POLICY TYPE: ACADEMIC

POLICY TITLE: Research Ethics Board (REB) Policy	POLICY NUMBER: 2P-2006
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RESPONSIBILITY: REB	AUTHORIZATION: Academic Council

A. PURPOSE

St. Mary's University (StMU) is committed to maintaining the highest standards of ethical practice in research involving humans. Recognizing the importance of academic freedom, university autonomy and respect for the dignity and individual rights of each participant, this policy aims to promote the ethical practice of research. This policy has been informed and, in some cases, taken directly from the Tri-Council Policy Statement 2 (TCPS-2): Ethical Conduct for Research Involving Humans (Secretariat on Responsible Conduct of Research, 2018). Faculty, staff and students requiring guidance not available in this policy should reference the TCPS-2.

An electronic copy of this policy along with supporting documents may be found on the StMU website at http://www.stmu.ca/research-ethics/
More information about TCPS-2 can be found at https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html

Affiliated StMU policies include:
St. Mary's University Policy 2A-2003: Statement of Academic Freedom
St. Mary's University Policy 2G-2006: Integrity in Research and Scholarship

B. DEFINITIONS

Ad-hoc Advisor: a person with relevant and competent knowledge and expertise consulted by a research ethics board for a specific review. Not a member of the research ethics board.
Anonymous: information that never has identifiers associated with it (e.g., anonymous surveys). Risk of identification of participants is low or very low.
Minimal Risk: where the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those

aspects of their everyday life that relate to the research.

More than Minimal Risk: where the probability and magnitude of possible harms implied byparticipation in the research is greater than those encountered by participants in those aspects of their everyday life that relate to the research.
Harm: anything that has a negative effect on participant's welfare, broadly construed the nature of the harm may be social, behavioural, psychological, physical or economic.
Participants: individuals whose data, or responses to interventions, stimuli, or questions, are relevant to answering a research question.
Principal Investigator: The Researcher taking overall responsibility for the research project and the main point of contact.
Proportionate Approach: the assessment of foreseeable risk to determine the level of scrutiny a research proposal will receive, as well as the consideration of foreseeable risks, potential benefits, and ethical implications of the research in the context of initial and continuing review.
REB: Research Ethics Board
Research: an undertaking intended to extend knowledge through disciplined inquiry and/or systematic investigation.
Researcher: a StMU faculty, student, or staff member who conducts research with human participants under the auspices of StMU only, not for an external agency. This includes the Principal Investigator.
TCPS-2: Tri-council Policy Statement 2: Ethical Conduct for Research Involving Humans.
University/StMU/the Institution: St. Mary's University
**Many definitions have been taken directly from the glossary of the TCPS-2.

SECTION I

C. SCOPE OF POLICY

1. As per article 2.1 of the TCPS-2, any StMU faculty, student or staff member must apply to the REB before commencing research involving human participants (see Procedures, Part 1). The REB provides reports to the Academic Council of StMU.

D. MANDATE

1. 1.1 The REB shall function independently as the decision-making body of StMU with regards to the ethical acceptability of research involving human participants;

   1.2 The REB shall function impartially and provide a proportionate approach to review;

   1.3 The REB shall ensure that personal information hosted in applications, reviews and records will i) be kept in the confidence of the REB, and ii) meet the standards set out in StMU's 'Institutional Privacy Policy' (6.A – 2008);

   1.4 The REB shall approve, reject, propose modifications to, or terminate proposed or ongoing research involving humans at StMU;

   1.5 The REB shall endeavor to keep current on ethical issues related to research to formulate policy and to educate faculty, students and staff;

   1.6 The REB shall meet regularly to discharge their responsibilities, and keep and maintain minutes of such meetings;

   1.7 The REB shall ensure that outcomes of reviews will be made accessible to researchers, as it pertains to their application;

   1.8 The REB will submit an annual report of submissions and actions taken to Academic Council of St. Mary's University. These reports are accessible to the members of the REB, the Vice-President Academic, the research director of each project, and representatives of any applicable external funding agencies (i.e., NSERC, SSHRC, etc.), as requested by those agencies.

E. SUPPORT

1. In achieving this mandate the REB, as outlined in TCPS-2, requires the support of the University for the following:

   The Vice-President Academic shall insure that faculty members are informed each year about

the need to comply with TCPS-2 and facilitate ongoing faculty education regarding compliance with ethical review standards, as well as the implications of non-compliance.

F. MEMBERSHIP

1. The composition of the REB will be in accordance with Article 6.4 of the TCPS-2. The REB shall consist of:
   - At least five voting members, including both men and women;
   - At least two of the members shall have broad expertise in the methods or areas of research covered by the REB;
   - At least one member will be knowledgeable in ethics;
   - One community member with no formal affiliation with StMU.

   It is advisable that at least one member be knowledgeable in the law. The role of the member knowledgeable in the applicable law is to alert the REB to legal issues and their implications, not to provide formal legal opinions, nor to serve as legal counsel for the REB. The institution's legal counsel cannot be a member of the REB.

2. Important points relevant to REB members:

   - Members will be appointed by Academic Council;
   - The term of member appointments will normally be 5 years in length and staggered to ensure continuity;
   - REB shall elect as Chair an REB member with relevant expertise;
   - The term of the REB Chair is not limited but must be put to election every 3 years;
   - REB shall elect a Vice-Chair from the REB membership
   - The term of the REB Vice-Chair shall last until the end of their appointment;
   - When relevant expertise is necessary the Chair of the REB may invite other appropriate consultants (i.e., legal counsel) to advise the voting members (TCPS-2, Article 6.5);
   - Quorum shall consist of at least 4 members including the Chair, the REB member with ethical expertise, and an REB member with disciplinary expertise relevant to proposals under consideration;
   - As per Article 6.5 of the TCPS-2, in the event that the REB is reviewing a project that requires particular disciplinary or methodological expertise not available from its existing members, an ad-hoc advisor, internal or external to StMU, will be consulted;
   - Within the first 3 months of joining the REB new members must have acquired the TCPS-2 CORE online certificate. This will be supervised and recorded by the Chair;
   - Irregular participation the REB may result in membership being revoked.

