University Human Research Ethics Board (UHREB)

POLICIES AND PROCEDURES

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INTRODUCTION

This document contains University policies regarding the ethical conduct and the ethics review of human participant research, scholarship, and teaching exercises, as well as the procedures for review. Researchers, instructors, and students should read this document before making an ethics review submission. Faculty and graduate student ethics applications must be submitted using WebGrants. All undergraduate ethics protocols must be submitted using the application forms and checklist available on the University's web site at: http://www.uwinnipeg.ca/index/research-ethics.

Researchers and any member of their research teams (including Research Assistants and supervisors for student applications) interacting with human research participants or handling their identifiable data must demonstrate familiarity with and commitment to abide by the guidelines embodied in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2nd Edition (TCPS 2) by completing the online Course on Research Ethics (CORE) Tutorial and submitting a copy of their CORE certificate to the University Human Research Ethics Board at ethics@uwinnipeg.ca

The CORE tutorial is available at http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/

Please read the *Policy on Human Research Ethics Education Training*

Note: *Separate University policies and procedures apply to research with non-human vertebrate animal subjects.*

Ethics Review

The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2nd Edition* (TCPS 2)[1] incorporates the principle of proportionate review: the more invasive the study, and/or the greater the risk to participants, the greater the level of ethical scrutiny (see Article 6.12). Also, review involves weighing potential harms against potential benefits. Investigators must consider carefully the level of risk posed by the study, making every possible effort to eliminate or minimize potential harms. The investigator must also consider the potential benefits of the study (to the participants, to science/scholarship, and/or to society) and attempt to maximize these. Where the risk is minimal, scrutiny of a research project will be proportionally reduced, while adhering to the core principles of the TCPS 2. As the level of foreseeable risk rises, the level of scrutiny of the ethics application and subsequent conduct of an approved project will increase. In preparing a proposal, you should keep in mind the necessity to address fully all potential risks and benefits.

Given the breadth of possible research/scholarly topics and methods to be reviewed, neither these *Policies and Procedures* nor the application forms can cover all possible circumstances or ethical issues that might arise. Circumstances might occur in which a principle or standard of conduct implied in these materials is inappropriate, or should be applied differently from what is implied or

1 Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2010.
www.pre.ethics.gc.ca

stated. The principles and standards of conduct reflected in these materials have been selected to apply to frequently encountered research/scholarly situations. If a study has less typical aspects, the researcher should explain the circumstances thoroughly and provide ethical rationales for proceeding in a different way. For example, most research involving minors rightly requires parental consent but there may well be compelling reasons for waiving the requirement for parental consent. Also, informal consultation often is as important as formal review interactions. **Researchers are encouraged to consult with the Departmental Ethics Committee, the Research Office, and/or University Human Research Ethics Board members if it is unclear what items or standards apply, what documentation is needed, or how a particular ethical issue might be handled. Consultation during proposal preparation may save time during later review.** During review, the committees will consult with the researcher if unanticipated issues arise or if clarification is needed, and will work with the researcher to try to solve problems. For student research, consultation with the instructor or supervisor also is an important avenue for clarifying submission procedures and resolving ethical issues.

POLICIES

Undertakings Requiring Review

Research, scholarship, and teaching exercises involving living human participants or human biological materials (see TCPS 2, Chapter 12) undertaken under the aegis of The University of Winnipeg require review and approval by the appropriate ethics committee(s) before the project is begun. Review and approval are required whether the work is undertaken by faculty, staff, or students; whether or not it is funded by or jointly conducted with outside agencies; whether it is funded or unfunded; whether it is conducted inside or outside Canada; whether or not it is intended for publication; whether or not it is a pilot study; whether or not it is conducted as a pedagogical exercise; and regardless of the number of participants involved. Contract research must be approved if in securing the contract and/or conducting the research, the researcher makes reference to his/her University of Winnipeg affiliation and/or uses any of the resources of the University. All undertakings that involve the collection of information regarding living human participants, including but not limited to tests, observations, questionnaires, interviews, written communications, and/or representations (such as photographs, audio recordings, video or digital recordings, etc.) of living human participants, normally require approval, except as indicated below.

Exceptions

1. Ethics review is not required if the information collected is restricted to that which is publicly available, including open-access web documents, archival documents and records of public interviews or performances.
2. Research about an individual involved in the public arena, or about an artist, does not require ethics review if it is based exclusively on publicly available information. However, it does require review if the individual and/or third parties are approached directly for interviews or for access to private materials under their control.
3. Ethics review is not intended to preclude critical commentary or free inquiry. Critical research may be justifiable even in cases where the careers or social status of people in positions of power could be harmed by reporting the results of the research. Please read the full text of TCPS 2, Articles 3.6 and 3.7 for guidance.
4. Ethics review is not required for quality assurance studies, performance reviews, and testing within normal educational requirements. TCPS 2, Article 2.5 indicates that studies related directly to assessing the performance of an organization or its employees or students, within the mandate of the organization or according to the terms and conditions of employment or training, should not be subject to REB review. However, if performance reviews or studies are also intended in part for research purposes, ethics review is required. If any identifiable data collected is later proposed for research purposes, ethics review will be required (see TCPS 2, Section D of Chapter 5). “Research purposes” as used in this document signifies the researchers’ intention to report on the data analysis in scholarly venues.
5. Use of research methods for the purpose of clinical/professional skills development does not require ethics review if the data collected will not also be used for research purposes. Examples are measuring, recording, analyzing and reporting on biometric indicators of fellow students in an Athletic Therapy course; recording observations of K-12 students in an

Education practicum and drawing on them in a class assignment. However, as with the examples in 4 above, even though the research activity is not used for research purposes and therefore outside the mandate of UHREB, many of the same issues are involved (e.g., confidentiality, consent) and faculty and staff leading such activities may wish to consult the Research Office on these matters.

6. Observational studies of persons in public places where there is no reasonable expectation of privacy do not require ethics review as long as (1) the study does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups; **and** (2) any dissemination of research results will not allow identification of specific individuals. See TCPS 2, Article 2.3. However, all other categories of observational research require review, as described in Chapter 10, Observational Studies (page 141) and Article 10.3 of the TCPS 2. See Appendix H for ethics review of observational research involving children, captive or dependent populations, and vulnerable individuals.

Principles Guiding Review

1. The purpose of human participants ethics review is to foster and ensure research/scholarly practices that respect the rights and dignity of participants, promote the integrity of researchers/scholars, and uphold the principle of academic freedom.

2. All proposals require review using common ethical criteria, regardless of the proposal's disciplinary origin or the status of the investigator(s).

3. The University requires adherence to the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2010* (TCPS 2), both on the part of investigators and on the part of review committees. Compliance with relevant disciplinary ethics guidelines is also expected.

4. Research and review must be guided by the core principles of (a) Respect for Persons, (b) Concern for Welfare, and (c) Justice, as articulated in the TCPS 2 (see Chapter 1 – Ethics Framework). These core principles expressing the underlying value for human dignity serve to balance the goals of protecting participants and serving the legitimate requirements of research (page 11). This involves identifying levels of risk, and may involve peer review of the project's science/scholarship when the risk is more than minimal.

5. Although all undertakings require adequate review, the level of ethical scrutiny (i.e., full review/delegated review; frequency of reporting) will be proportionate to the invasiveness and potential harm of the research/scholarship (level of risk).

6. All investigators, whether faculty, staff, or students, are responsible for the ethical conduct of undertakings in which they are involved.

7. Ethical review does not end with the project's approval. A project lasting longer than one year requires renewal. Renewals require an annual progress report, and certain projects may require more frequent progress reports and/or ongoing monitoring. Please note, 2-2-1 Delegated Reviews generally require progress reports at the time of renewal.

8. Although it is the ultimate responsibility of ethics committees to decide whether or not to approve projects, departmental ethics committee and UHREB reviews should always be conducted in an atmosphere of respect for both ethical rigour and academic inquiry, and through collegial practices that facilitate the conduct of research by helping researchers to develop protocols that meet TCPS 2 requirements,.

Levels of Risk

The type of review and the ongoing review procedures that are required depend upon the level of risk posed by the proposed undertaking. Investigators have a responsibility to minimize any possible harms and to ensure that these are merited by potential research outcomes and potential benefits. The onus rests with investigators and ethics review committees to consider carefully the level of risk and the potential benefits of proposed projects. No simple definition of risk level can be provided, because of the complexity of considerations that might be involved. The following descriptions are not definitive, but rather are intended as a rough guide to determining risk level:

1. **Minimal Risk:** The TCPS 2 defines "minimal risk" research as that in which "…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" (Chapter 2, Section B). Minimal-risk research/scholarship is minimally invasive (physically, socially, and/or in terms of participants' emotions and personal privacy). It does not involve any sort of temporary concealment from the participants of information that reasonably might be expected to affect their decision to participate were disclosure complete, nor does it involve vulnerable persons. Minimal risk research does not require peer review of the research design for ethics vetting. Nonetheless, investigators should ensure that their research design is sound so that participants can be confident that the study they are being asked to contribute to is methodologically capable of achieving its objectives.

