UNIVERSITY OF MANITOBA
PROCEDURE

Procedure:	**THE ETHICS OF RESEARCH INVOLVING HUMANS**
Parent Policy:	The Ethics of Research Involving Humans Policy
Effective Date:	January 28, 2025
Revised Date:	
Review Date:	January 28, 2035
Approving Body:	Vice-President (Research and International) in conjunction with the Senate Committee on University Research
Authority:	
Responsible Executive Officer:	Vice-President (Research and International)
Delegate: **(If applicable)**	Associate Vice-President (Research)
Contact:	Associate Vice-President (Research)
Application:	Board of Governors members; Senate members; Faculty/School Councils; Students; All Employees, All REB Members

Part I
Reason for Procedure

1.1 To give effect to the policy on The Ethics of Research Involving Humans, the University of Manitoba (the "University") shall establish certain procedures and mechanisms. These procedures and mechanisms shall include the articulation of:

(a) The responsibilities of central administrators, the Office of Human Research Ethics ("OHRE"), faculty deans/directors, department heads, Researchers, and the Human Ethics Resource Committee ("HERC");

(b) The composition and terms of reference of the University's Research Ethics Boards (REBs) responsible for the review and approval of Protocols involving human Participants;

(c) Procedures for human Research ethics Protocol review and approval, ongoing management, including scholarly review where appropriate;

(d) Procedures for reviewing Multi-Jurisdictional Research;

(e) The appeal process in cases where the Researcher disagrees with the REB decision not to approve the Protocol;

(f) Miscellaneous procedures.

Part II
Procedural Content

2.1 Definitions

(a) **Advisor** means an academic staff member of the University who is responsible for instructing a student Researcher on the ethical conduct of Research, assisting in the preparation of the Protocol, reviewing and approving the Protocol before submission to an REB, attesting to the scholarly merit of the Research, acknowledging their responsibility to uphold University policy, and taking an active role in ensuring the Research is conducted in accordance with the approved Protocol.

(b) **Anonymized information** means information that has been irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of Participants from remaining indirect identifiers is low or very low.

(c) **Anonymous information** means information which never had identifiers associated with it and risk of identification of Participants is low or very low.

(d) **Coded Information** means information in which direct identifiers are removed from the information and replaced with a code. Depending on access to the code, it may be possible to re-identify specific Participants.

(e) **Delegated Board Review** means the level of REB review assigned to Minimal Risk Research Projects.

(f) **Department** means a Department in a faculty, college, or school established by the University. For a faculty, college, or school not organized into Departments, “Department” means faculty or school.

(g) **Directly Identifying Information** means information that identifies a specific individual through direct identifiers (e.g., name, social insurance number, personal health number).

(h) **Director** means the Director, Human Research Ethics and Compliance.

(i) **Ethics Review Agreement** means an official agreement between two or more institutions, in which they accept, with an agreed level of oversight, the research ethics reviews of each other's REBs or in which they appoint an external, specialized or multi-institutional REB where one exists.

(j) **Full Board Review** means the level of review assigned to above Minimal Risk Research Projects. Conducted by the full membership of the REB, it is the default requirement for the ethics review of Research involving humans.

(k) **Human Ethics Resource Committee or "HERC"** means a committee responsible for providing advice and consulting to OHRE and REBs on matters related to human research ethics including recommendations on policies, procedures, and processes.

(l) **Indirectly Identifying Information** means information that can reasonably be expected to identify an individual, including through a combination of indirect identifiers (e.g., date of birth, place of residence, unique personal characteristic).

(m) **Minimal Risk Research** means Research in which the probability and magnitude of possible harms implied by participation in the Research are no greater than those encountered by Participants in those aspects of their everyday life that relate to the Research.

