



UNIVERSITY OF MANITOBA Procedure

Procedure:	THE ETHICS OF RESEARCH INVOLVING HUMANS
Parent Policy:	The Ethics of Research Involving Humans Policy
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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:	Associate Vice-President (Research)
Contact:	Associate Vice-President (Research)
Application:	Board of Governors members; Senate members; Faculty/School Councils; Students; All Employees

Part I Reason for Procedure

- 1.1 To give effect to the policy on The Ethics of Research Involving Humans, the University shall establish certain procedures and mechanisms. These procedures and mechanisms shall include the articulation of:
- (a) responsibilities of administrative officers, faculty members, staff and students;
 - (b) the composition and terms of reference of the Research Ethics Boards (REBs) which are responsible for the review and approval of research protocols involving the use of human participants;
 - (c) procedures for protocol management and review, including the assessment of the scientific/scholarly merit, where appropriate, of the proposal to conduct research with humans, as well as mechanisms to ensure adequate communication between faculty members and the REBs; and an appeal process, in cases where there is a dispute over the process

by which a decision was reached to deny ethical approval for the use of humans in a research project;

- (d) procedures for modifying and monitoring approved protocols; and
- (e) procedures concerning the reporting and handling of noncompliance by researchers.

Part II Procedural Content

Responsibilities

2.1 Implementing and adhering to policies on the ethical use of humans in research is an institutional responsibility shared by: the administration, including Central, Faculty and Departmental administration, the Office of Research Services and researchers, including faculty members, staff and students. Notwithstanding this shared responsibility, the specific responsibilities of these individuals, and groups or units are as follows:

2.2 Responsibilities of the Administration:

- (a) **Central Administration.** The University's Provost and Vice-President (Academic), Vice-President (Administration), and Vice-President (Research and International) jointly bear executive responsibility for the implementation of the University's policies respecting the use of humans in research. The University of Manitoba will exercise appropriate administrative overview, carried out at least annually, to ensure that its practices and procedures that are designed to protect the rights and welfare of human participants are being applied and are in compliance with the requirements of the TCPS 2 and this policy. This administrative overview shall be the responsibility of the Associate Vice-President (Research).
- (b) **Human Ethics Secretariat.** The University will provide administrative support for the REBs, including receiving, recording, and processing of protocol submissions, correspondence with applicants and Committee chairs, secretarial services to Committee meetings, and maintenance of records of REB decisions. This support will be provided to the REBs on the Fort Garry Campus through the Office of the Vice-President (Research), and to the Bannatyne Campus REBs through the Dean's Office, Max Rady College of Medicine. The Secretariat will promote awareness of the TCPS 2 and of this policy, and educate researchers on campus on the ethical conduct of research through workshops, and other methods as deemed appropriate.

- (c) **Responsibilities of Faculty/School Deans/Directors and Department Heads.** Faculty/School Deans/Directors and Department Heads have a general responsibility for the research carried out in their Faculty/School or Department, and for encouraging and ensuring compliance with applicable University policies and procedures. Faculty/School Deans/Directors and Department Heads or their designates have the authority to suspend research using humans which, in their opinion, does not comply with this policy. The relevant REB should be immediately notified of this action, and should initiate a review within 5 working days.

2.3 **Responsibilities of Researchers.** Whenever research involving humans is to be performed under the auspices of the University of Manitoba or by any University researcher (see Part II: Policy Content), the researcher is responsible for meeting the following requirements:

- (a) Ensuring that the research being conducted is scientifically valid and/or appropriate in a scholarly sense, and that the benefits to knowledge that will result from the research warrant the investment of time, effort and risks to be incurred by the number of human participants for which the research is planned. Scientifically invalid research, or research that is more intrusive or requires more participants to experience the research procedures than those warranted by the research design is unethical. The researcher shall carefully monitor and assure the validity of the research submitted to the REB (see Procedures section 2.20).
- (b) Reading and becoming thoroughly familiar with applicable ethical guidelines.
- (c) Determining if their proposed research requires ethics review (see Policy section 2.3(c)). If there is any uncertainty about whether the research requires ethics review and approval, the researcher shall consult the appropriate REB for advice and decision.
- (d) Notifying the appropriate REB of the proposed research by submitting a completed Research Ethics Protocol (see the website of Human Ethics or the Max Rady College of Medicine), accompanied by any supplementary materials necessary for full ethics review, and providing any additional information requested by the REB in a timely fashion.
- (e) Not involving human participants in the proposed research until the REB has informed him/her of approval for the use of humans in the research.
- (f) Abiding by all decisions of the REB, including following all modifications required for REB approval and not undertaking the research if it has not been approved.