2. **Greater than Minimal Risk**: Research/scholarship can be regarded as involving moderate (or higher) risk if it exceeds the standard of everyday life risk described above, and/or is at least moderately invasive. Greater than minimal risk is also present if the research involves temporary concealment of information or incomplete disclosure to participants in advance of participation (unless this would be unlikely to influence the decision to participate), if informed consent cannot be obtained, if a breach of confidentiality or publication of the results might place the participants or their membership group at risk, if the participants are legally incompetent or institutionalized, if large inducements to participate are present, etc. For research involving greater than a minimal level of risk, it must be demonstrated that all possible steps have been taken to minimize harm, and that the potential benefits of the research outweigh the potential harms. Thus, peer review of the science/scholarship will be required, in order to establish that the project is capable of answering the questions posed and that beneficial knowledge and/or direct benefits to participants are likely to result.

   ***Note**: Research/scholarship that involves greater than minimal risk requires full review (face-to-face meetings of the full UHREB). In general, greater-than-minimal-risk projects will be*

approved, providing that the ethical issues raised have been addressed adequately.

3. **Significant Risk**: Research/scholarship can be regarded as involving significant risk either if the potential unwanted risk to any one participant is great (e.g., of physical harm, mental anguish, legal conviction, harassment by other persons, etc.), or if the research poses a significant risk to any group should the results become public. In addition, risk increases from moderate to significant as the degree of invasiveness increases, as the degree of incomplete disclosure increases, as the likelihood that participants would refuse consent were they fully informed increases, as the degree of incompetence of or the degree of constraint on participants increases, as the attractiveness of inducements to participate increases, etc. Normally, outside of biomedical research that involves great potential benefit to the participant, research involving significant risk should not be undertaken. In extraordinary circumstances, such research might be approved if it can be demonstrated that no alternative investigative method exists, that everything possible will be done to minimize risk, and that the probable benefits (as assessed in peer review) are so exceptional as to outweigh the potential harms.

Matters of Particular Concern in Ethics Review

Notwithstanding the necessity to address **all** ethical issues fully, the following key elements of the TCPS 2 should receive particularly careful attention in preparing your proposal. (Please note, general references are provided but many of these issues are also dealt with throughout the TCPS 2.)

1. **Free and Informed Consent (Chapter 3):** Free and informed consent must be given individually, and must be maintained throughout the study. Ordinarily it should be obtained in writing. Where there are good reasons for not doing so, alternative consent procedures should be proposed. In some observational studies (see *Observational Research* above) or in other appropriate circumstances (which must be described fully), informed consent procedures may be altered or waived by the UHREB. If your study involves unusual circumstances that preclude obtaining free and informed consent (written or other), you might wish to consult informally before submitting your proposal. Information provided to inform participants about the study before obtaining consent must be comprehensible to them (i.e., written or spoken in plain language, and/or translated fully if necessary). It must include a statement of the research purposes, the identity of the investigator(s), the expected nature and duration of participation, a description of research procedures, and a description of any foreseeable harms or benefits that might arise from participation. Participants must be informed that they are free to withdraw without compromising their entitlement to any inducement offered (3.19b). Other information typically provided on a consent form (but which may be provided in some other way) includes the names and contact numbers of the Departmental Ethics Chair and UHREB Program Officer, information on how participants may obtain the findings of the study, any special procedures for ensuring privacy and confidentiality, study withdrawal, and information about the uses to be made of the information collected. If at all possible, participants must be given a copy of the consent form to retain, or an alternative document that contains the above information. **Sample consent forms are appended.** See TCPS2, Article 10.2 for implied-consent guidelines for individuals in positions of power and individuals who routinely provide information in the course of their work.

Please note that for University of Winnipeg students under the age of 18, parental consent is not required.

2. **Temporary Concealment and/or Incomplete Disclosure (Article 3.7):** If you plan any temporary concealment of the study's purposes or of any other aspect of the research/scholarship (e.g., the use of role-playing research confederates, the use of "distracter" questions to draw away attention from the questions of interest, implying that one behavior is under study when in fact something else is being observed, etc.), or if your study involves deliberate partial disclosure, you must discuss this fully in your proposal. In some kinds of studies, the purposes initially are only partially disclosed to avoid over-sensitizing participants to particular issues, but the undisclosed information would not be likely to affect informed consent. If this is the case for you, describe the way in which disclosure is incomplete, provide a rationale, and if you are suggesting the study involves minimal risk, provide assurance that the information left undisclosed would not reasonably be expected to influence informed consent. Ethics committees will review the issue, and may decide that your study poses minimal risk in this regard. However, if there is concealment or partial disclosure about matters that reasonably might be expected to influence informed consent, the proposal will be categorized as "greater-than-minimal risk" or higher. In such cases, you must discuss the potential risks, explain how you will eliminate or minimize them, and explain how you will debrief the participants (i.e., inform them after data collection of any undisclosed or concealed features of the study). You must also describe how you will explain the reasons for the concealment or incomplete disclosure, and how you will try to dispel any negative feelings or loss of trust/respect that have been created. In addition, where feasible, you must offer an opportunity to withdraw consent for the use of the data after debriefing. Where there is a moderate or greater risk of harm to participants, or where they cannot later be debriefed, ethics committees may not approve the research. Note that if your proposal is classified as moderate (or higher) risk, it will require Full Review, and additional review time may be required to address fully the ethical issues raised.

3. **Privacy, Anonymity, and Confidentiality (Chapter 5):** In many kinds of research/scholarship, participants have the right to expect that their identities will be kept anonymous and that the private information they provide will be kept confidential. Even when the investigator has reason to believe that people will agree to being identified publicly, they must be asked whether they consent to this. You must specify in your proposal whether you will protect privacy, anonymity, and/or confidentiality, and if so, how you will do so. You should refer to this in your informed consent material as well. If there are risks attached to the accidental revelation of participants' identities or private information, describe these, explain how they will be minimized, and take them into account in assessing you study's risk level. In some studies, the risk of accidental revelations might conceivably result in serious consequences, such as public ridicule, loss of employment, legal charges, exposure to harassment or attack, etc. In such cases, you must ensure that unintentional revelation of information is impossible (e.g., by keeping no records that include names, identifying information, handwriting, photographs, tapes, etc.) or must otherwise incorporate substantial safeguards. Describe these fully in your proposal. Where the actual risk is low, but reviewers might perceive it as higher, be sure to explain carefully. Should the risk of revelation of

information present a greater risk than participants encounter in related aspects of their everyday lives, the proposal will be classified as moderate (or higher) risk, and will require Full Review. Also, note that even where everyday risk is high (e.g., risk of attack by an estranged abusive spouse), the risk created by participation in a study (e.g., risk that an estranged abusive spouse could become aware of the participant's location) might not be justifiable.

4. **Vulnerable Persons (Article 4.7)**: Ethical conduct precludes the exploitation of persons who are legally or otherwise not competent to provide informed consent. However, research/scholarship involving such people may provide benefits to them or to the group that they represent. Thus, investigators should not automatically exclude vulnerable persons from research participation. However, if research/scholarship conceivably could be conducted effectively using a legally-competent population, that alternative should be given careful consideration. If vulnerable persons are the participants in your study, your consent procedures must comply with all legal requirements that might apply. Consent must be obtained from an authorized representative who is able to advocate independently for the vulnerable person. Also, you must demonstrate that the study will not pose more than minimal risks to participants without the potential for direct benefits to them. Special care must be taken to ensure that there is no coercion, constraint, or undue inducement to participate. You must indicate clearly in your proposal how these requirements will be met. The participation of vulnerable persons will place the proposal in the moderate (or higher) risk category, regardless of the degree of actual risk to participants. Thus, Full Review will be required, and additional review time may be required to address the ethical issues raised.

5. **Children (Articles 3.9, 4.4, 4.6):** Revised TCPS2 guidelines clarify that capacity for self-consent should not be determined by participants' chronological age, but by their decision-making capacity with respect to the ability to understand the benefits and harms of participating in the research. The informed consent of parents or authorized representatives must be obtained where children have not yet developed the capacity to consent for themselves in those aspects of their lives related to the research. Even in cases where it is determined that children lack the requisite competence and parental consent is required, the child also must be given an independent opportunity to decline to participate in the study, if he/she is old enough to do so. Information provided to children must be comprehensible for their age or developmental level. Particular care must be taken to prevent real or apparent coercion, constraint, or undue inducement to participate. These matters must be discussed fully in the proposal. However, the involvement of persons under 18 years of age as participants does not, in and of itself, place a study in the moderate (or higher) risk category. Schools, day care centres, etc., often have review procedures that must be followed in addition to those of the University, and additional time should be allowed for this. Also, if relevant, note that the law requires the reporting of any disclosures of abuse of persons under the age of 18. If this is a potential issue, discuss it fully in your proposal.