(n) **Multi-Jurisdictional Research** means research involving multiple institutions and/or multiple Research Ethics Boards (REBs). It is not intended to apply to ethics review mechanisms for Research involving multiple REBs within the jurisdiction or under the auspices of a single institution. Research involving humans that may require the involvement of multiple institutions and/or multiple REBs includes, but is not limited to, the following situations:

(i) a Research project conducted by a team of Researchers affiliated with different institutions;

(ii) several Research projects independently conducted by Researchers affiliated with different institutions, with data combined at some point to form one overall Research project;

(iii) a Research project conducted by a Researcher affiliated with one institution, but that involves collecting data or recruiting Participants at different institutions;

(iv) a Research project conducted by a Researcher who has multiple institutional affiliations (e.g., two universities, a university and a college, or a university and a hospital);

(v) a Research project conducted by a Researcher at one institution that requires the limited collaboration of individuals affiliated with different institutions or organizations (e.g., statisticians, lab or X-ray technicians, social workers and school teachers); or

(vi) a Research project that Researcher(s) working under the auspices of a Canadian research institution conduct in another province, territory or country.

(o) Office of Human Research Ethics or "OHRE" means the office responsible for providing administrative support for the University's constituted REBs.

(p) **Participant** means an individual whose data, biological materials, or responses to interventions, stimuli, or questions by a Researcher are relevant to answering the research question(s).

(q) **Principal Investigator** means the Researcher who is responsible for the ethical conduct of the research, and for the actions of any member of the research team at a local site.

(r) **Research** is defined as an undertaking intended to extend knowledges through, for example, a disciplined inquiry or systematic investigation involving Participants.

(a) **Researcher** means any individual associated with and under the auspices of the University who engages in or supports Research including, but not limited to, faculty, staff, students, post-doctoral fellows, research associates, community researchers, research assistants, lab assistants, visiting researchers and anyone holding an academic appointment with the University (including geographic full time, nil salaried and adjunct appointments).

(b) **Research Ethics Board or "REB"** means a body of Researchers, community members, and others with specific expertise established to review the ethical acceptability of all Research involving humans conducted within an institution's jurisdiction or under its auspices. The University may constitute an REB or appoint an REB by agreement.

(c) **Research Ethics Protocol or "Protocol"** means information submitted in the appropriate format to the REB by the Researcher for review and approval of the ethical acceptability of the Research prior to the start of recruitment of Participants, data collection, access to data, or collection of human biological materials.

(d) **The Agencies** means the Canadian Institutes of Health Research, (CIHR and originally the Medical Research Council of Canada), the Social

Sciences and Humanities Research Council of Canada (SSHRC) and the Natural Sciences and Engineering Research Council of Canada (NSERC).

(e) **University** means The University of Manitoba.

Responsibilities

2.2 The University will have responsibility for the ethics review of Research involving human Participants conducted under its auspices. The University shall constitute or appoint REBs as it deems appropriate, with responsibility for the ethics reviews of Research involving humans at or under the auspices of the University. Implementing and adhering to policies on the ethical involvement of human Participants in Research is an institutional responsibility shared by: central administrators, OHRE, faculty and department administrators, Researchers, and administrative and academic units conducting Research. Notwithstanding this shared responsibility, the specific responsibilities of these individuals, and groups or units are as follows:

2.3 Responsibilities of Administrators:

(a) **Central Administrators**. The University's Provost and Vice-President (Academic) ("Provost"), Vice-President (Administration), and Vice-President (Research and International) ("VPRI") jointly bear executive responsibility for the implementation of the University's policies respecting the participation of human Participants in Research. The University will exercise appropriate administrative overview, carried out at least annually, to ensure that its practices and procedures designed to protect the rights and welfare of human Participants are being applied and are in compliance with the requirements of the TCPS2 (2022) and this Policy and Procedure. This administrative overview shall primarily be the responsibility of the Director.

(b) **OHRE**. The VPRI, through OHRE, will provide administrative support for the University's constituted REBs, including:

(i) receiving, recording, and processing Protocol submissions;

(ii) corresponding with Researchers;

(iii) providing support to REB Chairs and members;

(iv) scheduling and communicating REB meetings and deadlines;

(v) maintaining records of REB decisions;

(vi) ensuring compliance with this Policy and Procedure; OHRE

(vii) promoting awareness of the TCPS2 (2022) and of this Policy and Procedure, and educating Researchers on the ethical conduct of Research with human Participants through workshops, educational material, and other methods as deemed appropriate; and

(viii) on behalf of the University-constituted REBs, managing and retaining all relevant REB records, including Protocols and related correspondence, for a period of time following the submission of a notice of closure by the Researcher in accordance with University record retention procedures and relevant legislation and regulatory requirements.