- (g) Obtaining informed consent from all participants as required by the TCPS 2 policy and the REB, ensuring that participant consent is documented in the prescribed manner, and maintaining consent documents signed by participants in a secure repository.
- (h) Maintaining the confidentiality of data obtained from participants in the manner required by the REB, applicable federal and provincial privacy legislation, and relevant organizations.
- (i) Promptly reporting to the Chair of the REB 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. Initial reports may be verbal; subsequent reports shall be in the manner required by the REB.
- (j) Promptly reporting to the REB any proposed changes in the research which would result in a significantly different involvement of humans and obtaining the approval of the REB prior to the changes being made, except where necessary to eliminate apparent and immediate hazards to participants.
- (k) Promptly reporting to the Chair of the REB any proposed involvement of humans in research which previously had no plans, or only indefinite plans, for participant involvement and obtaining the approval of the REB prior to the involvement of any participants.
- (l) Promptly reporting to the REB Chair any serious or continuing non-compliance with the requirements of this policy or of the procedures stipulated by an REB by any individual associated with the research.

2.4 **Responsibilities of Graduate and Undergraduate Students.** As stipulated in policy content, graduate and undergraduate students conducting research with humans must comply with this policy statement in the conduct of their research. Although students' research must be sponsored by the faculty member who supervises their research, such sponsorship does not in any way diminish the obligation of students as members of the University of Manitoba community to comply with this policy, the TCPS 2, or other codes that govern the ethical conduct of research involving humans.

- (a) **Independent Student Research.** All independent student research projects conducted with human participants where the data are collected prior to writing an undergraduate or graduate research paper, Honours or Master's thesis, or doctoral dissertation must be reviewed and receive REB approval before the data are collected. Such projects shall be supervised by a faculty member (see Procedures section 2.5) who accepts responsibility for their ethical conduct. In the case of

undergraduate or graduate course-based independent study projects or assignments, in consultation with and at the discretion of the appropriate REB, projects may be considered for review by the Faculty/Department-based Coursework Research Review Committee (CRRC).

(b) Projects as Part of Formal Course Requirements:

- (i) Student research projects that are conducted for a course and which involve research participants solicited from outside of the classroom setting, whether or not with an expectation that the results of the research will be made public through publication, must be reviewed and approved by the REB before the project begins. (Please see “Guidelines for Ethics Review of Course-based Research Projects”.)
- (ii) In circumstances where the frequency or nature of course-based research warrants, the REB may delegate its review of course-based research projects to a formally constituted Faculty/Department-based Coursework Research Review Committee (CRRC). This delegation is based on condition that the review process of each CRRC is in compliance with the TCPS 2 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.
- (iii) With the approval of the appropriate REB or CRRC Chair, the instructor may submit the protocol to be followed on behalf of the entire class or large groups of students, with REB approval given to the instructor who takes responsibility for the ethical conduct of the data collection exercise. Under these conditions, the instructor takes on added responsibility to ensure that all students understand and follow principles of ethical conduct.
- (iv) As stipulated in Policy section 2.4(c), student research projects which involve humans and that are conducted by students on other members of the class as exercises to learn how to conduct research do not require review by the REB or CRRC.
- (v) In cases where the instructor is uncertain whether a course exercise constitutes research, whether it is necessary to submit a single protocol on behalf of the class or individual protocols, or

whether ethics approval is required at all, the written opinion of the REB or CRRC Chair must be sought before undertaking the class exercise. Instructors should consult the document "Guidelines for Ethics Review of Course-Based Research Projects" for guidance on what constitutes research that requires REB approval, and which activities do not require review because they both do not constitute research and are employed primarily for professional skill development, or pedagogic purposes. It is advisable for instructors to clarify the status of class exercises with the appropriate REB or CRRC Chair at the beginning of each academic term.