6. **Captive or Dependent Populations (Article 3.1):** If the participants are drawn from "captive or dependent" populations (e.g., in prisons, schools, hospitals, psychiatric facilities, treatment programs, etc.) special care must be taken to ensure that consent is given freely, and that no actual or perceived coercion, constraint, or undue inducement to participate is present. Often, because the investigator has good intentions, he/she may fail to note some way in which

potential participants might feel subtle pressure to participate. For example, a payment of five or ten dollars for research participation might represent a large inducement to someone who has no other means of obtaining extra money. Even if the investigator has no connection to participants' doctor or therapist, they might nonetheless feel that refusal to participate might compromise their treatment or therapy. The onus is on the investigator to identify potential problems of free and informed consent and/or actual or perceived coercion, to devise safeguards to prevent or minimize such problems, and to explain these matters fully in the proposal.

7. **Research on Aboriginal Peoples (Chapter 9):** Considerable debate and sensitivity exist around issues involving the study of Aboriginal peoples (e.g., community involvement in research design, role of governing authority, community consent, opportunities for community commentary on research findings, cultural appropriation, etc.). If your study involves Aboriginal participants or their cultural property as a focus of research/scholarship, you should read the full text of Chapter 9 of the TCPS 2. Also, you should read any discipline-specific ethics guidelines that may apply to your study. You might wish to consult with Aboriginal groups, colleagues, and/or Departmental or the University ethics committees before designing the study. In addition, you should note that depending upon the study's characteristics, the Departmental and/or University ethics committees might require that Aboriginal representatives be present during review meetings. If so, additional time might be required to make the necessary arrangements for review and to resolve issues that arise. Other sources of information may be found via the following links:

    1. **Canada Institutes of Health Research (CIHR)**
       Guidelines for Health Research Involving Aboriginal Peoples:
       http://www.cihr-irsc.gc.ca/e/29134.html
    2. **Social Sciences and Humanities Research Council of Canada (SSHRC)**
       SSHRC'S position paper *Opportunities in Aboriginal Research*:
       http://www.sshrc.ca/web/apply/background/aboriginal_backgrounder_e.pdf
    3. **Royal Commission on Aboriginal Peoples**
       http://www.ainc-inac.gc.ca/ch/rcap/index_e.html
    4. **The First Nations Information Governance Centre**
       The First Nations Principles of **OCAP**
       http://www.rhs-ers.ca/node/2
    5. **Metis Centre at NAHO**
       Principles of Ethical Metis Research
       http://www.naho.ca/documents/metiscentre/english/PrinciplesofEthicalMetisResearch-descriptive_003.pdf

Types of Review

Proposals will be subject to one or more of the four types of review described below:

1. **Full Review**: This is the normal (default) review process. Except as described in (2) and (3) below, all proposals will receive initial review by the appropriate Departmental/Program ethics review committee, and then by the UHREB. At the University level, review will occur in scheduled, face-to-face meetings of the full ethics committee. Should the proposal involve more than a minimal degree of risk (see above), the University committee will require peer review of the project's science/scholarship. Please note, most funded research has already

undergone peer review.

2. **Delegated Review**: Projects involving only minimal risk (as described above) **may** be eligible for Delegated Review, provided that the investigator requests such review, that the Departmental Ethics Committee recommends Delegated Review, and that the Chair of the UHREB concurs. In such cases, proposals for which investigators request Delegated Review will receive the normal form of scrutiny at the departmental level, and the Departmental Ethics Committee will decide whether or not to recommend Delegated Review to the UHREB. If this recommendation is positive, the Chair of the UHREB will then make a provisional decision as to whether or not Delegated Review is appropriate. Should either the Department's recommendation or the UHREB Chair's decision be negative, the proposal will thereafter be subject to the provisions for Full Review. If the Chair's decision is positive, the proposal will then be reviewed individually by the Chair and two UHREB members. Should any of these reviewers decide that Full Review is necessary; the proposal will then be subject to the provisions for such review.

   Should Delegated Review result in provisional project approval, this will be reported to the next meeting of the full UHREB. If any objections to the provisional approval arise at that meeting, the proposal will be subject to further Full Review. It should be noted that Delegated Review is available **only** for minimal-risk proposals for which the Department and University committees concur that such review is appropriate, and is **not available** solely because of investigators' time constraints.

3. **Undergraduate Student and Course Project Review**: Course labs, demonstrations, honours theses, fourth-year projects, senior student research, independent studies courses, and other undertakings that are **minimal risk require only Departmental Ethics Committee review and approval,** and do not require review and approval at the UHREB level. Such departmental review must comply with the relevant provisions set out below under *Procedures*. At its sole discretion, the DEC may request UHREB review for any student project. *Please note that graduate students are required to undergo the regular UHREB review process where the research is not covered by an approved course project ethics protocol.

4. **Multi-Site Research Review:** When a **minimal risk** ethics proposal has been reviewed and approved by an institution (other than The University of Winnipeg) working under the *Tri-Council Policy Statement (TCPS)* it may be submitted to the UHREB for review under the Multi-Site Research Review process. In this process, the UHREB Chair is given the discretion to decide whether the ethics protocol may be approved or requires UHREB vetting. In the case where the Chair believes all University of Winnipeg ethics requirements have been met, they have the authority to accept the approval from the other institution without further review. In the case where further expertise is needed to determine whether The University of Winnipeg is likely to approve the proposal, the Chair may consult experts and/or may initiate normal UHREB review procedures. **Ethics protocols higher than minimal risk must undergo a Full Review by the UHREB**.

Note: *For the procedures on protocol Renewal, Amendment and Subsequent Stage of Research, as well as the above types of review, please see the Procedures section.*

Researcher/Scholar/Instructor Responsibilities

All members of the University community (faculty, staff and students) who conduct research, scholarship, or teaching activities involving human participants have the responsibility to:

- familiarize themselves with the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans,* December 2010 (TCPS 2) and the University's *UHREB Policies and Procedures*, as well as any relevant disciplinary ethics guidelines, and to abide by these;

- complete the CORE tutorial and submit a copy of their certificate to the UHEB;

- consider and resolve satisfactorily any ethical issues raised by the project they plan to undertake, consulting as appropriate with colleagues, instructors, and members of Departmental or University ethics committees;

- not undertake any project involving human participants that requires review (see above) without obtaining the necessary approval;

- ensure that proposals submitted for review are complete, and describe all aspects of the project relevant to ethics review;

- disclose in their proposals any real or apparent conflicts of interest regarding their relationship with potential participants or regarding the potential uses of the research findings;

- conduct their research in accordance with the contents of their approved proposals; and

- comply with all undertakings, reporting procedures, and monitoring procedures that form conditions of project approval.

Additional Faculty/Staff Responsibilities

Individual faculty and staff members are responsible for ensuring that:

- any projects undertaken under their supervision have received the necessary ethics approval, and that persons under their supervision are aware of the applicable ethics policies;

- proposals submitted under their supervision are complete and properly address the ethical issues involved; and

- all ethical undertakings made in the proposal are honored in the conduct of the approved project, both by themselves and by persons under their supervision.

Adverse Event Reports

Adverse event reports should be submitted **WITHOUT DELAY** to the UHREB via the Research Office. An adverse event is one that exceeds the level of response anticipated and provided for in the approved proposal. Adverse Event forms are available from the Research Office or from the Research Office's web site at: http://www.uwinnipeg.ca/index/research-ethics.

Final Reports

Final reports must be submitted to the Research Office in a timely manner upon termination of projects and where ethics approvals are no longer required. Final Report Forms are available from the Research Office or from the University's web site at: http://www.uwinnipeg.ca/index/research-ethics.

Final Reports are required for ALL ethics projects.

Departmental Responsibilities

It is the responsibility of each University department, program, or affiliated institution or college to:

- establish and maintain a Departmental Human Research Ethics Committee (DEC), and to ensure that all departmental projects are reviewed as required. In small departments or those that infrequently conduct human participants research or scholarship, the Department Chair or their designate may fulfill the responsibilities of the DEC (if the Department needs assistance, it may seek consultation from the Research Office and/or the Chair of the UHREB);

- ensure that all members of the DEC have completed the CORE tutorial and submitted a copy of their certificate to the Research Office before conducting ethics reviews;

- establish and maintain guidelines for the ethical conduct of human participants research/scholarship. These must include the TCPS 2 and the *UHREB Policies and Procedures*, and should also include accepted disciplinary guidelines relevant to the nature of the project;

- ensure that all ethics proposals arising from the Department are appropriately reviewed, that proposals forwarded to the UHREB are complete and address any ethical issues that arise, and that projects do not proceed without the necessary approval;

- report to the Research Office on an annual basis the names of the DEC Chair and DEC members, as well as a list of any disciplinary guidelines that are used in Departmental review;

- ensure that all Departmental faculty and staff are aware of these *Policies and Procedures*, and that students and research assistants who are expected to design and/or conduct projects covered by these *Policies* are informed of them as well; and

- abide by UHREB Procedures for ethics review (below).