(c) **Faculty/School/College Deans/Directors and Department Heads**.

(i) Faculty/School/College Deans/Directors and Department Heads have a general responsibility for the Research carried out in their Faculty/School/College or Department, and for encouraging and ensuring compliance with applicable University policies and procedures.

(ii) A Department may formally constitute a Department-based Coursework Research Review Committee (CRRC) in accordance with the SOP "Creation of Coursework Research Review Committee". The CRRC may review minimal-risk course-based Research activities with a primarily pedagogical purpose normally required of students to provide them with exposure to research methods in their field of study. The CRRC must consult with the REB Chair to determine the appropriateness of a particular student project where the purpose may be Research. The CRRC must comply with the TCPS2 and this policy and its attendant procedures. Everything that applies to an REB within these policies and procedures also applies to a CRRC. The CRRC shall require and maintain minutes of CRRC meetings, records of Protocol submissions, and all recommendations and decisions resulting from the reviews. The CRRC shall report twice annually to the REB under which it has been constituted, to enable the REB to fulfill its responsibility for ethics oversight.

2.4 **Responsibilities of Researchers**. Whenever Research involving human Participants is to be performed at or under the auspices of the University or by any University Researcher (see Part II: Policy Content), the Researcher is responsible for meeting the following requirements:

(a) Not engaging in Research deemed to be unethical in accordance with the TCPS2 (2022).

(b) Consulting with the appropriate REB Chair to determine whether REB review is required for their Research.

(c) Completing the most recent version of the Panel on Research Ethics TCPS2: Course of Research Ethics (CORE) prior to applying for ethics approval.

(d) Completing UM's Privacy Training for Researchers.

(e) Ensuring all Research team members have completed either CORE certification, or relevant provisions thereof, through specific training as approved by the REB Chair, UM's Privacy Training for Researchers, and an Oath of Confidentiality as appropriate. This includes team members at the time of the application and those who join the team thereafter.

(f) Ensuring that they and their team members are appropriately qualified by education, training and experience to assume responsibility for the proper conduct of the Research and for protection of human Research Participants.

(g) Obtaining required permits as it relates to the proposed Research.

(h) Ensuring that their submitted Protocol is for valid Research that warrants the costs, risks, and specific procedures to be used with the number of Research Participants indicated within the Protocol.

(i) Notifying the appropriate REB of record of the proposed Research by submitting a Protocol in the prescribed manner, and providing any additional information requested by the REB in a timely fashion. This should include demonstrating to the appropriate REB of record whether, when, and how appropriate scholarly review has been or will be undertaken for their Research.

(j) Ensuring human Participants are not interacting with or involved in the proposed Research until the appropriate REB of record has approved the Protocol.

(k) Abiding by all decisions of the REB of record and following the Protocol as approved. This includes obtaining informed consent using the most current informed consent document(s) approved by the REB, ensuring that Participant consent is documented in the prescribed manner, maintaining consent documents signed by Participants in a secure repository, and maintaining privacy and confidentiality as required by the REB, relevant organizations, the TCPS2, and applicable legislation.

(l) Promptly seeking approval from the appropriate REB of record of any proposed changes to the approved Protocol through the amendment mechanism prior to implementation.

(m) Promptly reporting to the appropriate REB of record through the prescribed manner:

(i) Any injuries to human Participants, any unanticipated problems which involve risks or unusual costs to the Participants, or other adverse events resulting from the Research.

(ii) Any proposed changes in the Research which would result in a significantly different involvement of Participants and obtaining the approval of the appropriate REB prior to the changes being made, except where necessary to eliminate apparent and immediate hazards to Participants.

(iii) Any deviations from the approved Protocol or any serious or continuing non-compliance the requirements of this Policy or of the Procedures stipulated by the REB of record by any individual associated with the Research.

(iv) Submitting a renewal or study closure request in the prescribed manner to the REB of record prior to the expiration of the Protocol approval period.