G. RESEARCHERS

1. A. Researchers themselves are first responsible for determining the advisability of requesting an ethics evaluation for research. Whenever there is uncertainty with regards to the

relevance of such an evaluation, they must consult the REB.

B. Researchers, or faculty supervising student research projects, who are conducting research with human participants are required to complete the TCPS-2 CORE online certificate (starting July 1st, 2021).

C. Ensuring a high standard of ethical practice in research is primarily the responsibility of researchers, whether faculty, staff, or students. StMU also has a collective responsibility to ensure and enable ethical research and to hold each other accountable for meeting these standards.

D. Researchers must be honest in proposing, seeking support for, conducting, and reporting research; researchers must respect the rights of others in these activities. This applies to all those conducting research at or under the aegis of StMU. It is incumbent upon all members of the university community to practice and to promote ethical behavior.

E. StMU requires that all researchers adhere to this policy. Noncompliance is a serious offence, subject to penalties including but not limited to formal written notification and documentation, withdrawal of privileges to conduct research involving humans, and/or disciplinary action. In the case of failure by StMU researchers to comply with this policy the Chair will give notice to the researcher, in writing that a) the research in question stop, (TCPS-2, Article 6.3) and that b) the case has been reported to the office of the Vice-President Academic. In cases where researchers not affiliated with StMU collect data or recruit participants within StMU jurisdiction without an “approval” ruling from the StMU REB, the StMU Chair will demand they stop collecting data and may contact their governing REB or line manager to report the case.

F. Researchers shall safeguard information entrusted to them and not misuse or wrongfully disclose it. The university shall support researchers in maintaining promises of confidentiality (TCPS-2, Article 5.1).

G. In preparing applications for review by the REB, researchers must “present the proposed research in the context of a systematic review of the literature on that topic. The systematic review should be carried out according to professional standards of the relevant disciplines(s) or field(s) of research” (TCPS-2, Chapter 11, A).

SECTION II

H. REVIEW

1. Research undertaken by StMU researchers in which humans participate, including research involving human remains, tissues, or biological fluids, must receive ethics approval from the StMU REB prior to recruiting participants, collecting or accessing data. This includes pilot studies, but not necessarily the exploratory phases of research (TCPS-2, Articles 2.1 & 6.11).

2. Due to the limited resources of the StMU REB this body will only review applications where the research is conducted by StMU researchers acting in their University capacity. This would exclude, for example, industry/privately sponsored research, wherein StMU researchers receive a salary from said industry/private enterprises. This differs from research supported by project funding agencies that provide university-based researchers with grants that enable them to conduct research.

3. A. The REB distinguishes between two levels of research ethics review based upon a proportionate appraisal of risk wherein the level of scrutiny will be commensurate with the level of risk.

   - *Full REB Review* - involving all members of the REB, this is the default level of review for research involving humans.
   - *Delegated REB Review* – involves only the Chair (or Vice-Chair or other Designate) where delegated review is deemed appropriate.

   The assignment to either full or delegated review involves consideration of foreseeable risks, the potential benefits, and the ethical implications of the research (TCPS-2, Article 2.9). In addition, the REB will only evaluate and comment on the scholarly standards of a research proposal to the extent that these elements are relevant in assessing ethical standards. General scholarly standards are reviewed by the REB or, where appropriate, an REB member with design and methodological expertise in the research area (TCPS-2, Article 2.7). In the case where no REB member has the necessary expertise the REB will consult an ad-hoc advisor with the relevant scholarly expertise.

   B. The REB Chair assigns level of review based upon information provided in the application, paying particular attention to the degree of research risk and the vulnerability of participant circumstances (see Procedures - Part 2). To evaluate this risk, the REB Chair considers the probability and magnitude of harms participants may experience as a result of the proposed methods to be used and types of data to be collected, the physiological or health issues such as clinical diagnoses or side effects, cognitive or emotional factors such as stress or anxiety during data collection, and socio-economic or legal ramifications such as stigma, loss of employment, deportation, or criminal investigation. This is done while considering the pre-existing vulnerabilities associated with proposed participant

groups, e.g., relating to pre-existing physiological or health conditions, cognitive or emotional factors, and socio-economic or legal status. The matrix below is used to aid the REB Chair to discriminate the necessary level of review.

Vulnerability	**Research Risk**		
	Low	**Medium**	**High**
Low	Delegated	Delegated	Full
Medium	Delegated	Full	Full
High	Full	Full	Full

4. A. It is important to note that a variety of additional factors might also lead to an application being escalated to full review, for instance, if the project is unusual, complex, or large scale, there could be an increased probability of harm and need for close review.

   B. For full reviews, the REB will attempt to reach its decision by consensus. In the event when consensus is not possible, a decision can be made by majority vote. In the event of a tie vote, the matter under consideration will be deemed to have not passed.

5. The REB notes that certain types of research, particularly in the social sciences and the humanities, may legitimately have a negative effect on public figures in politics, business, labour, the arts or other walks of life, or on organizations. Such research should not be blocked through the use of harms/benefits analysis or because of the potentially negative nature of the findings. The safeguard for those in the public arena is through public debate and discourse and in extremis, through action in the courts for libel.