UHREB Responsibilities

See *The University of Winnipeg University Human Research Ethics Board Terms of Reference* for information on the mandate, authority, accountability, composition, meetings, and membership of the UHREB.

- The UHREB will review and approve/disapprove individual proposals in accordance with this Policies and Guidelines document and the UHREB *Terms of Reference*.

- Minutes of the UHREB deliberations shall be kept. For proposal reviews, the minutes shall document clearly the decisions, any dissents, and the reasons for them. Although proposal deliberation minutes are generally confidential, such minutes (or relevant portions of them) shall be accessible to all UHREB members, investigators (regarding only their own proposals), authorized administrative assistants, and the Vice-President (Academic). In addition, UHREB members may discuss portions of the minutes dealing with proposals arising from particular departments/programs with the relevant Department Chairs (or the equivalent) and/or members of Department Ethics Committees. Portions of the minutes may be made available, when requested, to Tri-Council representatives, for purposes of review and policy-compliance monitoring.

- The UHREB will review these Policies and Procedures periodically, and will recommend any necessary changes for University approval.

UHREB Chair Responsibilities

In addition to such other responsibilities as may be delegated to the UHREB Chair, or outlined in the UHREB *Terms of Reference*, they are responsible for:

1. Reviewing all proposals received by the UHREB, whether for Full or Delegated Review.

2. Authorizing proposal approvals, doing so only when they are satisfied that all relevant *Policies and Procedures* have been followed.

3. Making provisional decisions regarding proposal eligibility for Delegated Review.

4. Seeking (at the UHREB's direction) appropriate peer reviews of the proposed research/scholarship when the risk is more than minimal, and when the investigator cannot provide adequate existing peer reviews.

5. Determining whether proposals to change substantive elements of previously approved projects require full UHREB review, and if not, to review them on behalf of the UHREB.

6. Conducting any aspects of ongoing review delegated to the Chair by the UHREB.

7. Communicating with investigators as required concerning their proposals.

8. Consulting as required with investigators and Departmental Ethics Committees.

9. Ensuring that the UHREB meets at reasonable, scheduled, publicized time intervals.

10. Making recommendations to the Vice-President, Research and Innovation for the appointment of UHREB members.

11. Appointing *ad hoc* temporary UHREB members as required.

12. Consulting with the Community Representative in the event that she/he cannot attend a meeting.

13. Participating in UHREB educational undertakings.

14. Ensuring that problems arising with these Policies and Procedures are noted for the purpose of future revision, and that such revision occurs as required.

Appeals of DEC or UHREB Decisions

1. Investigators may request in writing that the DEC, the UHREB, or both, reconsider decisions made regarding their proposals. In the case of the UHREB, reconsideration normally will take place at a regularly scheduled UHREB meeting (i.e., not a special meeting called for the purpose of reconsideration). Investigators may also request that the UHREB review a decision of a DEC (after Departmental reconsideration), in which case the proposal in question will receive Full Review at the UHREB level, taking into consideration both the Departmental decision and the reasons therefore, and the contrary arguments of the investigator.

2. Decisions of the UHREB **may not** be appealed to The University Executive or to The University. Instead, appeals of such decisions will be heard in Brandon by the Brandon University Human Research Ethics Board, under the conditions of a joint appeal agreement between Brandon University and The University of Winnipeg. Appeal decisions of the Brandon University Human Research Ethics Board are final (see the UHREB *Terms of Reference*, section (C) Reconsideration and Appeal Process).

PROCEDURES – FACULTY APPLICATIONS

All Faculty and Graduate Student ethics applications must be submitted through the WebGrants web-based program:
http://www.uwinnipeg.ca/index/research-webgrants

Time Frame and Procedures for Review

It is the responsibility of the investigator to allow sufficient time for review in advance of the anticipated project start day. Time frame considerations include the following:

1. **Submission completeness**: Proposals that lack required items, do not provide sufficient detail for review, or are not submitted with the necessary attachments will be returned for completion and resubmission.

2. **Ethical complexities**: Proposals involving ethical issues that necessitate further consideration may require time for consultation, revision, and/or committee discussion at more than one scheduled meeting. Careful review at the DEC level may help to reduce the time later required for review at the UHREB level.

3. **Type of review required**: The level of review (Full or Delegated) will affect the review time frame. **Provided that no additional time is needed because of submission incompleteness or ethical complexities**, the guidelines for review timing are as follows:

    i. **Full review** (the default procedure, where all members of UHREB participate in the review): Before submitting the application through WebGrants, the investigator submits a PDF copy of the complete proposal including application, proposal, research measures, etc., to the Departmental Ethics Committee. That Committee reviews the proposal within five (5) working days. The DEC Chair completes and signs the Departmental Ethics Committee (DEC) Review form (available on Research Office website). One copy is retained for departmental files and one copy is returned to the investigator with a recommendation. If the recommendation involves proposal revision, the DEC has five (5) further working days to review the resubmitted revised proposal. If it is recommended departmentally that the proposal move forward to the UHREB, the investigator then submits the complete proposal, including a PDF attachment of the completed Departmental Recommendation page, to the Research Office through WebGrants. Proposals received by the Research Office **prior to the publicized deadline** will be reviewed at the next scheduled UHREB meeting. Because the UHREB needs sufficient time to distribute and read submissions prior to the meeting, proposals received between the submission deadline and the meeting date **will not be reviewed until the subsequent scheduled UHREB meeting**.

    Investigators will be notified of the outcome of UHREB review within two (2) working days. **More time** may be required if the UHREB requires peer reviews of the

research design (i.e., in the case of unfunded research which has not been peer reviewed), if issues arise in the UHREB meeting that necessitate consultation or proposal revision, and/or if the UHREB requires that the proposal be revised and considered further at the next scheduled UHREB meeting.

ii. **Delegated Review (available only under the conditions described in the *Policies* section above, where the UHREB Chair delegates a protocol for review by one or two members of UHREB):** Before submitting the application through WebGrants, the investigator submits a PDF copy of the complete proposal including application, proposal, research measures, etc., to the DEC. That Committee reviews the proposal within five (5) working days. The DEC Chair completes and signs the Departmental Ethics Committee (DEC) Review form (available on Research Office website). One copy is retained for departmental files and one copy is returned to the investigator with a recommendation. If the recommendation involves proposal revision, the Departmental Ethics Committee has five (5) further working days to review the resubmitted revised proposal. If it is recommended departmentally that the proposal move forward to the UHREB, the investigator then submits the complete proposal, including a PDF attachment of the completed Departmental Recommendation page, to the Research Office through WebGrants. **If Delegated Review is not recommended, the procedure reverts to Full Review**, as described above. Within five (5) working days, the UHREB Chair makes a provisional decision regarding eligibility for Delegated Review**. If this decision is negative, the procedure reverts to Full Review**, and the submission will be considered at the next full UHREB meeting for which the deadline has not passed. If the decision is positive, at least five (5) further working days are required for UHREB Delegated Review, following which investigators will be notified of the outcome within two (2) further working days.

iii. **2-2-1 Delegated Review:** Should a research project require more than one year to complete, a researcher may select the 2-2-1 option of ethics review. In such cases **minimal risk** ethics submissions are reviewed under the Delegated Review process and approved for two years with the option to renew for another two years followed by an option to renew for an additional year (2-2-1). This review and renewal process is in place to reflect the term of Tri-Council grants and to assist researchers whose research will last longer than the usual one year approval with the one year renewal option. In this case, the researcher must indicate on the WebGrants application why this type of review is necessary for the research project.

***If reviewers decide that Full Review is required, the procedure reverts to Full Review**, and the submission will be considered at the next full UHREB meeting for which the deadline has not passed.