2.5 **Responsibilities Specific to Graduate and Undergraduate Students**. Graduate and undergraduate students conducting Research with human Participants must comply with the TCPS2 and this Policy and Procedure. It is the responsibility of the student to ensure they have an Advisor supervising their Research, who must sponsor the Protocol submission. Students must receive approval from their Advisor (and committee where appropriate) before submitting their Protocol to the appropriate REB.

(a) **Independent Student Research for Undergraduate Research Awardee Projects, Honours Projects, Theses, and Dissertations.** All student Research conducted with human Participants as part of a Research project, thesis or dissertation must receive REB approval from the appropriate REB before an interaction occurs with potential Participants and/or Participants, and/or before the collecting of data, including secondary-use data.

(b) Projects as Part of Formal Course Requirements:

(i) Student Research projects that are exercises in how to conduct Research involving human Participants do not require review by the REB or CRRC if the Participants are other members of the class.

(ii) Course-based student projects which involve human Participants recruited from outside of the classroom setting must be reviewed and approved by the appropriate REB of record or CRRC before the project begins.

(iii) In circumstances where the frequency or nature of course-based Research warrants, the REB Chair may delegate the review of course-based Research projects to a formally constituted Department-based CRRC in accordance with s. 2.3(c)(ii).

2.6 **Responsibilities of Advisors**. The Advisor, even if a student is the Researcher collecting the data, has the following responsibilities:

(a) During the design of the Research, the Advisor shall instruct students on the ethical conduct of Research, ensure they complete all required training as set in s. 2.4, and help them prepare and submit Protocols for REB approval. This assistance includes scholarly review by the Advisor (and committee as appropriate). The Advisor shall sign off on the student's Protocol. This indicates both that the Advisor has reviewed and approved the student's Protocol and that the Advisor acknowledges their responsibility to see that the University's policies and procedures are being followed. These responsibilities apply to undergraduate student awardee projects, honours projects, theses, dissertations, as well as course-based projects.

(b) After approval by the REB of record, Advisors must take an active role in ensuring that the Research is conducted in accordance with the REB's requirements and the approved Protocol.

(c) In any consultations with OHRE or the REB (as appropriate) both the Advisor and student must take an active role.

2.7 **Responsibilities of Administrative and Academic Units Conducting Research**. Information gathering activities, such as interviews and surveys undertaken by University Administration with a clear Research orientation, are subject to review and approval by the appropriate REB. In cases where the administrator is uncertain, advice should be sought from the appropriate REB Chair, whose decision must be rendered in writing.

2.8 **Responsibilities of the Human Ethics Resource Committee (HERC).** HERC acts as an independent voice in supporting human Research ethics and University-constituted REBs under the purview of the Senate Committee on University Research (SCUR). Terms of Reference for HERC are set out in Appendix II.

Research Ethics Boards

2.9 **Responsibilities of Research Ethics Boards (REBs**). REBs are responsible for reviewing, approving, and managing, on a continuing basis, the ethical acceptability of all Research involving human Participants conducted within the University's jurisdiction or under its auspices in accordance with TCPS2 (2022). The REB Chair provides overall leadership to the REB, including facilitating dialogue between Researchers and the REB, monitoring the REB's decisions for consistency and

ensuring that these decisions are recorded accurately and communicated clearly to Researchers in writing. It is the responsibility of an REB to:

(a) ensure that all Protocols that propose the involvement of human Participants comply with the Policy, this Procedure, and all applicable ethics guidelines;

(b) ensure that the potential benefits of Research outlined in these Protocols are sufficient to warrant the participation of human Participants; and

(c) take corrective action regarding, or terminate any ongoing Research which is in contravention of the TCPS2 (2022), applicable laws and regulations, the Policy, this Procedure, or of a previously approved Protocol.

2.10 **Composition.** The number and constitution of University-constituted REBs, which may change from time to time upon recommendation by SCUR to VPRI, is set out in the OHRE Standard Operating Procedure (SOP), "Composition of the REB". The Director, in consultation with the Chairs of the University-constituted REBs, will review the composition of the REBs and REB member expertise from time to time to ensure efficiency and maximize expertise of Protocol reviews and recommend changes to SCUR as necessary. The Terms of Reference for the University-constituted REBs are set out in the OHRE SOP, "Duties of REB Members". In all respects, the SOPs are consistent with the guidelines of the TCPS2 (2022).