2.5 Responsibilities of Faculty Members as Supervisors of Student Researchers. Even if a student is the primary researcher collecting the data, the supervising faculty member has the following responsibilities for the protection of the human participants:

- (a) During the design of a project, faculty members should instruct students on the ethical conduct of research and help them prepare protocol submissions for REB approval. The faculty member as Research Supervisor is required to sign the student's protocol submission to the REB. The signature indicates both that the Supervisor has reviewed and approved the student's submission and that the Supervisor acknowledges his or her responsibility to see that University policy will be followed.
- (b) After REB approval, faculty members must take an active role to ensure that projects are conducted in accordance with the REB's requirements. Meeting periodically with students to review their progress is one way to meet this responsibility.

2.6 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 Research Ethics Board review and approval. If there is uncertainty regarding the requirement for Research Ethics Board approval, the individual administering the activity must seek the written opinion of the appropriate Research Ethics Board Chair. Individuals may find it useful to refer to "Guidelines for Administrative Research" posted on the Human Ethics website and contained in an Administrative Bulletin on this topic.

Committee Structure/Composition/Terms of Reference

2.7 Human Ethics Resource Committee (HERC), reporting to the Senate Committee on University Research (SCUR). As stipulated in policy section 2.3, the Human Ethics Resource Committee, under the auspices of the Senate Committee on University Research is responsible for ensuring University-wide understanding of, and compliance with, the applicable guidelines. This Committee is responsible for

ensuring that all human participants in research are treated with the highest possible ethical standards in accordance with applicable guidelines. The composition and terms of reference of HERC are outlined in Appendix I.

2.8 **Research Ethics Boards (REBs).** The REBs are responsible for the ethics review of all protocols involving the use of humans in research. It is the responsibility of the REBs to:

- (a) ensure that all protocols that propose the use of humans comply with this policy and all applicable ethics guidelines;
- (b) ensure that the potential benefits of these protocols are sufficient to warrant the use of humans; and
- (c) take corrective action regarding, or even terminate any ongoing research project which is in contravention of this policy or of a previously approved protocol.
 - (i) Approval to conduct research on humans will be granted only after the research ethics protocol has been examined by members of a REB.
 - (ii) There shall be five REBs, with responsibility for the ethics reviews of research with humans at the University of Manitoba as outlined below.
 - (iii) **Bannatyne Campus REBs.** Two REBs have responsibility for monitoring protocols at the Bannatyne Campus: the Biomedical Research Ethics Board (BREB) is to receive and review all research ethics protocols involving clinical trials and other biomedical research interventions. The Health Research Ethics Board (HREB) shall receive and review research ethics protocols from the Bannatyne Campus involving the behavioural sciences, surveys, examinations of medical records and protocols of generally lesser risk. Members of the Colleges of Medicine, Dentistry, and Pharmacy, the affiliated teaching hospitals, their associated research foundations and the College of Rehabilitation Sciences, shall submit their protocols to the REB they consider appropriate. The Chairs of these REBs have the final authority in deciding whether the BREB or the HREB is appropriate for the review of all submitted protocols. In addition to Bannatyne Campus protocols, the BREB shall review any protocols that may be referred from REBs on the Fort Garry Campus.
 - (iv) **Fort Garry Campus REBs.** Two REBs have responsibility for the ethics review of research with humans on the Fort Garry Campus.

These areas of responsibility will be reviewed from time to time and may be re-designated by HERC to ensure approximately equal division of numbers of protocol submissions arising from the Faculties, Schools and Departments on the Fort Garry Campus. Unlike the Bannatyne Campus, Faculties and Departments on the Fort Garry Campus are assigned to specific REBs and all protocols shall be submitted to their designated REB. Researchers may not submit their protocols to alternative REBs and REBs may not review protocols from units other than those within their mandate, or that have been properly referred by another REB Chair. Protocols from the Fort Garry Campus that involve biomedical interventions should be appropriately indicated on the protocol submission form so that the Chair of the REB to which it is submitted may immediately refer it to the BREB for review. The REBs on the Fort Garry Campus are:

1. the REB 1 which will review protocols submitted from the Departments of Psychology and Sociology, Faculty of Social Work, Student Counselling and Career Centre, Faculty of Kinesiology and Recreation Management, College of Nursing, and the Asper School of Business;
2. the REB 2 which will review protocols submitted from the Faculty of Education, Extended Education, Price Faculty of Engineering, Faculty of Agricultural and Food Sciences, Faculty of Architecture, Faculty of Arts (except Psychology and Sociology), Faculty of Law, Faculty of Science, Department of Environment and Geography, the Schools of Art and Music, the Libraries, the Natural Resources Institute, the Centre for the Advancement of Teaching and Learning, Peace and Conflict Studies, and research conducted by central administration (see Procedure section 2.6).