6. For applications that have been submitted to the REB which the REB has requested additional information or clarification, the researcher has 30 days to reply or their application will be closed and the researcher will be required to submit a new application to be considered in a future round of applications.

7. Student-led research is supervised by a Faculty member, usually as part of a capstone/honours degree requirement (thesis or equivalent research projects), and may require an ethics application to the REB. This is different from course-based student research activities which

are intended solely for pedagogical purposes (TCPS-2, Article 2.1 & 6.12). Ethics review of such course-based research activities may be delegated to the responsible StMU faculty member (see Procedures- Part 3). Ethics review of minimal risk course-based research activities with a primarily pedagogical purpose are often delegated to faculty/non-REB members as, "(such) pedagogical activities are normally required of students (at all levels) with the objective of providing them with exposure to research methods in their field of study (e.g., interviewing techniques). If these activities are used for the purposes of research (e.g., as part of a researcher's own research program), they should be reviewed by the regular institutional REB procedures" (TCPS-2, Article 6.12).

I. EXCEPTIONS TO REVIEW

1. All research that involves living human participants requires review and approval by the REB in accordance with this policy before research is started except as stipulated below:

   A. Researchers in the exploratory phase do not need to seek REB review. This refers to researchers who are making contact with individuals, communities or organizations with intention of establishing research partnerships or to inform the research design, not to collect data related to a research question.

   B. REB review is not required for research about any living individuals involved in the public arena and based exclusively on information that is legally accessible to the public, or information that is publicly accessible, and where there is no reasonable expectation of privacy (TCPS-2, Article 2.2). Such information includes documents, records, publications, works, performances, archival materials or third-party interviews, either in print, digital or cyber format. Such research only requires ethics review if the participant is approached directly for interviews, for access to private papers, or if the information is gathered from publicly accessible digital sites where there is reasonable expectation of privacy, such as sites with restricted membership. In addition, if the data links different sources of publicly available information resulting in new forms of identifiable information, and thus raising privacy and confidentiality concerns, the research requires REB review.

   C. REB review is not required for research involving the observation of people in public places (TCPS-2, Article 2.3) when this research does not involve a staged environment, or an interaction or intervention on the part of the researcher, when individuals have no reasonable expectation of privacy, and/or when the dissemination of the research does not identify individuals.

   D. REB review is not required for research that relies on secondary use of anonymous information, provided the data or results do not generate identifiable data (TCPS-2, Article 2.4).

   E. Data collected for the specific purpose of quality assurance and improvement (e.g., performance reviews, course evaluations, educational testing, etc.). Research conducted on this type of data shall be considered secondary and out of the scope of REB provided it is unidentifiable (TCPS-2, Article 2.5).

J. TERMS FOR RECONSIDERATIONS AND APPEALS

1. In the case where a researcher is not granted ethics approval the following apply:

   A. The researcher may first ask the REB to reconsider their decision and must provide the REB with a written rationale for reconsideration; The REB is responsible for establishing timelines around this process.

   B. If the application was denied based on delegated review it will be reconsidered under full REB Review. Reconsideration will be given on both procedural and substantive grounds.

   C. Where the researcher and REB cannot reach agreement through reconsideration and have exhausted all avenues of deliberation, consultation and advice, the REB must issue a final, written decision. Following this the researcher (now: Appellant) may then submit a written appeal to the University of Calgary (U of C) Research Ethics Appeal Board.

   D. The Appeal Board will be conducted in accordance with the procedures of the University of Calgary (U of C) Appeal Board. See http://www.ucalgary.ca/research/researchers/ethics-compliance/research-ethics-appeal-board

   E. The Appeal Board will notify the Appellant, Chair of the REB and Vice-President Academic of its decision and grounds. Decisions of the Appeal Board will be final.

SECTION III

K. CONFLICT OF INTEREST

1. Conflict of Interest is defined as: a situation in which there is a divergence between the private interest or benefit (financial or otherwise) of a researcher, the researcher's family, the institution, and that researcher's obligations to conduct research ethically such that an impartial observer might reasonably question whether related actions to be taken or decisions made by the researcher would be influenced by consideration of these other interests.

Institutions and Researchers

2. Institutions and researchers have an obligation to ensure that the ethical conduct of research is not compromised by real, potential, or perceived conflicts of interest. All parties (e.g., researchers, administrators, REB members) should act in a transparent manner in identifying and addressing conflicts of interest. Institutions and researchers should ensure that real, potential, or perceived conflicts of interest that may affect research are reported to the REB. This will involve a written disclosure submitted to the REB along with their application, or as soon as the conflict develops during the course of research.

3. In reviewing cases of actual or potential conflict of interest, the full REB shall consider the following:

   A. Where the research is assessed as not having the potential for conflict, the researcher is free to proceed upon receiving notice to that effect from the REB;

   B. Where the research is assessed as having the potential for conflict, but where it is seen that the actual or potential benefits of the research are sufficient to justify proceeding, and would withstand the test of reasonable and independent scrutiny, a suitable method of minimizing and managing the allowed conflicts is to be determined and implemented before the research project may proceed provided participants are informed of the conflict (TCPS-2, Article 7.4);

   C. Where the research is assessed as having the potential of conflict and the actual or potential benefits of the research are NOT sufficient to justify proceeding and the conflict is neither manageable nor able to withstand the test of reasonable and independent scrutiny, the research project may not proceed.

REB Members

4. A. If a full or delegated REB is reviewing research in which a member of the REB has a personal interest in the research under review that member will, for the duration of this review, withdraw from the committee and the REB will find a suitable replacement. This

does not apply in the case where a member of the REB is a supervisor to a student applicant – here the member may stay on the committee to answer questions but may not hold any voting power.

