Principles Guiding the University of Winnipeg Human Research Ethics Board (UHREB) Review

1.0 In accordance with the latest version of the *Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans* (2018), all research, scholarship, and teaching exercises involving living human participants or human biological materials undertaken under the aegis of The University of Winnipeg shall reflect the core principles of: **respect for persons**; **concern for welfare**; and **justice**. 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. This involves identifying levels of risk, and may involve peer review of the project's science/scholarship when the risk is more than minimal.

2.0 Principles Guiding Review

2.1 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.

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

2.3 The University requires adherence to the latest version of the TCPS, both on the part of investigators and on the part of review committees. Compliance with relevant disciplinary ethics guidelines is also expected.

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

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

2.6 Ethics review does not end with the project's approval by the UHREB. 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.

2.7 Although it is the ultimate responsibility of the UHREB to decide whether or not to approve projects, Departmental Ethics Committee (DEC) and UHREB reviews should always be conducted in an atmosphere of respect for both ethical rigor and academic inquiry, and through collegial practices that facilitate the conduct of research by helping researchers to develop protocols that meet TCPS2, 2018 requirements.

3.0 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:

3.1 Minimal Risk: The TCPS 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 normally require peer (scholarly) 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.

3.2 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 by the UHREB. In general, greater-than-minimal-risk projects will be approved, providing that the ethical issues raised have been addressed adequately.*

3.3 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., 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.

4.0 Matters of Particular Concern in Ethics Review

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

4.1 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 Guidance Document 6) or in other appropriate circumstances (which must be described fully), informed consent procedures may be altered or waived by the UHREB. If a study involves unusual circumstances that preclude obtaining free and informed consent (written or other), the investigator should consult informally with the Ethics Office or the UHREB Chair before submitting a 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 purpose, 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 (for projects limited to departmental review) and University of Winnipeg Ethics 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. Good research practices involve providing participants with a copy of the consent form to retain, or an alternative document that contains the important information about the research, investigator(s), and contact information for the Ethics Office at the University of Winnipeg. See TCPS2 2018, 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. See also Guiding Document 5 on The Consent Process and Consent Templates.

When research involves vulnerable persons, an investigator may require the consent of an individual's legally authorized representative. Exceptions may apply to mature minors able to provide consent. For example, for University of Winnipeg students under the age of 18, parental consent is not required.

4.2 Temporary Concealment and/or Incomplete Disclosure (Article 3.7): If a researcher plans 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 a study involves deliberate partial disclosure, the researcher must discuss this fully in the proposal, providing a justification for the temporary concealment and/or incomplete disclosure. 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. In such circumstances, the researcher should describe the way in which disclosure is incomplete and provide a rationale. If the research involves minimal risk, the researcher must provide assurance that the information left undisclosed would not reasonably be expected to influence informed consent. Ethics committees (the DEC and the UHREB) will review the issue, and may decide that a 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, the researcher must discuss the potential risks, explain how the risks will be eliminated or minimized, and explain how the participants will be debriefed (i.e., inform them after data collection of any undisclosed or concealed features of the study). The researcher must also

describe how the reasons for the concealment or incomplete disclosure will be explained, and how any negative feelings or loss of trust/respect that have been created will be dispelled. In addition, where feasible, the researcher 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 a 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.

4.3 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. The researcher must specify whether and how privacy, anonymity, and/or confidentiality will be protected, including in the informed consent material. Risks attached to the accidental revelation of participants' identities or private information (if any) should be described in detail along with how they will be minimized. This information will be taken into account in assessing a 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, the researcher 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. The proposal must provide detailed information on the potential for unintended disclosure of personal information, including all mitigation strategies to be employed. Where the actual risk is low, but reviewers might perceive it as higher, it is essential that such matters be explained thoroughly and 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, 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.

4.4 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 to which they belong. 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 a study, consent procedures must comply with all legal requirements that might apply. Consent must be obtained from a legally authorized representative who is able to advocate independently for the vulnerable person. Also, the researcher 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. The researcher must indicate clearly in the 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.