2.11 **Multi-Jurisdictional Research.** The University may appoint an external REB to conduct ethics reviews pursuant to an Ethics Review Agreement. Where Research involving human Participants requires the involvement of multiple institutions and/or multiple REBs, the University may establish mechanisms, including SOPs, for streamlining the ethics review process including entering into an Ethics Review Agreement to allow review by the REB of another institution or an external REB in accordance with the TCPS2 (2022).

2.12 **Appropriate REB.** To ensure their Protocol is reviewed with the appropriate expertise, Researchers shall submit their Protocol to the appropriate University-constituted or University-appointed REB. The Chair of the REB to whom the Protocol is submitted shall make the final determination on the most appropriate REB and shall notify the Researcher as necessary.

2.13 **Multi-Disciplinary Research.** In multi-disciplinary Research, the primary Department to which the Researcher is appointed will determine the appropriate REB of record unless the University has appointed another REB under an agreement or has entered into an Ethics Review Agreement to facilitate collaborative Research projects and allow for review by the REB of another institution.

2.14 **REB Chairs.** REB Chairs for University-constituted REBs are appointed by SCUR on the nomination of the Director and the recommendation of the Associate Vice-

President (Research) ("AVPR"). Chairs have delegated authority for signature, on behalf of the University, of all approved Protocols under their jurisdiction. When an REB Chair is being appointed temporarily to replace a Chair on leave, the temporary appointment may be recommended by the Director and approved by the AVPR.

2.15 **REB Members.** Voting members of University-constituted REBs shall be appointed in accordance with the OHRE SOP "Management of the REB Membership", taking into account a diversity of subject-matter expertise, methodological expertise, identities, and experience. Normally, all Departments with Researchers submitting Protocols will have representation on a University-constituted REB. Nominees may be selected in a manner determined by the Department. Community members (meeting membership requirements) are solicited by the Director from the greater local community.

2.16 Upon recommendation by the Director, the AVPR may appoint OHRE staff members with the requisite expertise as non-voting University-constituted REB members.

2.17 **Ad Hoc Advisors.** At the request of the REB Chair, the Director may appoint ad hoc advisors to advise University-constituted REB Chairs and members if, in the opinion of the REB Chair, the University constituted REB lacks the specific expertise or knowledge to review the ethical acceptability of a Protocol competently. Ad hoc advisors are not REB members and should not be counted in the quorum or vote.

2.18 **Meetings of the REB.** In advance of the start of each academic year, regular meetings of the REBs shall be scheduled and announced to the University research community so Researchers may plan their Protocol submissions for the most appropriate meeting. Researchers should also be informed of the dates by which their Protocol must be received by the REB in order to be considered at scheduled meetings. REBs shall meet in a manner that allows for a fulsome discussion of Protocol reviews and formal reporting of all delegated review decisions. REBs shall meet in such a way as to ensure timely review of Protocols but no less than once in each academic term. Cohorts of REB members may meet more often at the request of the Chair or any member.

2.19 **Quorum, Decision-making, and Minutes of REB Meetings**. The quorum for meetings of the REB to review Protocols shall consist of at least five duly appointed voting REB members reflecting the principles of diversity, with at least two members having expertise in relevant Research disciplines, fields and methodologies, one member who is knowledgeable in ethics, one member knowledgeable in the relevant law (for biomedical research only) and one community member who has no affiliation with the University and meets additional funder and/or governmental requirements. In the event that this number is not achieved, the meeting may proceed only if in the judgment of the Chair the number and range of expertise present is adequate for the conduct of reviews. Decisions

without a quorum are not valid or binding and will require an approval at a subsequent meeting that meets quorum.

2.20 Decisions shall normally be arrived at by consensus. Where this is not possible, decisions shall be reached by a simple majority vote. Should a disagreement among committee members persist, the minority position may be communicated to the Researcher.

2.21 **Conflict of Interest of REB Chairs.** In the event that an REB Chair declares a COI to the Co-Chair(s) or Vice-Chair(s), either the Co-Chair, Vice-Chair, or alternate REB member will assume the REB Chair's responsibilities for the specific Protocol(s).