B. In the event that the Chair believes that it is not appropriate to act in a particular application as Chair, he/she will appoint a Designate (normally, the Vice-Chair) to act on the Chair's behalf (e.g., when it is the Chair's application that is under review).

C. This policy supercedes the 2.H-2006 Research and Conflict of Interest Policy.

L. RECRUITMENT

1. Researchers shall not exclude individuals from participation because of their language, religion, race, sexual orientation or identity, gender or age, unless the focus, objective, nature and/or context of the research precludes inclusion (TCPS-2, Article 4.1).

Undue Influence & Coercion

2. Researchers should avoid using their own students or employees, colleagues or subordinates as research participants, as undue influence, manipulation, and subtle coercion can occur in these cases (TCPS-2, Article 4.1).

   If there is reason for including one's own students (i.e., course-based student research, see Section II, H, 7 of this policy), researchers must:

   - Provide a rationale other than convenience for selecting them and must show that the recruitment method does not lead students to think they will be compromised by not participating;
   - Should make sure students are confident that their participation will not influence class standing, grades, or other benefits under the control of the researcher;
   - Shall not use extra credit points as a reward for participating unless the research is closely tied to the course's subject matter, and they should not raise a student's grade inordinately;
   - Should not use class time to recruit participants or complete study instruments unless this is part of the course's subject matter;
   - Shall inform students who might participate about the review process, the rationale for the study, the process of data collection and the researcher's interest.

3. If there is reason to include colleagues or subordinates as research participants, researchers must be able to provide a rationale for selecting them and must show that the recruitment method does not lead colleagues or subordinates to think they will be compromised by not participating.

Incentives

4. Incentives are anything offered to participants, monetary or otherwise, for participation in research. Because incentives are used to encourage participation in a research project, they are an important consideration in assessing voluntariness. Where incentives are offered to participants, they should not be so large or attractive as to encourage reckless disregard of risks, keeping in mind the economic circumstances and vulnerabilities of participants (TCPS-2, Article 3.1). Guardians and authorized third-parties should not receive incentives for arranging the involvement in research of the individual they represent. However, they may accept reasonable compensation on behalf of that individual, as long as this is suitable to the circumstances.

5. Researchers have an ethical duty of confidentiality to participants which includes safeguarding their information regarding the disbursement of financial incentives. Researchers must satisfy the REB that their institutional requirements for reporting the use of funds to pay participants do not impact confidentiality. For example, to satisfy both obligations, researchers may submit a coded list of participants who received incentives/compensation. This would offer a degree of privacy protection for participants while providing an acceptable audit trail for the use of funds. Researchers could then make the code available upon request to third-party auditors (e.g., a sealed envelope containing participant initials or signatures, and dates and amounts of incentive distribution).

M. CONSENT

1. A. Any research that involves human participants requires the free, informed, and ongoing consent of participants. Consent must be obtained prior to participation in the project, anytime a project is changed in a way that may affect participants, and periodically throughout longitudinal projects as approved by the REB. Consent must be given voluntarily and may be withdrawn at any time; participants may also request that their data be withdrawn provided this is possible (i.e., the data is identifiable) (TCPS-2, Article 3.1).

   B. The REB and the researcher must attend to the role of undue influences in gaining consent, wherein voluntary consent may be hampered when the person seeking consent is in a position of power or authority (e.g., employers & employees, teachers & students, etc.), or in a trusting relationship with the potential participant (e.g., professor & student, physician & patient, etc.) (see Section III.L.2). Coercing potential or existing participants invalidates the consent process.

   C. Researchers are responsible for providing potential participants with written (where possible) invitations to the research project that in plain language provides all information necessary to make an informed decision regarding consent. Consent must be given in writing unless cultural or methodological considerations deem otherwise. StMU researchers must use the template provided by the REB.

D. The information generally required for informed consent includes (TCPS-2, Article 3.2) the following:

- An invitation to participate in a research project;
- A description of the purpose of the research;
- The identity of the researcher(s)/sponsor/funder;
- The anticipated duration of participation;
- A description of the procedures involved in research;
- Participant's role and responsibilities;
- A description of risks & potential benefits arising from participation;
- Assurance that there is no obligation to participate in the research;
- Assurance that they may withdraw their consent at any time;
- Clarification about their right to withdraw their data;
- Confirmation of the confidentiality of data and how this will be protected;
- Confirmation of whether or not data will be identifiable;
- A description of any conflicts of interest;
- A description of incentives or compensation;
- How the results will be disseminated;
- Contact details for participants seeking further details;
- Contact details for a REB contact;
- A statement that participants have not waived their rights to legal recourse;

E. The opportunity to keep a copy of the consent form for their records, if this written statement does not compromise participant safety, confidentiality, or cultural standards. As per Article 10.3 of the TCPS-2, research involving observation in natural environments or virtual settings where people have a reasonable or limited expectation of privacy, the researcher must explain the need for an exception to the general requirement for consent. The REB may approve research without requiring that the researcher obtain consent from individuals being observed on the basis of the justification provided by the researcher and appropriate privacy protection.

F. Article 3.3 of the TCPS-2 defines an "incidental finding as a discovery about research participants or prospective participants that is made in the course of research, but is outside the objectives of the research study. Material incidental findings discovered in the course of research must be disclosed to participants by the researcher(s)" (Article 3.4).

Participant Decision-Making Capacity

2. A. Safeguards are necessary to protect the dignity, interests, and integrity of those who are in circumstances that might make them vulnerable or either permanently or temporarily lacking decision-making capacity (e.g., children, the elderly, members of marginal groups, people who are ill, or people with mental or physical disabilities) in the context of research.