- (v) **Research Within Multi-Disciplinary Research Centres/Institutes.** Protocols of researchers affiliated with multi-disciplinary research centres/institutes shall be submitted to and reviewed by the REB that reviews research from the academic unit in which the researcher holds their primary academic appointment. The appropriate REB for ethics review is consistently to be determined by the principal researcher's appointment, not by the varying topic or approach of the specific project, nor by the disciplines of co-researchers.
- (vi) **Administrative Research.** Administrative research conducted by the central administration that requires ethics review and approval (See Procedures section 2.7-2.8) should be submitted to the REB 2. Unit-based administrative research deemed to require ethics

review and approval, i.e., research conducted by or for a Faculty or Department, should be submitted to the discipline-relevant REB.

- (vii) The composition and general terms of reference of the REBs are determined by the Human Ethics Resource Committee under the auspices of the Senate Committee on University Research and are outlined for each of the five REBs in Appendices II and III. In all respects, the terms of reference of these REBs are consistent with the guidelines of the TCPS 2. The REBs and HERC report to the Senate Committee on University Research and to the Associate Vice-President (Research) and maintain ongoing liaison with faculty members.
- (viii) The Chairs of the REBs are appointed by the Senate Committee on University Research on the recommendation of the Associate Vice-President (Research) and HERC. Chairs have delegated authority for signature, on behalf of the University, of approved protocols under their jurisdiction. Chairs also have the authority to approve any protocol that qualifies for delegated review, any request for time/participant extension, any request for an amendment to an approved protocol, and any request for renewal of approved protocols. Chairs also have the authority to refer a protocol to another more appropriate REB for review, and to assign, in their absence, a delegate to perform Chair duties. Chairs of REBs are members, ex officio, on the Human Ethics Resource Committee.
- (ix) Members for each REB shall be nominated to the Associate Vice-President (Research) by the REB Chair, on the recommendation of the Departments and/or Faculties/Schools submitting protocols to that REB. Each REB Chair shall propose to HERC and SCUR the specific configuration of the REB and the number of members to be nominated from each Faculty or Department, in proportion to the number of each Department's or Faculty's submissions. The specific nominees for each faculty position allotted to each Faculty or Department shall be elected or selected in a manner determined by that Faculty or Department. Within REBs that cover a number of Faculties/Schools and Departments, such as the REB 2, effort shall be made to rotate REB membership so that all units submitting protocols to that REB have opportunities for representation.
- (x) Meetings of the REB. REBs shall meet face-to-face on a regular basis at dates and times that are publicly announced in advance (preferably for the entire academic year). Whereas REBs normally meet monthly, this may not be necessary at certain times of the year (e.g. July or December) and researchers should be informed well in advance so that they may plan their protocol submission for

the most appropriate meeting. Researchers should also be informed of the dates by which their materials must be received by the REB in order to be considered at scheduled meetings.

Regularly scheduled monthly REB meetings may be cancelled if no protocols for full-board review have been received by the submission deadline. Even under these circumstances, each REB must meet at least once each academic term. Where circumstances require, members may attend, and meetings may be held, by a communications medium (such as telephone) if all members participating in the meeting are able to communicate with each other.

- (xi) **Quorum, Decision-making, and Minutes of REB Meetings.** The quorum for the conduct of an REB meeting normally shall be a minimum of five duly appointed REB members, including both women and men, and including a community member, a member knowledgeable in ethics, two members with expertise in relevant research areas covered by the REB and, for the biomedical research projects, a member with legal expertise. 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.

Normally decisions shall be arrived at by consensus. After all reasonable efforts to reach a consensus have been exhausted, decisions shall be taken on the basis of a simple majority vote. Minutes of all REB meetings shall be prepared and maintained for the REB by the Human Ethics Secretariat or Research Ethics Board Coordinator.