2.22 **Conflict of Interest of REB Members.** Before undertaking a review, REB members must disclose any real and/or perceived conflicts of interest to the REB Chair, who will determine whether the circumstances should be defined as a conflict of interest and the member must follow the REB's decision regarding any actions required to mitigate their real or perceived conflict.

2.23 **Conflict of Interest of Researchers.** The REB has the responsibility to identify situations where the interests of the Researcher may be in conflict. In these instances, the REB may require the Researcher to disclose the conflict to potential Participants or to abandon one of the interests in conflict.

2.24 Minutes of all University-constituted REB meetings shall be prepared and maintained for the REB by the OHRE.

Protocol Submission, Review, and Approval Processes

2.25 **Protocol Submission**. All Protocol submissions shall be submitted in the manner prescribed by the REB of record and include all documentation and information required to adhere to the TCPS2 (2022), as well as applicable regulatory agencies, relevant privacy and impact assessments, applicable legislation, and other requirements.

2.26 **Types of Review**. The selection of the level of REB review shall be determined by the level of foreseeable risks to Participants: the lower the level of risk, the lower the level of scrutiny (Delegated Board Review); the higher the level of risk, the higher the level of scrutiny (Full Board Review). The REB Chair will determine the type of review required in keeping with this proportionate approach and advise the Researcher in writing.

2.27 **Delegated Board Review**. Where the REB Chair determines that the Research is Minimal Risk Research, they may authorize a Delegated Board Review.

(a) **Procedures for a Delegated Board Review**. Normally, delegated reviewers are selected from the REB membership. In some circumstances, nonmembers may also act as reviewers. Protocols assigned to a delegated

review may be reviewed by the REB Chair alone or with any number of REB members as determined by the Chair. The Chair may also call upon ad hoc advisors to assist in the review. The Chair renders the decision on behalf of the members based on consensus. If no consensus is reached, the Chair may seek the input of other REB members or seek further information from the Researcher prior to making a final decision. The Chair may also decide based on this review that the Protocol requires a Full Board Review.

(b) **Reporting of Delegated Board Reviews by the REB**. At each regular meeting of the REB, all approvals by Delegated Board Review since the previous meeting must be reported to the full REB.

2.28 **Full Board Review**. Research that involves greater than Minimal Risk requires Full Board Review and approval by an REB, which may be a University-constituted REB, an appointed REB, or an REB of another institution under an Ethics Review Agreement, as applicable, in a meeting that allows for discussion and exchange of information. Research that requires Full Board Review includes, but is not limited to, Research that may cause physical, psychological, social, economic, legal, or other harms. The REB may invite Researchers to attend an REB meeting to provide further information about their Protocols. The Researcher shall not be present when the REB is making its decision.

2.29 **Scholarly Review.** As part of research ethics review, the REB shall review the ethical implications of the methods and design of the Research. The primary test to be used by REBs in evaluating Research should be ethical acceptability and, where appropriate, relevant disciplinary scholarly standards. The REB should consider what scholarly review has been undertaken. This may involve requiring the researcher to provide the REB with the full documentation of scholarly reviews already completed. If a scholarly review as indicated by the relevant disciplinary tradition has not yet been done, the REB may:

(a) Undertake a scholarly review itself if member expertise is available; or

(b) Request an ad hoc independent peer review committee with the appropriate expertise undertake the review.

The REB should not be driven by factors such as personal biases or preferences, and should not reject Protocols because they are controversial, challenge mainstream thought, or offend powerful or vocal interest groups.

2.30 Research in the humanities and the social sciences that poses, at most, minimal risk shall not normally be required by the REB to undergo scholarly review.

2.31 **Permission to Conduct Research at Another Institution or Organization**. A Protocol submission by a University Researcher to conduct Research at another institution or organization normally should be accompanied by a document indicating permission from that institution or organization for the Research to be undertaken. If approval from a University-constituted REB is required before such

documentation may be obtained, the Researcher should state this in their Protocol submission. In this instance, the REB may grant approval, with the expectation that the Researcher submits an amendment with the approval documentation from the other institution or organization as soon as possible and before the Research commences.