Note: *Prior to review or at any stage of review, investigators are encouraged to work informally with the DEC or UHREB to resolve ethical and procedural difficulties, and thereby to improve the likelihood of proposal approval in the formal review process. Investigators should contact the Chair of the relevant committee should they wish to engage in informal consultation.*

iv. **Multi-Site Research Review:** For minimal risk projects that the Chair reviews on their own, one copy of the complete APPROVED protocol with cover letter is required, (including the application, proposal, approval, research measures, etc. from the original submission). The only new information required from the researcher is the cover letter.

v. **Post-Approval Activities**: A *Post-Approval Activity form (available in WebGrants once a protocol is approved)* needs to be completed and submitted (with all accompanying information) to the Research Office for the following:

a. **Renewal**: Ethics approval is normally granted for a period of **one year only (two in the case of a 2-2-1 approval)**. If any project will extend beyond that time, the investigator must apply for a renewal of the project to the UHREB before the original approval has lapsed. Normally, a renewal will be granted once without further Full Review for one year, except in the case of substantive change to the research method, adverse participant responses, or major changes to the University's ethics policy. All renewals will be reviewed and approved by the UHREB Chair. Investigators must also reapply if **at any time** their procedures change in any substantive way from those proposed originally. On the recommendation of the DEC, and/or at the discretion of the UHREB, it may be required for **any** proposal that progress reports be submitted and/or that the committee monitor the ongoing project in some specified way. The form of review given to such reports (e.g., Full, Delegated, UHREB Chair, DEC only) will be specified when the ongoing review provisions are set. However, depending upon circumstances (e.g., increased risk levels, compliance difficulties, etc.) these may be changed as the project proceeds. For all projects the investigator is required to propose monitoring and reporting procedures at the time of proposal submission. In appropriate circumstances, where no ongoing review seems needed, the investigator may propose that no such procedures be applied.

i. **2-2-1 Delegated Review Renewal:** Should an ethics project require more than one year to complete, a researcher may select the 2-2-1 option of submission. In such cases minimal risk ethics submissions would be reviewed under the Delegated Review process and be approved for two years with the option to renew for another two years followed by a renewal of one year. This renewal is in place to reflect Tri-Council funding and to assist researchers whose research will last longer than the one year with one year renewal option.

ii. **Renewing a Lapsed Protocol:** There may be situations when a protocol is not renewed as no human participatory research was occurring at the time of renewal. Should a researcher wish to conduct further human participatory research within the same protocol after this time, but still within the renewal window (one year following the original expiry date), they must go through the renewal process and have approval in place before resuming the research. The approval will be granted for the time remaining in the renewal window, not for an additional year from the date

of renewal. For example, a protocol originally approved on April 1, 2013 and not renewed prior to April 1, 2014 would lapse. If the researcher wanted to resume human participatory research on the original project and submitted documentation on August 15, 2014, the maximum time of renewal would be until April 1, 2015. Should the protocol lapse after the renewal end date, the researcher would need to submit a new protocol.

b. **Amendment**: Where changes or additions to an approved ethics protocol are required, the appropriate Post-Approval Activity form in WebGrants is to be completed and submitted through WebGrants, along with any accompanying documentation. The UHREB Chair reviews and approves all amendments of an approved research protocol unless there is an increase in the level of risk, which would result in a Full Review.

c. **Subsequent Stages of a Research Project**: Where a successive stage (or stages) of an already approved ethics protocol is undertaken **within the same research project**, an updated submission must be made to secure ethics approval for the succeeding stage. (See Article 10.5)The *Request Change to Existing Ethics Protocol Form – Subsequent Stage of Research Project* is to be completed and submitted through WebGrants, along with any accompanying documentation. The UHREB Chair reviews and approves any subsequent stages of an approved research protocol unless there is an increase in the level of risk, which would result in a Full Review.

PROCEDURES – UNDERGRADUATE STUDENT REVIEW

NOTE: All student ethics review applications are to be submitted using application forms available on the Research Office website http://www.uwinnipeg.ca/index/research-human-ethics.

Undergraduate students do not currently have access to the online WebGrants application forms.

All **minimal risk** undergraduate student research is reviewed and approved at the Departmental Ethics Committee level. ******However, all Full Review, greater-than-minimal risk Undergraduate student protocols, as well as all Graduate Student protocols, will be forwarded to the Research Office, after Departmental review, for final approval by the UHREB**.

In cases where all students engage in an identical pedagogical exercise (e.g., all are conducting person-on-the-street surveys, or all are conducting in-class interviews), the course instructor may submit a single course protocol on their behalf to the departmental committee, and the instructor is responsible for ensuring that all students understand the protocol and the importance of following it correctly. The departmental committee may at its discretion delegate responsibility for approving minor variations from the approved protocol to the course instructor, provided the variation does not involve an elevation of risk or interaction with minors or captive populations.

In cases of student-directed minimal-risk research, including research intended for publication, the student will submit an ethics protocol for departmental review only. In some cases, the departmental committee may at its discretion delegate responsibility for review to the course instructor. However, all thesis research, whether undergraduate or graduate, must be reviewed by the departmental committee. All **greater-than-minimal-risk** research conducted by any student, staff or faculty member must be reviewed at the departmental and UHREB level.

i. **Full Review:** The investigator submits two copies of the complete proposal (including application, proposal, research measures, etc.) to the Departmental Ethics Committee. That Committee reviews the proposal within five (5) working days, retains one copy for departmental files, and returns the second copy to the investigator with a recommendation. If the recommendation involves proposal revision, the DEC has five (5) further working days to review the resubmitted revised proposal. If it is recommended departmentally that the proposal move forward to the UHREB, the investigator then submits **one electronic and one original signed copy** of the complete proposal, including the completed Departmental Recommendation page, to the Research Office. Proposals received by the Research Office prior to the publicized deadline will be reviewed at the next scheduled UHREB meeting. Because the UHREB needs sufficient time to distribute and read submissions prior to the meeting, proposals received between the submission deadline and the meeting date will not be reviewed until the subsequent scheduled UHREB meeting.

Ethics Review Delegated to the Departmental Ethics Committee

1. Senior Student Research/Scholarship, such as honors theses, fourth-year projects, independent studies courses, and other undertakings in which the student takes substantial responsibility for the design and conduct of a full-scale project are reviewed and approved by the appropriate Departmental Ethics Committee.

2. Course Project Review, such as course labs, assignments, demonstrations, papers, and projects, including senior student research, require only Departmental Ethics Committee review. Normally, the DEC will review submissions within five (5) working days of receipt. However, Departmental Ethics Committees may establish and publicize longer time lines, e.g., in the case of multiple-submission methods courses. **Two copies** of the complete proposal are required. Procedures for different categories of course projects are as follows:

a. For **fully instructor-designed labs, exercises, and demonstrations conducted with class members as participants**, the instructor submits **two copies** of the complete proposal to the Departmental Ethics Committee for approval before the first use of the procedure. It is the instructor's responsibility to notify the DEC of any subsequent use of the same classroom procedure. The DEC may or may not require further Departmental review.

b. For **fully instructor-designed course projects in which students collect data/information from participants who are not in the class**, the instructor submits to the Departmental Ethics Committee **two copies** of a single proposal, containing generic descriptions for each different project (if more than one is used). Following approval, it is the instructor's responsibility to notify the Departmental Committee of any subsequent use of the same project(s). The Departmental Committee may or may not require further Departmental review. In addition to Departmental Committee review of the instructor's proposal, **students individually submit complete proposals to the instructor.** (These must include the *Checklist* and copies of research instruments, but the level of required written project description is at the instructor's discretion.) The instructor only (not the DEC) reviews students' proposals, requiring modifications if necessary; approves them; and retains them on file for one academic year.

c. For **partially instructor-designed projects in which students contribute to design and collect data/information from participants who are not in the class**, students individually complete the *Checklist*, provide proposal descriptions that elaborate on any additions they have made to the instructor's design, and provide the necessary attachments. The instructor screens these for completeness and ethics compliance, then submits to the Departmental Ethics Committee a generic proposal description for each project used, relevant attachments, and all student submissions. By definition, such projects will vary on re-use depending on student contributions, so that they must be re-reviewed by the DEC each time they are used.

d. For fully student-designed projects in courses in which the project is only one course component, e.g., methods courses, students individually provide complete proposals. The instructor screens these for completeness and ethics compliance, and then submits them to the Departmental Ethics Committee. Any alterations made to a project after approval must be approved by the instructor (if they are minor) or by the DEC (if they are substantive).

The opinion of the UHREB should be sought regarding any questions or concerns about the policies and procedures or the need for ethics review.

Please note that pedagogical exercises such as role-playing an interview situation or designing a questionnaire that will not be used to collect data do not require ethics review.

PROPOSAL PREPARATION – FACULTY

Before preparing a proposal, investigators are urged to read thoroughly these UHREB Policies and Procedures, relevant sections of the TCPS 2, and any applicable professional ethics guidelines. They must also complete the CORE tutorial. The UHREB WebGrants application, and PDF copies of all research instruments must accompany all proposals, regardless of the type of review. Note that:

1. All applicable sections of the WebGrants form must be completed, or else marked as not applicable.

2. The investigator must identify the level of risk posed to the participants, propose the type of review the project should receive (Full, Delegated or Course Project), and if appropriate, propose an ongoing review mechanism.

3. All necessary signatures must be obtained on the Departmental Ethics Committee review form and a PDF attached to the WebGrants application.

4. The written project description must adhere to the page constraint indicated in the WebGrants application and must include all information that the application form indicates is required.

5. All responses that raise ethical questions must be addressed satisfactorily either in the appropriate spaces on the application form or in attached explanatory notes. Any other aspects of the project that are pertinent to ethics review also must be discussed.