Protocol Review and Approval

- 2.9 **Protocol Submission.** Before a project involving the use of humans for research is initiated, a Research Ethics Protocol submission form describing the proposed procedures must be filed with the Human Ethics Secretariat, either in the Fort Garry Ethics Office or the Bannatyne Campus Research Ethics Board Office. The protocol must indicate the REB to which it is addressed, whether referral to another REB is advisable, and should provide a clear statement of the proposed research (scientific rationale and details of the procedures to be used with the humans, including obtaining their informed consent). In short, it should include all the information required by the TCPS 2, applicable regulatory agencies, relevant privacy legislation and submission requirements posted on the Fort Garry Human Ethics Website or Bannatyne Campus Ethics Website.

- 2.10 Pilot studies should be identified as such in protocol submissions to the REB. A single protocol submission outlining a range of treatment procedures may be a practical way of obtaining ethics approval for the variations the researcher wishes to pilot test. Following identification of a workable treatment or procedure, the researcher must resubmit a new ethics protocol submission that may receive delegated review and approval.
- 2.11 On receipt of the protocol submission, the REB Chair or delegate will review the submission to determine if it is complete. If additional information is required, the Chair will either return it to the applicant for completion, or request additional information.
- 2.12 If it is determined that the submission is complete, the Chair or designate of the relevant REB will decide whether a delegated or full review is required. The Chair or designate will also determine if the protocol would be more appropriately reviewed elsewhere and, if so, refer it to that other REB. For example, a protocol from Nursing or Kinesiology and Recreation Management that involves invasive procedures, might be referred to the BREB for review. In such cases the REB reviewing the “referred protocol” shall report its decision to the referring REB as well as to the researcher.
- 2.13 **Types of Review.** Proposals for research will receive proportionate reviews; that is, the degree, depth and extent of the ethics review will be proportional to the anticipated degree of risk to participants. In cases where the anticipated risk is negligible or low, REBs have the authority to delegate review of such protocols (Delegated Reviews). Protocols that involve greater than minimal risk must be reviewed in face-to-face meetings of the REB (Full REB Review). Hence, research projects are reviewed at one of two levels, depending upon the REB's (Chair's) interpretation of the project's risk to participants. The final determination of whether a delegated or full review is required will be made by the REB Chair. Accordingly, applicants should anticipate the possibility of a full review in the timing of their submission. REBs will assess applications proportionate to the magnitude and probability of potential harm to the participant inherent in the research under review, and if appropriate, may refer the application to another REB with the appropriate expertise, or to the full REB if a subgroup is conducting the review.
- 2.14 **Delegated Review.** To qualify for a delegated review, a research project must involve an activity that incurs no more than minimal risk for participants (see Policy section 2.1), or be a minor change in a previously approved research ethics protocol that involves no additional risk to the research participant(s).
- (a) **Procedures for a Delegated Review.** Decisions on protocols subject to delegated reviews are reached by a review of the protocol by either a subgroup of the REB, the applicable Chair or a designated individual member specified by the applicable Chair. If reviewed by a subgroup, two

members (the Chair may be one of these) read the submission and forward their decision/recommendations in writing (in print or by electronic means) to the Chair. The Chair of the REB renders the decision for the Committee based on the judgment of these REB members. If both members approve the protocol as submitted, the project may be approved; however, if one or more members (including the Chair) raise concerns, normally the Chair will provide feedback to the applicant and assess revisions made by the applicant to determine to what extent the concerns have been resolved. The Chair may also attempt to resolve these informally with the applicant, or decide that the protocol warrants a full review, in which case the protocol submission must be referred to the next regular meeting of the REB.

- (b) **Time Line for Delegated Reviews.** Every effort shall be made by the REB to provide rapid decisions. The goal shall be to achieve a turnaround time of 15 working days for such reviews.
- (c) **Reporting of Delegated Reviews by the REB.** At each regular meeting of the REB, all approvals by delegated review since the previous meeting must be reported to the full REB.

2.15 **Full Review.** A project that involves greater than minimal risk requires approval by an REB in a face-to-face meeting that allows discussion and exchange of information regarding the protocol. Research that requires full Committee review includes, but is not limited to:

- (a) research that involves direct contact or interaction with children or other vulnerable populations, such as those with mental disabilities or dementia;
- (b) research that involves experimental drugs or devices;
- (c) research that involves invasive procedures;
- (d) research that involves significant deception; and/or
- (e) research on sensitive topics that could cause distress to research participants.