B. When seeking free, informed consent from individuals who lack capacity to consent all efforts should be made to assure the following (TCPS-2, Article 3.9):

- Individuals must be given the opportunity to decide, to the greatest extent possible, whether to participate. For example, if a child becomes fussy or irritable during the research all data collection should stop to see if the child is willing to continue;
- Consent must also be sought from authorized representative(s). This must not be the researcher or a member of the research team;
- The research does not expose them to more than minimal risk without the potential for direct benefits for them.

C. Where free and informed consent has been obtained from an authorized third-party, and in those circumstances where the legally incompetent individual acquires/regains decision-making capacity, the researcher must gain consent of the individual as a condition of continued participation.

Alterations to Consent

3. The REB may approve a consent procedure which alters (this includes waiving) some or all of the elements of free and informed consent set forth above provided that the REB files and documents that all of the following have been met (TCPS-2, Article 3.7A):

- The research involves no more than minimal risk to participants;
- The alteration of consent is unlikely to adversely affect the rights and welfare of the participants;
- The precise nature of the alteration is defined;
- The research could not be practicably carried out without the waiver or alteration;
- Whenever possible and appropriate, the participants will be debriefed (TCPS-2, Article 3.7B, also see Section III.O.1.A-C).

4. When a study does depart from the general principles of consent it is noted that:

- Where people who may be experiencing circumstances that make them vulnerable are potential participants there must be greater effort on the part of the REB and the researcher to minimize the risks and/or maximize potential benefits;
- Participants in naturalistic observation studies normally do not give informed consent because they are unaware they are being observed;
- Participants in research involving random assignment and single- or double-blind

procedures must be informed of the probability of being assigned to a particular condition.

N. CONFIDENTIALITY & PRIVACY

1. A. The researcher has an obligation to safeguard entrusted information and use it only for the purpose for which it was given (TCPS-2, Article 5.0). Research participants have a right to privacy and researchers have a corresponding duty to treat private information in a respectful and confidential manner. When reviewing applications for approval, the REB must balance the need for research against infringements of privacy, and invasions of privacy must be minimized as much as possible. The value of privacy of research participants is not absolute: some public interest such as protection of health, life and safety may require infringement of the right to privacy, as may the type of research being conducted. Without access to personal information, it would be difficult if not impossible to conduct important societal research in such fields as epidemiology, history, genetics and politics.

   B. Different cultures will define and exercise privacy in different ways and these values must be respected. The issue of privacy must be looked at from the cultural perspective of the subject, not the researcher. As a general guide, the best protection of the confidentiality of personal information and records will be achieved through anonymity.

   C. Researchers are responsible for ensuring the confidentiality of data on human participants by maintaining such data in secure storage (e.g. locked cabinet/drawer, password protected file) and by limiting access to data to authorized individuals.

   D. The research design must include procedures appropriate to securing the degree of confidentiality guaranteed to the research participant by the researcher, as outlined in the informed consent process.

O. FEEDBACK TO PARTICIPANTS

1. A. As a general principle, participants in human research shall be involved in a debriefing session at the end of their participation in the research (TCPS-2, Article 3.7B).

   B. Often, the debriefing can be quite simple and straightforward. In cases where deception was used, researchers should provide a full explanation as to why participants were misled or given less than full disclosure. In cases where the research may have impacted upon the psychological health or well-being of the participant, it may be appropriate to provide additional follow-up or to offer counseling or other types of assistance.

   C. Immediate full debriefing may not be feasible in all cases, for example where data has been collected over an extended time, debriefing may have to be deferred until the end of the project. In some cases, it may be more appropriate to debrief the parents, guardians or authorized third-parties, or an entire family or community. StMU researchers must consult the template provided by the REB (see website).

P. ONLINE DATA COLLECTION

1. The Internet has many dimensions that can be studied (textual information sites, notices, pictures, archives, online videos, etc.) or used as research tools (email, discussion groups, chate rooms, online questionnaires, online intervention sites, etc.). Researchers using online methods, regardless of type, must demonstrate that they understand the terms of service and privacy policies of the site from which they will be collecting data. In line with current guidance from the TCPS-2 and the Association of Internet Researchers (AoIR, 2012), the REB notes the following points for researchers to carefully consider before pursuing online research:

   A. The Expectation of Privacy: there are publicly accessible digital sites where there is a reasonable expectation of privacy. When accessing information in publicly accessible digital sites, such groups with restricted membership, the privacy expectation of contributors of these sites may be higher and may require REB review.

   B. Informed Consent: where informed consent is necessary researchers must explain how the researcher will use the data they collect from individual users of these sites. For online projects that require longer terms of data collection, researchers must stipulate how informed consent will be maintained during this time.

   C. Contextual Vulnerability: in certain online situations some individuals may be in circumstances that make them more vulnerable than others in the context of research (e.g., social media sites for individuals with eating disorders).

   D. Deception & Debriefing: online research may require deception (to reduce bias), which demands debriefing. Keeping in mind the general guidelines above, researchers must consider if debriefing is even possible, how it can be achieved and if deception/debriefing may be needed for one group vs. another.

2. When considering applications for projects that involve online data collection, the REB recognizes the evolving nature of technology will continually present new methodologies and ethical issues. That said, the REB, at time of this policy's publication, differentiates between online web-based survey tools, internet data collection, and crowd sourcing services.

