# Procedures Related to Faculty and Graduate Student Research

1.0 This guidance document provides direction to faculty researchers and graduate student researchers on the preparation of applications for ethics review. Before preparing a proposal, investigators are urged to familiarize themselves with the policies and procedures that guide reviews by the Human Research Ethics Board (UHREB).

1.1 Investigators may consult with the Ethics Office and/or the UHREB Chair if they are uncertain about what information is required or how the proposal preparation guidelines apply to their project. Such consultations may help to resolve ethical and procedural difficulties, and thereby improve the likelihood of expeditious proposal approval in the formal review process.

1.2 Incomplete proposals received by the Ethics Office will be returned for resubmission.

1.3 All faculty and graduate student ethics applications must be submitted through WebGrants.

**2.0 Responsibilities of all Researchers**

The Researcher is responsible for complying with the decisions and responsibilities set out by the UHREB. In addition:

2.1 Researchers should familiarize themselves with the latest version of the TCPS and any other applicable professional (discipline-based) ethics guidelines that are relevant to the proposed research.

2.2 Researchers MUST complete the TCPS2 CORE. A copy of the CORE certificate must be appended to applications submitted to the UHREB. Researchers should ensure that all research personnel are appropriately qualified by education, training and experience to assume responsibility for the proper conduct of the research and for the protection of human research participants.

2.3 Researchers should ensure they have adequate resources to properly conduct the research and conduct the research following acceptable practices.

2.4 Researchers must consider and resolve satisfactorily any ethical issues raised by the project they plan to undertake, consulting (as appropriate) with colleagues, instructors, and the UHREB.

2.5 Researchers are not authorized to undertake any research activities involving human participants in projects requiring review without obtaining the necessary UHREB approval. The UHREB will not provide retroactive ethics clearance.

2.6 Researchers must ensure that proposals submitted for review are complete, describe all aspects of the project relevant to ethics review, and all necessary documentation should be signed by the responsible Researcher. Informed Consent should follow *Guidance Document 5.*

2.7 Researchers must 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 at the time of application, and as they arise.

2.8 Researchers must personally conduct or supervise the research in accordance with the contents of their approved proposals, and report any deviations, premature suspension or

termination of the research, unanticipated adverse events and privacy breaches to UHREB without delay.

2.9 Researchers must comply with all undertakings, reporting procedures, and monitoring procedures that form conditions of project approval. Changes in the approved research should not generally be undertaken without REB review and approval. In the case where a change is necessary to eliminate an immediate hazard to the participant(s), Researchers should advise UHREB at the first opportunity. If the change is minor and does not have ethical implications, nor impact the level of risk to participants, Researchers can advise details at the time of the annual status report.

2.10 Researchers must provide an annual written update of the research, or more frequently if required by UHREB.

2.11 UHREB must be notified if there are any unexpected findings that impact the risk/benefit ratio of the research, a change in the Researcher or research team, and when the research was been completed.

**3.0 Responsibilities of Faculty Supervisors of Graduate Student Research**

Faculty supervisors must ensure that:

3.1 Proposals prepared by advisees are reviewed and recommended to the UHREB by the faculty supervisor using the *Graduate Student Supervisor Ethics Review form*;

3.2 graduate students under their supervision are aware of the applicable ethics policies, and graduate student projects have received the necessary ethics approval before commencing any research activities; and

3.3 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 (including, but not limited to, protocol deviations, adverse events, and final reporting).

**4.0 Guidance for a Successful Application**

The UHREB WebGrants application, and PDF copies of all research instruments must accompany all proposals, regardless of the type of review. In order to maximize the expeditious review of an application to the REB, researchers should ensure the following:

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

4.2 The investigator must identify the level of risk posed to the participants, propose the type of review the project should receive (full or delegated) and, if appropriate, propose an ongoing review mechanism.

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

4.4 All responses that raise ethical questions must be addressed satisfactorily in the appropriate spaces on the application form and summarized in an attached explanatory note. Any other aspects of the project that are pertinent to ethics review also must be discussed.

4.5 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.

4.6 The UHREB requires scholarly review of the project if the level of risk is more than minimal. (See UW-UHREB 3.001 for further details on scholarly reviews.) If peer reviews already exist, the investigator should submit them with the proposal. At its discretion, the UHREB may request scholarly reviews of minimal risk research.

4.7 Investigators must disclose in their submissions any real, potential, or perceived conflicts of interest (COI) that may arise in their relationships with participants and/or in the potential uses of the findings. If a COI exists or is possible or perceived, the investigators must outline steps for mitigating the conflict. The matter of COI also applies to any research staff on a project.

