approved July 2014]:*

a. *Approved*: The project is approved and an ethics certificate is issued. Recruitment and data collection may begin as outlined in the request form.

b. *Approved – Partial*: Part of the project is approved (recruitment and data collection may begin for that specific part) but the other part of the project requires additional review and/or documentation, which will need to be addressed further, before approval for the full project can be granted.

c. *Additional permissions/approvals required*: All ethical issues are addressed but additional permissions or approvals must be added to your ethics file before approval can be granted. Once the ethics certificate is issued, recruitment and data collection may begin as outlined in the request form. If multiple approvals are needed, once approval is obtained for one site and added to the ethics file, a certificate of partial ethics approval will be issued so that recruitment and data collection may begin at that specific site.

d. *Revisions required*: The request form requires some clarifications/revisions. The REB will provide the researcher with feedback outlining its concerns. Ethics approval will be granted and an ethics certificate issued once the feedback has been satisfactorily addressed.

e. *Resubmission required*: There are major ethical concerns or the request form is deemed incomplete by the REB. The project cannot be approved as submitted and a complete resubmission of the request 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.

f. *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 is issued. At this time, recruitment and data collection may begin as outlined in the request form. 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. *[Approved June 2014]*

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

Projects which have received the maximum number of renewals must be submitted for review if the project is ongoing. 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. *[Approved January 2015; Revised October 2018]*

**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 in order to comply with regulations outlined in the TCPS 2 (Article 6.14). *[Approved July 2014]*

**Article 1.9: Eligibility for ethics review for student research projects**

In order to submit a request for ethics review, 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. *[Approved July 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. *[Approved October 2013]*

In cases where there are no thesis committees or formal approval procedures, a copy of the "Supervisor Form - Confirmation of Methodology" signed by the project supervisor must be submitted along with the request. This form 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. [*Approved November 2012; Revised May 2017]*

**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 new request form for his or her project. *[Approved February 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 requests, requests for modification, and Annual/Final Reports), as an indication that they have read and approved the information included therein. Supervisors will be included in all communications regarding the project. *[Approved May 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. *[Approved November 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), request forms 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 respective 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. *[Approved January 2013; Revised January 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 student 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. *[Approved January 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 new standard request form 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. *[Approved February 2013; Revised January 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. *[Approved April 2013]*

**Article 1.18: Permission for recruiting uOttawa Faculty of Med Students**

Researchers working on a project in which students from the Faculty of Medicine will be recruited as participants must first obtain approval from the Faculty of Medicine to conduct the project. This approval must be obtained before an ethics application can be submitted for review by the uOttawa REB. Please contact Dr. Melissa Forgie or visit the Policies and Procedures website for further details. *[Approved January 2018]*

## SECTION 2 – GENERAL ETHICS GUIDELINES

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**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). *[Approved February 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. *[Approved April 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. *[Approved July 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. Researchers wanting to recruit students from the Faculty of Medicine must obtain approval from the Vice-Dean, Undergraduate Medical Education. *[Approved September 2012; Revised October 2018]*

**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. *[Approved February 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. *[Approved July 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. *[Approved June 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. *[Approved June 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 request forms, researchers using ISPR must include the text that will appear to inform students about the research project (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, draw) is not allowed, given it is impossible 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 Chapter 3). *[Approved August 2012; Revised January 2016]*

**Article 2.10: Compensation for withdrawal**

If compensation is offered to participants, individuals who choose to withdraw from the project should still receive the compensation. This information should be included in the consent form. *[Approved July 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. *[Approved June 2014]*

## SECTION 3 – PERMISSIONS AND APPROVALS

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**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. *[Approved June 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. *[Approved May 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. *[Approved August 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. *[Approved May 2009]*

## SECTION 4 – ANONYMITY, CONFIDENTIALITY, AND PRIVACY

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**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. *[Approved June 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." *[Approved May 2014]*

## SECTION 5 – DATA CONSERVATION

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**Article 5.1: Length of data conservation**

As stated in the University of Ottawa's Procedure 29-2, Article 5d), researchers must keep "complete and accurate records of Research Data, methodologies and findings, including graphs and images, in accordance with University Policies and Procedures, Research Sponsors' Policies and/or Requirements, professional and field-specific standards and Applicable Laws in a manner that will allow verification or replication of the work by others". The Office of Research Ethics and Integrity therefore suggests that a copy of all original data be securely stored for a minimum period of five years following the completion of data collection *[Approved June 2013; Revised June 2017]*

**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. *[Approved September 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. *[Approved February 2013]*