   A. Online web-based survey tools: Data anonymity and confidentiality are vulnerable when stored outside of Canada, particularly in the USA. Researchers planning to use online survey companies must acquaint themselves with the relevant laws. For example, survey companies that house data in the USA are subject to the US Patriot Act which allows authorities access to the records of internet service providers, thus access to research participants' information. One example of a popular survey provider with information housed in the USA is SurveyMonkey (https://www.surveymonkey.com/). Ideally, Canadian companies with servers located in Canada should be used for survey purposes rather than using online survey companies located outside of Canada. Use of enhanced security features is recommended for identifiable and/or sensitive data. Researchers must ensure that the survey provider they choose has appropriate privacy policies.

B. Internet data collection: Ethics review is not required for "research that is non-intrusive and does not involve direct interaction between the researcher and individuals through the Internet" and "for which there is no expectation of privacy" (TCPS-2, Article 2.2). Examples include uncontrolled public access via the Internet to cyber-material such as documents, records, performances, online archival materials or published third-party interviews. This includes uncontrolled access where there is no login or password required to access the information, video, etc.

However, researchers and the REB must keep in mind that non-intrusive real-world observation of an individual may afford them the freedom and/or knowledge to evade observation; non-intrusive observation of an individual's online presence may not afford the same freedom or knowledge. With this in mind, researchers and the REB must consider the following general guidelines as to whether or not an ethical assessment is required:

- If the medium is public and the information shared is not sensitive. Under those conditions, an ethics board review is not necessary;
- If the medium is public and sensitive information is posted, an ethical assessment is required;
- If the medium is private, an ethical assessment is required.

C. Crowd sourcing services: Online labour markets, known as crowdsourcing or data aggregators, are becoming popular mechanisms for data collection. Crowdsourcing is the act of outsourcing tasks to a large group of people (a "crowd") through an open request via the internet sometimes in exchange for remuneration. Crowdsourcing has become popular among social scientists as a source to recruit research participants from the general public for studies. The primary example is Amazon's Mechanical Turk (MTurk). Researchers using this type of online service must ensure that their research is appropriate to the medium and does not exploit participants.

Q. RESEARCH MAINTENANCE

1. The REB requires all researchers granted ethics approval to submit an annual status report (for projects lasting beyond 1 year) and/or an End of Project report (for projects lasting less than 1 year and for all completed projects). The REB may, at its discretion, request more frequent reports from a researcher at any time. All necessary report templates may be found on the StMU website. Upon submission of an annual report, the REB will come to a decision regarding the continued ethical suitability of the research. Upon submission of an End of Project report the REB will deem the research project closed. (Revival of this project will require another ethics application being submitted to the REB). The StMU REB expects that all researchers will monitor their own research and provide these reports as needed. Principal investigators are responsible for advising the REB of their project status within 3 months of the project's completion. Principal investigators are also responsible for informing the REB, in writing to the Chair, of any adverse effects (undesirable and unintended, although not necessarily unexpected events) arising out of the research (see below).

2. Should a researcher with current ethics approval find that unanticipated issues arise over the course of their research that deviates from the risk stipulated in the approved ethics application or has other ethical implications (see Article 6.15, TCPS-2, 2018) , the researcher must submit a 'Unanticipated Issues form' (available on REB website) to the REB as soon as possible.
3. Should a researcher with current ethics approval wish to make substantive changes to their REB application that may deviate from the risk stipulated in the approved ethics application (see Article 6.16, TCPS-2, 2018) the researcher must submit a 'Proposed Amendments form' (available on StMU REB website) to the REB before instigating any proposed changes.
4. Extensions to approved projects require researchers to submit an 'Extension form' (available on REB website) to the REB at least 30 days prior to the expiration date of their ethics certificate.
5. Researchers and Supervisors must keep the following in mind:

    - The research supervisor of a project holds primary responsibility to ensure that ethical principles are met on an approved project for the duration of the project;
    - The supervisor is accountable to the REB, which has the authority to terminate any project that does not meet ethical standards;
    - In the case of student-led research projects, the supervising faculty member and student are jointly responsible for ensuring that ethical criteria are met;
    - Supervisors must take measures to remind students to submit the necessary report to the REB upon course completion.

R. COLLABORATIVE/MULTI-CENTERED RESEARCH

1. The REB recognizes that research collaboration takes different forms that can involve multiple institutions, REBs, and researchers (see Chapter 8.A of the TCPS-2 for a listing of these forms). Researchers who are the Principal Investigators (see TCPS-2, Chapter 11, section A for more detail) in projects involving other institutions, organizations, countries or jurisdictions, within StMU jurisdiction or under its auspices, irrespective of where the research is conducted (TCPS-2, Article 8.1), must obtain ethics approval from the REB as well as from the other agencies involved in the project.
2. This requirement includes entire or partial research conducted outside of Canada, which must undergo review by the REB and that of the REB/responsible body at the research site (TCPS-2, Article 8.3). Where no REB/responsible body is available at the research site, the researcher must provide to the home REB (TCPS-2, Article 8.4):

    - Their efforts to identify appropriate mechanisms for ethics review at the site;
    - The rules of ethics review and contact information for individuals involved in such review at the site, should they exist;
    - Relevant information about the target population and circumstances that might have a bearing on research ethics review.

3. Should no such mechanisms, rules, contacts, be found, researchers must demonstrate their application of the core principles of this REB policy and that of the TCPS-2 (2018) in a manner that:

   - Is familiar with the norms and practices of the research site;
   - Is respectful of cultural practices;
   - Minimizes risk to individuals and communities.

4. The REB retains the right to communicate any concerns about a multi-centered project with other REBs reviewing the same project (TCPS-2, Article 8.1).

S. RESEARCH INVOLVING DISTINCT COMMUNITIES

Where researchers intend to conduct research involving humans based on their membership in specific communities (e.g., Indigenous, deaf), it is incumbent upon those researchers to consider relevant guidance from Chapter 9 of the TCPS-2 (2018) (see Article 2.11). When submitting an ethics application to the REB, researchers must attach an additional appendix that addresses all of the critical questions outlined in Procedures Part 4 (this has been adopted from Nipissing University, a leader in Indigenous research and education).