6. All information must be provided that is pertinent to the assessment of risk levels, balancing of risks and benefits of the research, and the possible need for ongoing review.

7. The UHREB may require peer review of the project's science/scholarship if the level of risk is more than minimal. Thus, if peer reviews already exist, the investigator may wish to submit them as PDF copies with the proposal.

8. Investigators must disclose in their submissions any potential conflicts of interest that may arise in their relationships with participants and/or in the potential uses of the findings.

9. PDF copies of all research instruments must be attached, including questionnaires and reproductions or adequate descriptions of visual and other sensory or electronic stimuli. In the case of observational research, the nature of observation and the behaviors to be observed must be described. In the case of interviews, either specific interview questions or a detailed description of the parameters of interview contents must be attached. If participants are to be photographed, audio taped, videotaped, or otherwise recorded, a detailed description of the parameters within which recording will occur must be provided. Research conducted over the Internet may require additional specifications of the conditions of data collection.

10. The proposal must include either a participant consent form or an explicit method of otherwise obtaining informed consent. If the investigator considers a consent form impossible or

inadvisable, they must explain satisfactorily why this is so. In any event, a copy of the consent form (or of the information that would be provided were a written consent form to be used) must be given to the participants to retain whenever possible.

11. For research/scholarship conducted within or in association with other institutions, a letter of permission from a person with institutional authority must be provided either with the proposal or before the project begins. In exceptional cases (e.g., where this requirement would stifle free expression integral to the aims of the research), the investigator may propose that this requirement be modified or waived.

12. Incomplete proposals received by either Departmental Ethics Committees or the Research Office will be returned for resubmission.

13. Investigators may consult with their DEC, the Research Office, and/or the UHREB Chair, if they are uncertain what information is required or how the proposal preparation guidelines apply to their project.

14. Prior to their implementation, any alterations to procedures described in an approved proposal must be reported to the UHREB via the Research Office. The UHREB Chair will determine whether additional review is required, and if so, of what type.

15. The proposal must specify a mechanism for providing a summary of the study's results to interested participants where practical and appropriate.

16. If information is to be recorded in a manner that might permit identification of individual participants, the proposal must describe the provisions that will be made for storing such information securely and maintaining the confidentiality of the information.

PROPOSAL PREPARATION – UNDERGRADUATE STUDENT

Before preparing a proposal, investigators are urged to read thoroughly these UHREB Policies and Procedures, relevant sections of the TCPS 2 and any applicable professional ethics guidelines, and must complete the CORE tutorial.

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The UHREB ***Ethics Checklist*, a written project description, and copies of all research instruments must accompany all proposals, regardless of the type of review.** Note that:

1. All applicable sections of the *Ethics Checklist* must be completed, or else labeled "Not Applicable".

2. The investigator must identify the level of risk posed to the subjects, propose the type of review the project should receive (Full, Delegated or Course Project), and if appropriate, propose an ongoing review mechanism.

3. All necessary signatures must be obtained on the *Checklist*.

4. The written project description must adhere to the page constraint indicated in the *Checklist*, and must include all information that the *Checklist* indicates is required.

5. All *Checklist* responses that raise ethical questions must be addressed satisfactorily either in the project description or in attached explanatory notes. The location of such elaborations must be noted beside the relevant *Checklist* response. Any other aspects of the project that are pertinent to ethics review also must be discussed.

6. All information must be provided that are pertinent to the assessment of risk levels, costs and benefits of the research, and the possible need for ongoing review.

7. The UHREB may require peer review of the project's science/scholarship if the level of risk is more than minimal. Thus, if peer reviews already exist, the investigator may wish to submit them with the proposal.

8. Investigators must disclose in their submissions any potential conflicts of interest that may arise in their relationships with subjects and/or in the potential uses of the findings.

9. Copies of all research instruments must be attached, including questionnaires and reproductions or adequate descriptions of visual and other sensory or electronic stimuli. In the case of observational research, the nature of observation and the behaviors to be observed must be described. In the case of interviews, either specific interview questions or a detailed description of the parameters of interview contents must be attached. If subjects are to be photographed, audio taped, videotaped, or otherwise recorded, a detailed description of the parameters within which recording will occur must be provided. Research conducted over the Internet may require additional specifications of the conditions of data collection.

10. The proposal must include either a subject consent form or an explicit method of otherwise obtaining informed consent. If the investigator considers a consent form impossible or

inadvisable, they must explain satisfactorily why this is so. In any event, a copy of the consent form (or of the information that would be provided were a written consent form to be used) must be given to the subjects to retain whenever possible.

11. For research/scholarship conducted within or in association with other institutions, a letter of permission from a person with institutional authority must be provided either with the proposal or before the project begins (see *Checklist*). In exceptional cases (e.g., where this requirement would stifle free expression integral to the aims of the research), the investigator may propose that this requirement be modified or waived.

12. The correct number of proposal copies must be submitted, as indicated above.

13. Incomplete proposals received by either Departmental Ethics Committees or the Research Office will be returned for resubmission when complete.

14. Investigators should consult with their course professor, if they are uncertain what information is required or how the proposal preparation guidelines apply to their project. The course professor may consult the DEC, Research Office, and/or the UHREB Chair, if they are unable to answer a student's question.

15. Prior to their implementation, any alterations to procedures described in an approved proposal must be reported to the DEC Chair who will report to the UHREB, if applicable, via the Research Office. The DEC Chair and/or the UHREB Chair will determine whether additional review is required, and if so, of what type.

16. The proposal must specify a mechanism for providing a summary of the study's results to interested subjects where practical and appropriate.

17. If sensitive information is to be recorded in a manner that might permit identification of individual subjects, the proposal must describe the provisions that will be made for storing such information securely.

Reconsideration and Appeal

1. Investigators may request that either the DEC or the UHREB reconsider a decision that affects their project. They must do so in writing, detailing the reasons for their request. Such requests should be directed to the Chair of the relevant Committee. Normally, reconsideration at the UHREB level will occur at the UHREB's next regularly scheduled meeting.

2. Investigators may request that a DEC decision be reviewed by the UHREB, in which case the proposal will undergo Full Review by the UHREB. Such requests must be made in writing, detailing the reasons for the request, and should be directed to the UHREB Chair via the Research Office.

3. Decisions of the UHREB may be appealed under the terms of a joint appeal agreement between Brandon University and The University of Winnipeg, in which case the appeal is heard by

the Brandon University Human Research Ethics Board. The terms of the agreement and the procedure for appeal may be obtained from the Research Office. The outcome of such an appeal is final.

APPENDICES

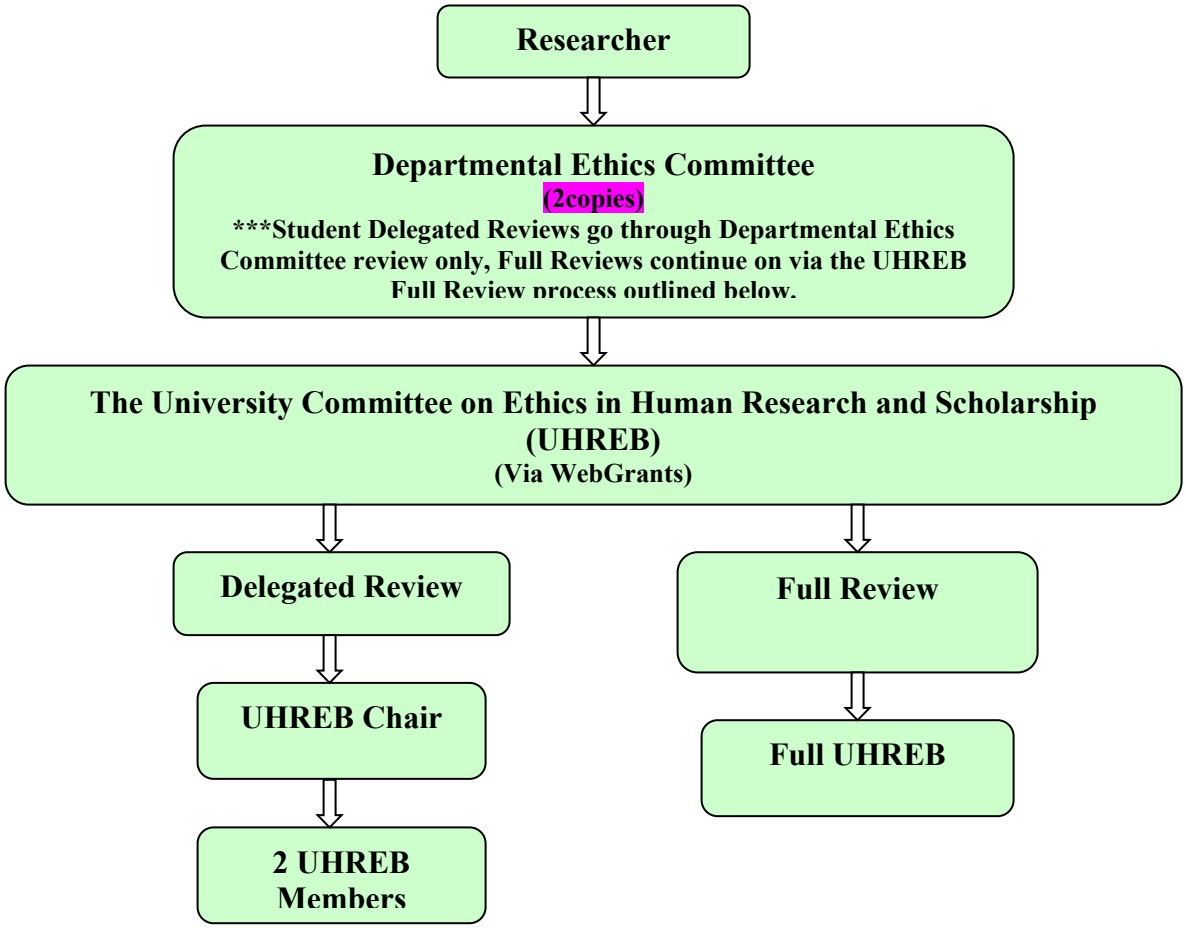
Appendix A: Scope of Research Requiring Ethics Review