2.32 **Ethics Review of Research to be Conducted at Multiple Universities**. Research conducted at other universities in addition to the University must receive ethics review and approval from the appropriate University-constituted or appointed REB, as well as approval at the other institutions unless the University has entered into an Ethics Review Agreement that authorizes an alternative model for REB review for that Research, or the Research is determined to be Minimal Risk Research which may follow an alternative model of ethics review as determined in accordance with the TCPS2 (2022). The Research may not proceed until required approval has been granted.

2.33 **Types of REB Decisions**. The REB Chair shall notify the Researcher in writing of the REB decision, which may be to:

(a) Approve the Protocol as submitted;

(b) Require modifications to the Protocol before approval can be granted;

(c) Defer the decision to request more information from and/or consult with the Researcher;

(d) Accept the approval of the REB of record in the case of Minimal Risk, Multi-Jurisdictional Research; or

(e) Not approve the Protocol.

2.34 Researchers and REBs will use best efforts to resolve disagreements they may have through deliberation, consultation or advice.

2.35 When an REB is considering a negative decision, the Chair must provide reasons to the Researcher prior to a final decision being made. The Researcher shall be given an opportunity to respond to the Chair in writing. The REB may, at its discretion, re-review and reconsider the Protocol.

2.36 The Researcher may withdraw their Protocol submission at any time.

Continuing Research Ethics Review

2.37 **Modification of an Approved Protocol**. If at any time the Researcher recognizes the need for modifications to the approved Protocol, an amendment must be submitted in the prescribed manner prior to any changes being implemented. The Chair or their designate may approve the amendment. Alternatively, the REB Chair may require revisions to the amendment, or seek input from the REB through a

Delegated or Full Board Review prior to making a decision. Researchers may not deviate from the approved Protocol without prior approval from the REB.

2.38 **Time Extensions**. All Protocols are approved for a maximum period of one year. Longer-term or ongoing Research shall be subject to annual reporting and renewal in the prescribed manner prior to the expiry date. A Protocol cannot be considered renewed until the Researcher receives official written notification from the REB of record.

2.39 Upon request from an REB, Researchers may be required to submit more frequent and/or substantive reporting in circumstances where there is more than Minimal Risk to Research Participants.

2.40 **Adverse Events, Unanticipated Issues, and Deviations**. Researchers are obliged to immediately report any known deviations from the approved Protocol to the REB of record. Deviations may include, but are not limited to, serious adverse events and any other unanticipated issues or events that may increase the level of risk to Participants or that have ethical implications that may affect their welfare, or any changes in which the REB has not reviewed and approved. All reporting must be done in the prescribed manner. The Researcher may also be required to report adverse events and/or unanticipated issues to other internal or external offices and to Research sponsors, funders or collaborators under the terms of agreements in place with respect to the Research or as required by applicable laws and regulations.

2.41 **End-of Study-Reporting.** At the conclusion of the Research, Researchers are required to submit an end-of-study report in the prescribed manner in lieu of an annual report before the expiry date.

2.42 If a Research study is terminated prematurely or suspended for any reason, the Researcher must promptly inform the REB of record in the prescribed manner. The reasons for the suspension/termination and a plan for ensuring appropriate follow-up with the Participants, including how they will be notified, is required.

Appeal Process

2.43 **Appeals of University-Constituted REB Decisions.** Disagreement between the Researcher and the REB over a decision that cannot be resolved through discussion and reconsideration can be resolved through the normal appeal process. A negative decision made by a University-constituted REB may be appealed to the Human Research Ethics Appeals Committee (HREAC). Appeals may be based on procedural grounds or substantive grounds. The appeal process will be guided by the principles of natural justice. The appeal committee shall function impartially, provide a fair hearing to those involved, and provide reasons and documented opinions and decisions. The appeal committee's decisions shall be final and communicated in writing to the Researcher and the REB whose decision was appealed. The process of HREAC is set out in Appendix I.

Part III

Noncompliance by Researchers.