4.5 Children (Articles 3.9, 4.4, 4.6): The TCPS guidelines make clear that capacity for self-consent should not be determined by a participant's chronological age, but by the individual's decision-making capacity (i.e., the ability to understand the benefits and harms of participating in the research). The informed consent of parents or legally 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 the child 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, it should be discussed fully in the proposal.

4.6 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/they may fail to note some way in which potential participants might feel subtle pressure to participate. For example, a payment of $5 or $10 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' service provider (e.g., a doctor or a 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.

4.7 Research on Indigenous or First Nations, Metis or Inuit Peoples (Chapter 9): Considerable debate and sensitivity exist around issues involving the study of Indigenous peoples (e.g., community involvement in the research design, the role of governing authority, community consent, opportunities for community commentary on research findings, cultural appropriation, etc.). If a study involves Indigenous participants or their cultural property as a focus of research/scholarship, the investigator should read the full text of Chapter 9 of the current version of the TCPS, as well as any discipline-specific ethics guidelines that may apply to the study. The researcher might wish to consult with Indigenous groups, colleagues, and/or Departmental or the University ethics committee Chairs before designing the study. In addition, depending upon the study's characteristics, the Departmental and/or University ethics committees might require that Indigenous 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 about conducting research with or about Indigenous populations may be found via the following links:

4.7.1 Canada Institutes of Health Research (CIHR), *Guidelines for Health Research Involving Aboriginal Peoples*

4.7.2 Social Sciences and Humanities Research Council of Canada (SSHRC), *Opportunities in Aboriginal Research*

Royal Commission on Aboriginal Peoples

4.7.3 The First Nations Information Governance Centre, The First Nations Principles of OCAP

5.0 Types of Review

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

5.1 Full Review of Faculty and Graduate Student Research: This is the normal (default) review process. Full reviews occur in scheduled, face-to-face or videoconference meetings of the full ethics board. It is expected that where research is proposed that has not been peer-reviewed, the researcher may need to arrange for a scholarly/peer review of the research prior to the submission of a proposal to the REB. Such reviews are required for research that involves more than minimal risk.

5.2 Delegated Review of Faculty and Graduate Student Research: Projects involving only minimal risk **may** be eligible for delegated review, provided that the investigator requests such review, and the UHREB Chair (or designate) concurs that a delegated review is appropriate. If the UHREB Chair decides delegated review is inappropriate, the proposal will thereafter be subject to the provisions for full review. If the Chair decides delegated review is appropriate, 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 full 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. Delegated review is available **only** for minimal risk and is **not available** solely because of investigators' time constraints.

5.3 Course-Based Research and Senior Independent Undergraduate Student Research 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 (DEC) review and approval, and do not require review and approval at the UHREB level. At its sole discretion, the DEC may request a UHREB review for any student project.

5.4 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 current version of the 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, the Chair has 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. **Multi-Site protocols that are greater than minimal risk must undergo a full review by the UHREB**.

5.5 Reviews Associated with Protocol Renewal, Amendment and Subsequent Stage of Research: Unless changes in the level of risk have occurred during the course of an investigation, the processes of determining whether a full or delegated review will be in accordance with the original review by the REB.

6.0 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:

6.1 Familiarize themselves with the current version of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS, 2018) and the University's *UHREB Policies and Procedures*, as well as any relevant disciplinary ethics guidelines, and to abide by these;

6.2 Complete the TCPS CORE tutorial and submit a copy of their certificate to the UHREB;

6.3 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;

6.4 Not undertake any project involving human participants that requires review without obtaining the necessary prior approval;

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

6.6 Disclose in their proposals any real, potential or perceived conflicts of interest regarding their relationship with potential participants or regarding the potential uses of the research findings;

6.7 Conduct their research in accordance with the contents of their approved proposals; and

6.8 Comply with all undertakings, reporting procedures, and monitoring procedures that form conditions of project approval.

7.0 Additional Faculty/Staff Responsibilities

Individual faculty and staff members are responsible for ensuring that:

7.1 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;

7.2 Proposals submitted under their supervision are complete and properly address the ethical issues involved; and

7.3 All ethical undertakings made in the proposal are honoured in the conduct of the approved project, both by themselves and by persons under their supervision.