2.16 **Time Frame for Decisions on Projects Requiring Full Review.** Because the REBs normally meet for full reviews only monthly, it is extremely important for the researcher to allow ample time for the review process to take place in advance of their plan to conduct the research. It is also essential to be certain that the protocol submission is complete and answers all questions that might be anticipated. Submissions must be received no later than 10 working days prior to the REB's published meeting date in order to be considered at that month's meeting. Decisions of the full board meeting will be reported to the applicant in writing (in print or by electronic means) within approximately 5-10 working days.

- 2.17 **Conflict of Interest.** When an REB is reviewing research in which a member of the REB has a real or perceived personal interest, conflict of interest principles require that the member not be present when the REB is discussing or making its decision. 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.
- 2.18 **Ethics Review of Research to be Conducted at Another Institution.** An ethics protocol submission for research to be conducted at another institution normally should be accompanied by a letter from the REB of that institution, indicating that permission has been granted for the research to proceed. If ethics approval from the University REB is required before such a letter may be obtained, the applicant should state this in their submission to the University REB. In this instance, the REB may grant approval, conditional upon receipt of the letter of approval from the other institution before the research commences. Special procedures to facilitate the review process may be negotiated between a University REB and another institution where research by university researchers may frequently occur, e.g. National Research Council laboratories, Winnipeg school divisions. Such agreements shall be reported to the Chair of HERC for comment and approval.
- 2.19 **Ethics Review of Research to be Conducted at Multiple Universities.** Research conducted at other universities in addition to the University of Manitoba must receive ethics review and approval from the appropriate University of Manitoba REB as well as those at the other institutions. The research may not proceed until approval has been granted.
- 2.20 **Scientific/Scholarly Standards and Ethics Review.** It is unethical to conduct research that is incapable of addressing the research question being asked. The researcher must ensure that his/her 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 research ethics protocol (see Procedure section 2.3(a)).
- 2.21 The REB also has the responsibility as part of its review to be assured that the research is valid. Normally, scientific validity is assumed for research that has received peer review by a grant adjudication Committee (internal or external), or by the REB following a “face-validity” test of the research, i.e. the research meets a reasonable scientific/scholarly standard. The extent of the scientific/scholarly review that is required will vary according to the risk associated with the research being carried out. In those circumstances where a REB is in agreement that the research warrants more careful assessment, the REB may request an ad hoc independent scientific/scholarly peer review of the research if appropriate expertise to make that determination is not available within the REB.

2.22 **Types of REB Decisions.** After review by a REB, the protocol submission may be:

- (a) approved as submitted;
- (b) approved with suggestions for minor changes (which can be implemented after final approval is granted);
- (c) approved with conditions (that must be met before final approval is granted);
- (d) deferred, pending receipt of additional information or major revisions;
- (e) not approved.

2.23 The REB shall notify each researcher in writing (in print or by electronic means) of its decision regarding his/her proposed research activity. Normally the researcher will accept the proposed modification or offer a counter-proposal to the Chair of the REB. This exchange is concluded normally when an ethically acceptable form for the research is agreed upon. To facilitate the continuing processing of such research ethics protocols between meetings, the REB should specify conditions that should be met to enable the Chair to review and grant approval on behalf of the REB. Researchers have the right to request, and REBs have an obligation to provide, reconsideration of decisions affecting a research project. In the case of student research projects supervised by a faculty member, any request for the reconsideration of a decision must be made jointly by the student and the faculty supervisor.

If the REB does not approve a research activity, the notification shall include a statement of the reasons for its decision and the researcher shall be given an opportunity to respond in writing (in print or by electronic means) or in person. The REB may, at its discretion, re-review and reconsider its decision to not approve the research activity.

Records of All REB Committee Decisions

2.24 All REBs must make provision to record and report to HERC all REB decisions in a form specified by HERC.

- (a) **Retention of Records.** All REBs must make provision for the retention of relevant records (protocols and related correspondence) for a period of time following completion of the research. Minimal risk protocols should be retained, either in paper copy or electronically, for a period of three years. All other protocols should be retained for a minimum of 7 years. At the conclusion of this period HERC shall annually review and approve the files

to be retained or removed from storage and shredded (if paper) or deleted (if electronic).