3.1 Instances of noncompliance with this Policy and the Procedures derived from it are to be brought to the attention of the Director and Chair of the REB of record for resolution. If an informal resolution of the matter is not reached with the Researcher and the REB Chair or the problem recurs, the Director, in consultation with members of the University's senior executive, as appropriate, shall attempt to obtain a satisfactory resolution through the appropriate Dean/Director/Department Head. Serious instances of noncompliance or repetitive Policy and Procedure breaches shall be forwarded to VPRI for reporting and disposition. The VPRI may consult with the Provost as appropriate.

Miscellaneous Procedures

3.2 **Record Keeping.** REBs shall prepare and maintain comprehensive records, including, but not limited to all documentation related to the Protocols submitted to the REB for review, attendance at all REB meetings, and accurate minutes reflecting REB decisions. Records shall be maintained in accordance with University policies and all relevant legislative and regulatory requirements.

3.3 **Research Ethics Review During Publicly Declared Emergencies**. Research ethics review during publicly declared emergencies, such as public health outbreaks or natural disasters, may follow modified procedures and practices, adhering to TCPS2 (2022) and institutional direction. At the discretion of the REB Chair, the normal Protocol process may be partially waived, and normal consent procedures modified; partial review and approval may be carried out by the applicable Chair, but full review by the REB will occur retroactively, after the Research has concluded and publicly declared emergency subsided.

3.4 **Research Involving First Nations, Inuit and Métis Peoples of Canada**. The TCPS2 (2022) acknowledges the unique status of the Indigenous Peoples of Canada. Researchers planning to involve Indigenous Peoples as part of their Research must consult Chapter 9 of the TCPS2 (2022). The guidance provided by the TCPS2 (2022) is not intended to override or replace ethical guidance offered by Indigenous Peoples themselves. Its purpose is to ensure, to the extent possible, that Research involving Indigenous Peoples is premised on respectful relationships.

3.5 **Educational Requirements**. The University requires those applying for Research ethics approval, including members of their Research teams and students to complete and provide proof of completion of the most recent version of TCPS2 CORE and Privacy Training for Researchers. Comparable ethics training or alternative training may be acceptable with justification. Other training may also be required from time to time.

Part IV
Accountability

4.1 The Office of Legal Counsel is responsible for advising the Vice-President (Research and International) that a formal review of this Procedure is required.

4.2 The Associate Vice-President (Research) is responsible for the implementation, administration and review of this Procedure.

4.3 Board of Governors members, Senate members, Faculty/School Councils, students, employees and all REB members are responsible for complying with this Procedure.

Part V
Review

5.1 Governing Document reviews shall be conducted every ten (10) years. The next scheduled review date for this Procedure is January 28, 2035.

5.2 In the interim, this Procedure may be revised or repealed if:

(a) the Vice-President (Research and International) for Approving Body deems it necessary or desirable to do so;

(b) the Procedure is no longer legislatively or statutorily compliant;

(c) the Procedure is now in conflict with another Governing Document; and/or

(d) the Parent Policy is revised or repealed.

Part VI
Effect on Previous Statements

6.1 This Procedure supersedes all of the following:

(a) all previous Faculty/School Council Procedures stemming from the Faculty/School Council Bylaw and academic and admission Regulations and any resolutions on the subject matter contained herein;

(b) all previous Board of Governors/Senate Governing Documents on the subject matter contained herein; and

(c) all previous Administration Governing Documents on the subject matter contained herein.

Part VII
Cross References

7.1 This Procedure should be cross referenced to the following relevant Governing Documents, legislation and/or forms:

(a) The Ethics of Research Involving Humans Policy

(b) Responsible Conduct of Research Policy

(c) The Responsible Conduct of Research – Code of Research Ethics Policy

(d) Respectful Rematriation and Repatriation Ceremony Policy and Procedure

(e) Access and Privacy Policy

(f) Access and Privacy Procedure

(g) Academic Freedom and Responsibilities Policy

(h) University of Manitoba - University of Manitoba Faculty Association Collective Agreement

(i) The Tri-Council Policy Statement Ethical Conduct for Research Involving Humans

(j) Freedom of Information and Protection of Privacy Act

(k) The Personal Health Information Act (PHIA)

(l) Conflict of Interest Policy

(m) Conflict of Interest Procedure