T. ETHICS REVIEW DURING PUBLICLY DECLARED EMERGENCIES

1. A publicly declared emergency as defined by the TCPS-2 (Chapter 6.D), is an emergency situation that arises suddenly and due to the extraordinary risks it presents, has been proclaimed as such by an authorized public official (Article 6.21-6.23).

   Research ethics review during publicly declared emergencies may necessitate innovative practices, although this should not override procedures to protect the welfare of participants. Any relaxation of review procedures should be proportionate to the complexity and severity of the emergency, as well as the risks posed by the research itself. During a publicly declared emergency, the REB Chair/Designee may instigate a reasonable quorum and may invite individuals with expertise in areas beyond that available to the REB to assist in the review. In addition, the REB Chair/Designee shall assess the level of impact of the publicly declared emergency to determine whether the impact on the REB and researchers is of a mild (no/little impact) or taxing (review procedures will be moderately or severely debilitated) nature. Finally, the following emergency preparedness plans for ethics review shall apply during times of publicly declared emergencies.

   Emergency Preparedness Plans

2. A. Regarding ongoing research not related to or arising from a 'mild' public emergency, researchers:

- Shall decide whether or not to continue to engage in participant recruitment and/or

B. contact, by prioritizing the safety, welfare and vulnerability of potential and existing participants. Regarding ongoing research not related to or arising from a 'taxing' public emergency, researchers:

- Shall cease all participant recruitment and/or contact, unless this poses a significant risk to participant safety;
- May continue with research activities not related to recruitment or participant contact.

C. Regarding applications for research not related to or arising from a public emergency, the REB Chair/Designee will determine whether the review of research should be postponed until after the emergency is over.

D. Regarding applications for research related to or arising from a public emergency the following apply:

- Such applications are not restricted to the typical submission deadlines and may be submitted (via any method) at any time during or after a publicly declared emergency. Depending on the level of impact of the emergency the review process may require more or less time than stipulated here under non-emergency circumstances;
- The REB Chair, Vice-Chair, or Designate will review the risk associated with the proposed research, as well as aspects of the research that may require enhanced scrutiny, while taking into account the level of impact of the emergency on the review process;
- When the impact of an emergency is deemed to be mild or taxing, time-sensitive review processes (e.g. delegated review, full review via email/teleconference) may be followed where possible.

REFERENCES

(AoIR) Association of Internet Researchers (2012). Ethical Decision-Making and Internet Research: Recommendations from the AoIR Ethics Committee Approved by the Ethics Working Committee. http://aoir.org/reports/ethics2.pdf

Secretariat on Responsible Conduct of Researchs (2018). Tri-council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS-2). Ottawa, ON: Government of Canada. http://www.pre.ethics.gc.ca/pdf/eng/tcps2-2018/TCPS_2_FINAL_Web.pdf

(SSHWC) Social Sciences and Humanities Working Committee (2008). Extending the Spectrum: The TCPS and Ethical Issues in Internet-based Research. http://www.pre.ethics.gc.ca./policy-politique/iniatives/docs/Internet_Research_-_February_2008_-_EN.pdf

**NOTE: Wording, phrasing, and guidance in this document has been taken, in some cases directly, from the TCPS-2 and from websites of other Canadian Universities (notably: McMaster University, University of Waterloo, University of Alberta, Nipissing University, and Lakehead University).

PROCEDURES

PART 1 - Submitting an application to the REB

Application forms and all up-to-date, relevant policy, guidance, templates and other forms may be found on the StMU website at http://www.stmu.ca/research-ethics/ Applications are only accepted on the 3rd Monday of every month. Should STMU be closed on such a Monday the deadline will instead be that Tuesday.

On or before the given deadline (before 4pm on the deadline) it is the responsibility of the Principal Investigator to submit a complete, coherent, signed, physical application, evidence of CORE certificate, and appendices to the REB Chair (see website for uptodate details). Applications must be typed and printed single-sided. Hand-written applications are not accepted. Applications must NOT be stapled (use a paperclip to fasten together your papers). During the covid-19 pandemic, emailed applications only are accepted (see website).

Applications deemed incomplete or in any way unclear may be returned to the applicant without review (rejected). In addition, applications submitted after a given deadline will not be considered until the next deadline.

Any questions and concerns should be directed to the REB Chair, Dr. Corinne Syrnyk, corinne.syrnyk@stmu.ca, 403-254-3736.

Applications must be submitted to the front office or mailed to:

Dr. Corinne Syrnyk
REB Chair
St. Mary's University
14500 Bannister Rd SE
Calgary, AB T2X 1Z4

PART 2 – REB Review Procedures

Following each deadline the REB Chair will decide if an application may be reviewed or returned to the Principal Investigator (PI). If the application is to be reviewed the Chair will decide whether the project qualifies for full or delegated review (see Section II.H.2.B).

Full & Delegated reviews of applications to the REB will consider the following:

1. The level of research risk (see Section II.H.2.B and Section II.H.3).
2. Whether the risks to participants are minimized by using procedures/methods which are consistent with sound research design but which do not expose participants to unnecessary harm.
3. Whether the risks are reasonable (balanced) in relation to the anticipated benefits to the participants.
4. Whether the protocol provides for informed and freely volunteered consent, including providing for withdrawal from the research.
5. Whether there is adequate protection of the privacy of the participants and the confidentiality of the information/data being obtained.
6. Whether the selection and recruitment of the participants is inclusive and appropriate in relation to the human participants and to the research.
7. Whether appropriate provisions are made for the on-going monitoring of the participant's welfare.
8. Whether the purpose of the study is fully outlined, or if deception is necessary, there is appropriate debriefing of the participants.
9. Whether there is any conflict of interest which should be considered, and if so, whether appropriate mechanisms for handling the conflict have been put into place.