2.25 Appeals of REB Decisions. The REB and the researcher should engage in negotiation to achieve a mutually agreed upon protocol that is scientifically and ethically acceptable. However, if all reasonable alternatives are explored and no agreement is achieved, i.e. the protocol is still deemed to be unsatisfactory, the REB shall reject the application. Under these circumstances the decision of the REB may be appealed to HERC. Appeals may be based on procedural grounds or on the substance of the protocol on which the researcher and the REB did not agree.

- (a) Appeals of an REB decision should be directed by the researcher to the Human Ethics Secretariat who will notify the HERC Chair of the receipt of an appeal. In the case of student research projects supervised by a faculty member, the appeal must be made jointly by the student and the faculty supervisor.
- (b) On receipt of an appeal, the Chair of HERC shall request a report in response to the appeal from the Chair of the REB. HERC will review the appeal and the report from the REB Chair and may seek additional external opinion. HERC shall invite both the appellant (or appellants, in the case of student and supervisor) and the REB Chair to attend its meeting to provide additional information and/or explanation. Both parties to the appeal, however, shall not be present during the decision-making process on the appeal.
- (c) Appeals may not result directly in approval of the research ethics protocol by HERC. HERC may either reject or uphold the appeal. In the latter instance, the REB shall be informed of the decision and shall be instructed to reconsider the protocol in light of the decision on the appeal. SCUR, having oversight for HERC, will then serve as the Final Appeal Committee (whose decisions shall be final and binding in all respects) for any appeal taken by any affected person or group against a decision by an REB. SCUR shall select three (3) committee members to hear the appeal. None of these members shall have been involved in any way with the protocol under appeal.

Modification/Monitoring Approved Research

2.26 Beginning the Research. Human participants may not be recruited and researchers may not begin collecting data until the research ethics protocol has been approved by the appropriate REB. Once approved, the researcher is obligated to follow the procedures contained in the protocol.

- 2.27 **Modification of an Approved Protocol.** The protocol is approved for the procedures, the number and characteristics of participants and the time period (up to a maximum period of one year) specified. An approved protocol is not to be modified subsequently without the prior written notification and approval of the Chair of the appropriate REB. During data collection, however, if the researcher recognizes the need for modifications to the procedures or to the number and characteristics of participants indicated in the original protocol submission, s/he is obligated to submit a written (in print or by electronic means) request for protocol amendment. Such correspondence should be sent directly to the Fort Garry Human Ethics Coordinator or Bannatyne Research Ethics Board Coordinator. Delegated review and approval of these changes, if appropriate, may be made by the REB Chair. If required, the REB may reconsider the protocol in light of the proposed revisions. The researcher may not proceed with the modified protocol until approval has been granted.
- 2.28 **Time Extensions.** All protocol approvals are for a maximum period of one year, and may be renewed by submission of an annual report on the anniversary date of the full approval or conditional approval at a full board meeting or the date of the original protocol approval vetted through delegated review procedures. Protocol submissions for data collection for a period less than one year lapse at the end of the time specified (unless a subsequent request for time extension and new end date are submitted to the REB for approval).

Monitoring Approved Research

- 2.29 **Serious Adverse Events Reports.** Normally it is anticipated that research will proceed with little or no special costs or harm to participants, beyond those noted in the protocol. However, unanticipated negative reactions by participants or other unexpected events may occur. Researchers are obliged to report immediately any known serious adverse event to the Fort Garry Human Ethics Coordinator or Bannatyne Research Ethics Board Coordinator.
- 2.30 **Annual Reports/Ethics Approval for Continuing Research.** Annual reports are required for long-term or ongoing research projects. Such reports should be submitted on the anniversary date of the full board meeting or final ethics approval date for delegated review projects to enable the REB to monitor the progress of the research and any ethical issues that may have emerged. Researchers must request renewal of ethics approval for any data collection that continues beyond the 12 months for which ethics approval had been given. Such requests should clearly indicate the status of data collection and, if there will be changes to the protocol that was approved, specify in detail the nature of any changes that are required. Depending on the changes, the protocol may require further REB review.
- 2.31 **Final Reports.** In accordance with the TCPS 2, researchers conducting studies with approval from a University of Manitoba Research Ethics Board are required

to submit a Final Study Status report to the REB upon closure of the study or study termination and to notify the REB when a study has been prematurely suspended. Such reports shall be submitted to the Human Ethics Secretariat (Fort Garry Campus) or Research Ethics Board Coordinator (Bannatyne Campus) no later than 30 days following the conclusion of the data collection or the final study closeout visit by the sponsor.