The following which is adapted from the University of Alberta, *General Faculty Council Policy Manual* indicates the range of research projects or instances that should be reviewed by the REB.

- Whether the research is funded or not;
- Whether the funding is internal or external;
- Whether the participants are from inside or outside the institution;
- Whether the participants are paid or unpaid;
- Whether the research is conducted inside or outside Canada;
- Whether the research is conducted inside or outside the institution;
- Whether the research is conducted by staff or by students;
- Whether the research is conducted in person or remotely (e.g., by mail, electronic mail, fax or telephone);
- Whether the information is collected directly from participants or from existing records not in the public domain;
- Whether the research is to be published or not;
- Whether the focus of the research is the participant;
- Whether the research is observational, experimental, correlational or descriptive;
- Whether a similar project has been approved elsewhere or not;
- Whether the research is a pilot study or a fully developed project;
- Whether the research is to acquire basic or applied knowledge; and
- Whether the research is primarily for teaching or training purposes or whether the primary purpose is the acquisition of knowledge.

The *Scope of Research Requiring Ethics Review* was taken from the Interagency Advisory Panel on Research Ethics web site at: **http://www.pre.ethics.gc.ca/english/policystatement/appendices.cfm.**

Appendix B: UHREB Review Flowchart



If needed:

1. **Renewal** – reviewed by UHREB Chair
2. **Amendment** – reviewed by UHREB Chair
3. **Subsequent Stage of Research Project** – reviewed by UHREB Chair
4. **Multi-Site Research** – for minimal risk research only, reviewed by UHREB Chair (1 copy of original approved protocol to the Research Office with cover letter)

NOTE: Final Reports are required for all completed projects.

Appendix C: Sample Consent Form – Children, School Study

THE UNIVERSITY OF WINNIPEG

THINK LINK
UWINNIPEG RESEARCH

We are asking for your consent for your child to participate in a voluntary research study taking place at your child's school, under the supervision of _____ of the Psychology Department at The University of Winnipeg. She may be reached at 204-786-9xxx. We will study how children of different ages understand the idea of friendship, and how they act when they are playing with children they see as friends, and with children they do not see as friends. A trained research assistant will interview your child individually, after he has been introduced by the teacher and has spent some time in the classroom getting to know the children. He will ask your child to name which children in the class are his/her friends, and then to talk about what a friend is. This will take about twenty minutes of class time. If the child seems uncomfortable, or does not name any friends, the interviewer will stop asking questions about friends, and instead will invite the child to play a board game for fun. During two recess periods, the research assistant will videotape your child in his/her normal play with classmates. The teacher will explain that he is making a videotape so that he can learn about how children play. We will examine the videotapes for things like cooperation, arguments, sharing, and helping among children.

The results of the study may be presented in a talk at a professional conference, and may be published in an academic book. The findings will add to our knowledge about children's social relationships. In the future, the findings might be useful for developing ways to help children who have trouble making and keeping friends.

No information that might identify your child will be given to anyone outside the research team. The interview form and the videotapes will be given a code number, and will be kept in a locked room at the university. In the future, we might use the videotapes for a separate study of possible differences in boys' and girls' physical play. We will do so only if you agree (see below). If you do not agree, we will erase the videotapes promptly after using them for the present study. If you do agree, we will not keep the tapes any longer than two years, and we will erase them when the second study is finished. This consent form will be kept separate from the videotapes and the interview form.

This study has been approved by your child's school, and The University of Winnipeg University Human Research Ethics Board (UHREB). If you have any concerns about the way the study is conducted, please contact Dr. _____ at 204-786-9xxx. If there are any concerns that she has been unable to address to your satisfaction, please contact the UHREB Program Officer at 204-786-9058. Even if you have already given your consent, the researchers will also ask the children individually whether they wish to be part of the study, and will tell them they may stop participating at any time if they wish. Please note that your child may refuse to answer any question(s) and is free to stop

participating in the study at any time before the paper is complete, without consequence. The classroom teacher will provide children who do not participate with an interesting and fun alternative activity. Children who have very few friends may feel uncomfortable participating in this study. If you think that your child might feel uncomfortable discussing friendship, you might wish not to have your child participate. If you would like to discuss this further before making a decision, please call Dr. _____ at 204-786-9xxx.

Thank you for considering this request. If your child participates, a summary of the results of the study will be sent home with your child when the study is finished. The extra copy of this consent form is yours to keep. Please complete the other copy, and send it to the school with your child.

Signature of Chief Investigator: _____ Date: _____

Please check one: ____ I **do** give permission for my child to participate in the study described above.

____ I **do not** give permission for my child to participate in the study.

If you **do** give permission for your child to participate, please check one:

____ I **do** permit the researchers to keep my child's videotapes in a secure place for up to two years for use in future research. I understand that I will be contacted at _____(please insert your phone number) to be told more about the future study, and that I will be asked again for permission to use the tapes, after I have heard more details about the future study. At that time I may refuse my child's further participation in the study without consequence. I understand that if, at the time the request is made, my child has reached the age of 18, parental consent will not be required.

____ I **do not** permit the researchers to keep my child's videotapes for future use. Please erase the tape at the end of the present study.

Child's name (please print): _____

Name of parent/guardian (please print): _____

Signature of parent/guardian: _____ Date: _____

A copy of this consent form will be provided to you. Thank you for your consideration.

Appendix D: Sample Consent Form – Adults, Experimental Study

THE UNIVERSITY OF WINNIPEG

THINK LINK
UWINNIPEG RESEARCH

We invite you to participate in a voluntary research study conducted by Dr. _____ of the Psychology Department of The University of Winnipeg, who may be reached at 204-123-4567. The study will investigate how adults learn new skills at different ages. We will ask you some written questions about your age, education level, and work experiences. Then we will show you how to solve an unusual kind of wooden puzzle. Following that, we will ask you to try to solve three similar puzzles on your own, and to "think out loud" while you do so. You will probably find the puzzles challenging and maybe somewhat frustrating, but we also hope you will enjoy them. We will videotape you while you work on the puzzles. The study will take approximately one hour of your time.

We hope to discuss the findings of the study at a conference of psychologists, and also to publish them in a professional journal. We expect the study to add to psychologists' understanding of learning processes in adulthood. In the future, this information might help teachers who work with adult learners to create better teaching techniques. It might also lead to techniques for helping older adults who are having trouble learning new skills.

Your name will not be placed on the written questionnaire or on the videotapes. No information that might identify you will be given to anyone outside the research team. This consent form will be kept separate from the questionnaire and videotapes. The videotapes will be kept in a locked room, and viewed only by the researchers. As quickly as possible, we will make written notes from the videotapes, and then erase them.

The University of Winnipeg University Human Research Ethics Board (UHREB) has approved this study. If you have any concerns about the way this study is conducted, please contact Dr. _____ at 204-786-9xxx. If there are any concerns that she has been unable to address to your satisfaction, please contact the UHREB Program Officer at 786-9058. Please note that you are free to stop participating in the study at any time, if you so choose, without consequence. We appreciate you taking the time to consider participating.

Signature of Principal Investigator: _____ Date: _____

Please check one: _____ I **do** agree to participate in the study described above.
_____ I **do not** agree to participate in the study.

June 2017

Name (please print): _____

Date: _____ Signature: _____

If you wish to receive a summary of the study's results, please provide your mailing address on the lines below:

_____
_____
_____

A copy of this consent form will be provided to you. Thank you for your consideration.