4.8 PDF copies of all research instruments must be attached. This includes:

a) questionnaires;
b) reproductions or adequate descriptions of visual and other sensory or electronic stimuli;
c) in the case of observational research, the nature of observation and the behaviours to be observed;
d) in the case of interviews, either specific interview questions or a detailed description of the parameters of interview contents;
e) if participants are to be photographed, audiotaped, videotaped, or otherwise recorded, a detailed description of the parameters within which recording will occur; and
f) research conducted over the Internet may require additional specifications of the conditions of data collection.

4.9 The proposal must outline the consent process, and any deviations that may apply because of the population included in the research. The researcher should include, as relevant, the following:

a) a participant consent form or an explicit method of otherwise obtaining informed consent;
b) if the investigator considers a consent form impossible or inadvisable, a justification must be provided for an alternative practice;
c) if consent is verbal or involves consent by a legally authorized representative, a copy of the consent form or the information that would be provided were a written consent form to be used; and
d) if consent forms and/or processes involve the use of translators and/or translated documents, the documents must correspond exactly to the English-language forms and/or processes.

4.10 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. 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.

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

4.12 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.

4.13 Only once a protocol has been approved by the UHREB can researchers begin any processes related to participant identification or enrolment. If, during the course of a study, any alterations to procedures described in an approved protocol must be reported to the UHREB via the Ethics Office. The UHREB Chair will determine whether additional review is required and, if so, what type.

**5.0 Timeframe and Procedures for Review**

It is the responsibility of the investigator to allow sufficient time for review in advance of the anticipated project start date. Factors to take into consideration include the following:

- **Scholarly Review**: If the research is **more than minimal risk** and has not been subject to peer review (by an adjudication panel at the University of Winnipeg or by an adjudication panel of a funding agency), the researcher will need to obtain a scholarly review to be included in the submission to the UHREB. For **minimal risk** studies, if the UHREB determines that a scholarly review is necessary, this can affect how quickly the UHREB review can be completed.

- **Submission completeness**: Proposals that lack required items, do not provide sufficient detail for review, or are submitted without the necessary attachments will be returned for completion and resubmission.

- **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.

**6.0 Types of Reviews**

**6.1 Full review** in which all members of UHREB participate in the review is the default position. Normally, any research that involves **more than minimal risk** will be reviewed by the full board.

6.2 Research that is **minimal risk** will usually be considered by **delegated review** in which the UHREB Chair (or designate) and normally two members of the UHREB review the application. The discretion to use delegated review rests entirely with the UHREB Chair (or designate).

**7.0 Review Processes**

The processes of the UHREB determine how long it will normally take for a review to be completed.

**7.1 Full Reviews**:

Using the WebGrants platform, the investigator submits a PDF copy of the complete proposal including application, proposal, research measures, etc. Proposals received by the Ethics Office **prior to the monthly published deadlines** 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 normally be notified of the outcome of UHREB review within two (2) working days of a UHREB meeting. More time may be required if the UHREB needs advice from an *ad hoc* advisor with expertise in the area of the research when no members of the UHREB are knowledgeable about aspects of the study design. Similarly, more time may be needed 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.

**7.2 Delegated Reviews:**

Using the WebGrants platform, the investigator completes all sections of the Human Research Ethics Application form and includes as attachments the informed consent form, research protocols, survey documents, letters of support proposal, etc. Upon receipt, the Ethics Officer reviews for completeness within three (3) working days, and then forwards to the Chair. The Chair then provides a preliminary review and provisional decision on eligibility for delegated review 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 UHREB meeting for which the deadline has not passed. If the decision is positive, at least ten (10) further working days are required for UHREB delegated review, following which investigators will normally be notified of the outcome within two (2) working days.

**7.3 Multi-Jurisdictional Research Review in which University of Winnipeg Researchers are NOT the Principal Investigator:**

In circumstances where the UHREB is not “the REB of record” (i.e., a University of Winnipeg researcher is co-investigator or collaborator, not the principal investigator) and the research involves minimal risk, the submission to “the REB of record” will be reviewed by the UHREB Chair alone. The researcher should submit a copy of the complete APPROVED protocol including the application, proposal, approval, research measures, etc. from the original submission. The University of Winnipeg researcher should prepare a cover letter that outlines how the research will be conducted by the University of Winnipeg researcher (e.g., enrolment of participants, analysis of data, etc.). At the Chair’s discretion, the protocol may be reviewed by the UHREB.