If a study is terminated prematurely or suspended for any reason, the researcher must promptly inform the appropriate REB in writing (in print or by electronic means) of this suspension; the reasons for the suspension and the appropriate measures in place to assure appropriate therapy and follow-up for the participants; and the procedures considered for notifying the participants. If the reason for suspension is related to an emergent safety issue, the notification should be either faxed to the REB office or preceded by a telephone call to either the Chair or Human Ethics Secretariat (Fort Garry Campus) or Research Ethics Board Coordinator (Bannatyne Campus).

Random Monitoring

- 2.32 The Human Ethics Resource Committee (HERC) or the Research Quality Management Office will select research sites for educational site visit purposes. As much as possible, these visits will be collaborative in nature and educational in scope.
- 2.33 Research sites will be randomly selected from Faculty and Student pools of research at the Fort Garry and Bannatyne campuses. Site visits will be conducted with as much emphasis as possible on collaborative and continual learning.
- 2.34 If, during the course of a site visit or if brought to the attention of the Research Quality Management Office, an instance of noncompliance with this policy is discovered, the Research Quality Management Office, in collaboration with the Chair of the appropriate REB, will meet with the researcher (and research supervisor, if applicable), to learn as much about the circumstances surrounding the noncompliance as possible. Every effort will be made to informally resolve the issue through educational supports and future site visits (REB, QM Office, HERC). If, however, a satisfactory resolution is not reached, or the noncompliance recurs, the appropriate Dean/Director/Department Head will then be consulted. Serious instances of noncompliance or repetitive policy breaches shall be forwarded to the Chairs of HERC and SCUR for reporting and to the Provost and Vice-President (Academic) for disposition.
- 2.35 **Noncompliance by Researchers.** Instances of noncompliance with this policy and the procedures derived from it are to be brought to the attention of the Chair of the appropriate REB for resolution. If a resolution is not reached with the researcher or the problem recurs, the Chair of the REB shall attempt to obtain a

satisfactory resolution through the appropriate Dean/Director/Department Head. Serious instances of noncompliance or repetitive policy breaches shall be forwarded to the Chair of SCUR for reporting and to the Provost and Vice-President (Academic) for disposition.

- 2.36 **Preparedness Plans for 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 a rule of reasonable, fair and principled design and for use only during publicly declared emergencies and at the discretion of the applicable REB Chair, the normal research ethics 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.
- 2.37 **Research Involving First Nations, Inuit and Métis Peoples of Canada.** The University of Manitoba and the TCPS 2 acknowledge the unique status of the Aboriginal peoples of Canada. The guidance provided by the TCPS 2 is based on the premise that engagement with the community is an integral part of ethical research involving Aboriginal peoples. Researchers planning to involve Aboriginal peoples as part of their research should consult Chapter 9 of the TCPS 2.
- 2.38 **Educational Requirements.** As educational tools (such as online tutorials) are implemented university-wide by HERC, those applying for research ethics approval may be required to complete and provide proof of completion to the applicable REB.

Part III Accountability

- 3.1 The Office of Legal Counsel is responsible for advising the Vice-President (Research and International) that a formal review of this Procedure is required.
- 3.2 The Associate Vice-President (Research) is responsible for the implementation, administration, and review of this Procedure.
- 3.3 Board of Governors members, Senate members, Faculty/School Councils, students and all employees are responsible for complying with this Procedure.

Part IV Review

- 4.1 Governing Document reviews shall be conducted every ten (10) years. The next scheduled review date for this Procedure is November 12, 2030.

- 4.2 In the interim, this Procedure may be revised or repealed if:
- (a) the Vice President (Research and International) or Approving Body deems it necessary or desirable to do so;
 - (b) the Procedure is no longer legislatively or statutorily compliant; and/or
 - (c) the Procedure is now in conflict with another Governing Document.
 - (d) the Parent Policy is revised or repealed.

Part V
Effect on Previous Statements

- 5.1 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 VI
Cross References

- 6.1 This Procedure should be cross referenced to the following relevant Governing Documents, legislation and/or forms:
- (a) [The Ethics of Research Involving Humans Policy](#)