Delegated reviews will normally be completed within 10 business days following each deadline. Regarding Full reviews, the REB will make every effort to meet within 10 business days following each deadline. The REB will endeavor to reply to applicants in a timely manner, noting that this is dependent on the nature of the risk and sensitivity of the application.

The REB will communicate, in a timely manner, one of the following decisions to the PI:

Approval: project fulfills ethical standards as proposed and will be issued a certificate of ethics of approval with an expiration date.

Approval with minor revisions: once the PI has replied to each of the revisions, and the Chair/REB are satisfied with the revisions, a certificate of ethics of approval with an expiration date will be issued and include, if necessary, any restrictions the PI must attend to before recruiting participants/collecting data.

Refusal with major revisions: specific, numerous, major and minor ethical/methodological problems (including a lack of clarity) with the application. The PI will receive written feedback and be invited to resubmit their application at the next deadline.

Refusal: the ethical difficulties associated with the application are such as to leave doubt whether acceptable redesign is possible. It may also be that the application is not robust enough to warrant review (overall lack of clarity, coherence). Finally, an application may be refused approval if the REB cannot find confidence in the application after considering the above review criteria. The PI will receive written feedback.

Decisions will be communicated to applicants via email. Regarding 'approved' applications, a pdf containing, in order, the certificate of approval, relevant email correspondence (if appropriate), and the original review application, will be attached to the decision email. Decisions of 'approved with minor revisions' will not include such a pdf until the PI has replied to each of the required revisions outlined in the decision email (see template below), and provided any revised documentation. In such cases PIs must reply within 5 working days of receipt of the decision email. Decisions of 'refusal' and 'refusal with major revisions' will be communicated to the PI via an email that describes the rational for the decision, including the major weaknesses of the application, and refers to the appeals policy (Section II.J.1.A-E). Only in the case of a 'refusal with major revisions' may an invitation to resubmit a revised application on another occasion be offered.

Example of an approved (with minor revisions) email to an applicant:

Dear PI,

Thank you for your REB application, <Title of Project>.

Your project has been granted approval pending minor revisions (below). To move forward, please reply to this email within 5 working days addressing each point in the table below (you must provide your responses in the 'Applicant's Response' column). Upon satisfactory review of your reply, your certificate of approval will be issued.

You are reminded that it is your responsibility as researcher to ensure that you submit an 'annual project review' form, should your project extend beyond one year, and/or an 'end of project' form upon completion of the project. Both forms are available at http://www.stmu.ca/research-ethics/

Revision/Comment/Query	***Applicant's Response***

PART 3 – Determining Course-Based Research

Faculty who are planning to have their students' conduct Course-Based Student Research must consider if any of the following apply:

1. The course-based research project is intended to extend knowledge through disciplined inquiry and/or systematic investigation (TCPS-2, Article 2.1).
2. The course-based research is associated with the faculty member's research program.
3. The research project is more than minimal risk.
4. The research participants are not drawn from the general population, and/or are not capable of giving free and informed consent, and/or may include participants in circumstances that make them vulnerable in the context of research.
5. The research project involves personal, sensitive or incriminating topics or questions that could place participants at risk.
6. The research project manipulates behavior of participants beyond the range of "normal" classroom activity or daily life.
7. The research project involves physically invasive contact with the research participants.
8. The research project involves deception.

Should any of the above apply instructors must submit an ethics application to the REB. If none of the above apply then the faculty member does not need to submit an ethics application. Faculty members are responsible for knowing if an ethics application is required based on the above criteria.

PART 4 – Application Procedures for Research with Distinct Individuals and Communities

Researchers wishing to conduct research with distinct individuals and communities must answer all of the following questions, and attach this as an additional appendix to their ethics application:

1. If the proposed research is likely to affect the welfare of the community/communities to which prospective participants belong, how will you seek engagement with the community/communities (see TCPS-2, Articles 9.1, 9.2 and 9.10)?
2. What steps have you taken, or will you take, to become informed about and respect the relevant customs and codes of research practice that apply in the particular community/communities affected by the research (TCPS-2, Article 9.8 and 9.9)?
3. If you will be formally engaging with the community through a designated representative, how will this be set out in a research agreement (TCPS-2, Article 9.11)?
4. To what extend will collaboration, participatory involvement, and ongoing engagement characterize this research (TCPS-2, Article 9.12)?
5. How is the research relevant to community needs/priorities and how will the research benefit the participating community (TCPS-2, Article 9.13)?
6. To what extent will community experts be involved in the design and execution of the research, the interpretation of findings in the context of cultural norms and traditional knowledge (TCPS-2, Article 9.15)?
7. Where appropriate, have special provisions been made to ensure privacy and confidentiality, or access to trauma counseling (TCPS-2, Article 9.16)?
8. How will intellectual property rights arising from this research be addressed (TCPS-2, Article 9.18)?
9. If the research will crucially examine the conduct of public institutions (including governments or organizations) or persons exercising authority over individuals/communities, how will this be carried out in an ethical manner (TCPS-2, Article 9.7)?
10. If the research is to be conducted on lands under the jurisdiction of an Indigenous authority, how will you seek the engagement of formal leaders of the community/communities (TCPS-2, Articles 9.3, 9.4, 9.5 and 9.6)?
11. Are there any other dimensions to this research that you need to disclose?