Appendix E: Sample Oral Consent Procedure for Interview – Qualitative (see accompanying notes on Ethics webpage)

THE UNIVERSITY OF WINNIPEG

THINK LINK
UWINNIPEG RESEARCH

(on letterhead)

Pauline Greenhill,
University of Winnipeg,
515 Portage Ave.,
Winnipeg, MB R3B 2E9
204 786-9439
p.greenhill@uwinnipeg.ca

Consent Form, Oral History of Costuming Traditions and Events

I am a researcher from the University of Winnipeg. I am studying events in which adults physically represent themselves as a person of another sex or gender, as an animal, or as an object. These kinds of costuming have long been part of traditional and popular games, rituals, celebrations, and protests. I'm interested in current as well as historic forms. I want to know about your experiences with these kinds of events, and how you feel about them.

I'm glad you've indicated that you are interested in doing this interview. I hope that it's still OK with you. If it isn't, I will not continue. I would appreciate your allowing me to audio record an interview with you. The interview will probably take from 40 minutes to 2 hours. If we start the interview and you do not wish to continue, please tell me and I will not continue. If I ask a question or questions you don't want to answer, that is perfectly OK with me--you don't have to answer. You can also contact me if you later decide you don't want me to use the information you gave me. I will do my best to ensure that your information is removed from any presentation or publication that has not already happened.

DO YOU AGREE TO LET ME AUDIORECORD THIS INTERVIEW? yes/no

I do not foresee any risks that could result from your participation in this research. However, if you think of any, please bring them to my attention. The information I get from you may be used in my teaching and further research. It could be published in books or articles, and/or on the Internet. I may give public talks about it at events in Canada and internationally.

DO YOU AGREE TO LET ME USE THE MATERIAL IN THESE WAYS? yes/no
DO YOU WANT TO RESTRICT ANY OF THESE USES? yes/no COMMENTS?

This is important oral history research, and it would be nice if I could recognise you as the source of the information. But it is up to you if you want to be named or not. The only time I can't promise to identify you would be when identifying you would make it possible for someone else who doesn't want THEIR name associated with the research to be identified. However, if you do NOT want to be identified in the research I will give you a pseudonym, or you can choose your own.

DO YOU WANT YOUR NAME ON THE RESEARCH? yes/no
CHOSEN PSEUDONYM, IF ANY:
You will be giving me a lot of valuable information for my research. I would be happy to give you a copy of the recording and/or a copy of the written transcript of the interview. I will also do my best to contact you before I present any of my research results to see if I have accurately represented what you told me.

DO YOU WANT A COPY OF THE RECORDING? yes/no
DO YOU WANT A COPY OF THE TRANSCRIPT? yes/no

It is standard practice in the field of oral history to keep the audio recordings of interviews permanently. Your interview will be securely kept on digital files. At a future date, if you choose, these interviews, including the audio recordings, questionnaires, and/or transcripts, will be archived so that future generations can benefit from your knowledge. You are under no obligation to agree to this. In addition, if at a later date you wish to have the interview, transcripts and questionnaire removed from the archives and/or destroyed, that authority is in your hands.

DO YOU AGREE TO HAVE YOUR INTERVIEW DEPOSITED IN AN ARCHIVE? yes/no

I hope everything will go well with your interview. But if you have any concerns about it or this work I hope you will discuss them with me. I can be reached at (204) 786-9439, at p.greenhill@uwinnipeg.ca, or at the University of Winnipeg, 515 Portage Ave., Winnipeg, Manitoba R3B 2E9. But if you are still unhappy with something after you've talked it over with me, I urge you to contact the University Human Research Ethics Board officer at (204) 786-9058, ethics@uwinnipeg.ca, or the University of Winnipeg address above.

PLEASE NOTE HERE ANY QUESTIONS OR CONCERNS.

Thank you so very much for helping me. Please give me your:

name:

address:

phone number:

e-mail:

signature:

date:

Appendix F: Sample Oral Consent Procedure – Humanities, Public Figure or Artist Interview

SAMPLE ORAL CONSENT PROCEDURE
(Humanities, Public Figure or Artist Interview)

1. Do I (we) have your permission to ask you questions about your work and life?

2. Do I (we) have your permission to ask you questions about other artists' work and lives, and about related participants?

3. Are you aware that the purpose of this interview is to publish a version of our conversation in appropriate scholarly journals or popular periodicals?

4. Do I have permission to record this conversation?

5. Do you consent to the editing, for clarity and coherence, of tapes of or notes on our conversation?

6. Do you consent to the publication of excerpts of this interview for scholarly purposes?

7. Are you aware that in the spirit of free enquiry, I will be determining the scope and critical perspective of any publication arising from this interview?

Appendix G: Consent Form Checklist and Consent Form Template

Consent Form Checklist

Please complete the following Consent Form Checklist by circling the answer that best suits. The following list is to ensure that all of the necessary elements of a Consent Form(s) have been addressed. If you circle "No" or "N/A" for any of the items listed below please provide brief explanation in the area at the bottom of the page.

1.	The University of Winnipeg's letterhead is used	Yes	No	N/A
2.	Identity of the researcher and contact information	Yes	No	N/A
3.	Research topic/question, nature of participation, duration, and research procedures	Yes	No	N/A
4.	Risks and benefits of participation	Yes	No	N/A
5.	State how feedback is provided to the participants	Yes	No	N/A
6.	Anonymity	Yes	No	N/A
7.	Confidentiality	Yes	No	N/A
8.	Point of withdrawal and refusal to answer questions For example, "Participants may refuse to answer any question(s) and may withdraw at any time before ***publication*** without consequence."	Yes	No	N/A
9.	Data storage, length of retention, and method of disposal	Yes	No	N/A
10.	UHREB contact information: University Human Research Ethics Board (#204-786-9058 or ethics@uwinnipeg.ca)	Yes	No	N/A
11.	Copy of the consent form provided to all participants	Yes	No	N/A

Researcher Comments:

CONSENT FORM

We invite you to participate in a research study conducted by (*principal investigator*) of the (*Department name*) Department of The University of Winnipeg, who may be reached at (*telephone #, email*). The study will investigate (*research topic/question*, *nature of participation, duration, research procedures, risk and benefits*).

(Address confidentiality)

(*Address anonymity)*

Data will be stored (*where*) for (*length of time*) and will be disposed of (*method*).

If you have any questions or concerns about this study or the way it is being conducted, please contact the researcher directly. If you have any remaining concerns about the conduct of this study that the researcher has not been able to address, you may contact the University Human Research Ethics Board at 204-786-9058 or by email at ethics@uwinnipeg.ca.

Please note that your participation is voluntary and you may refuse to answer any question(s) and are free to stop participating in the study any time prior to (*publication, presentation, etc.*) without consequence. By consenting to participate, you do not waive any rights to legal recourse in the event of research-related harm. If you wish to receive a summary of the study's results please contact (*principal investigator's name*).

Please check one: _____ I **do** agree to participate in the study described above.

[If applicable, add separate checkboxes for use of images, quotes, identifying information, etc.]

Name (please print): _____

Signature: _____ Date: _____

Principal Investigator's Signature: _____ Date: _____

A copy of this consent form will be provided to you. Thank you for your consideration.

Appendix H: Observational Studies

Observation of children

Observational research involving children (under the age of 18) does not, in and of itself, involve more than minimal risk. See the section on *Children* in *Matters of Particular Concern in Ethics Review* below. However, special considerations may be involved, e.g., regarding children's security, their capacity to understand the implications of their actions, and/or their status as legal minors. Thus, potential risks to children may require greater ethical scrutiny than those in similar observational studies involving adults, and the study might be deemed to involve more than minimal risk. If this is the case, you should explain the circumstances fully in your project description, taking particular care to address any special ethical considerations that might apply, as well as how you will balance the potential risks and benefits of the study.

Observation of "captive or dependent populations"

Observation involving captive or dependent populations (e.g., in prisons, schools, hospitals, psychiatric facilities, treatment programs, etc.) may or may not involve more than minimal risk. See the section on *Captive or Dependent Populations* in *Matters of Particular Concern in Ethics Review* (page 9). Where free and informed consent for observation cannot be obtained from participants, or from parents or authorized third parties (in the case of children who lack the maturity to self-consent in matters related to the subject of the research), the proposal will be considered to involve moderate or higher risk. In your project proposal, you should explain the circumstances fully, as well as describe the safeguards that will be used to protect the participants if informed consent cannot be obtained. You should also explain how potential risks will be balanced against potential benefits of the study. Extra review time may be required to resolve ethical issues.

Observation of vulnerable persons

Observation of vulnerable persons (those who are legally or otherwise not competent to give informed consent) will place the study in the moderate (or higher) risk category. If the informed consent of authorized third parties cannot be obtained for the observation, the risks of the study may be too great for the project to proceed. See the section on *Vulnerable Persons* in *Matters of Particular Concern in Ethics Review* (page 10).