THE UNIVERSITY OF WINNIPEG

Post-Approval Activities

1.0 When a researcher submits a protocol for review by the University Human Research Ethics Board (UHREB), approval will normally be granted for a period of one (1) year or less than one year if the research is of a shorter duration.

2.0 Reporting of Protocol Deviations or Amendments

2.1 Protocol deviations or amendments refer to any action or inaction that does not correspond to the DEC-approved or the UHREB-approved protocol. A protocol deviation may include accidental/unintentional or intentional changes, including changes made to eliminate an immediate hazard to subjects or others, or their rights and welfare. Protocol deviations may relate to the consent process, the research instruments and/or research process. Protocol deviations may also be needed to ensure the continuing participation of research participants and/or to protect the integrity of the study data. Protocol deviations may be ***major*** or ***minor***.

2.2 Faculty and graduate student investigators must advise the UHREB if, **at any time**, their procedures change in any substantive way from those originally proposed to, and approved by, the UHREB. At the discretion of the UHREB Chair, researchers may be required to provide the UHREB with progress reports. Similarly, at the discretion of the UHREB Chair, the committee may monitor the ongoing approved project. The form of review given to such reports (e.g., full review, delegated review, review by the UHREB Chair) 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.

2.3 For all projects, faculty and graduate student investigators are required to propose monitoring and reporting procedures at the time of proposal submission. In appropriate circumstances, where no ongoing review seems needed for projects under 1 year the investigator may propose that no such procedures be applied. For any projects longer than 1 year, annual updates are required.

2.4 Where changes or additions to an approved ethics protocol are required, the researcher must complete and submit a ***Request Change to Existing Ethics Protocol Form*** on Webgrants along with any accompanying documentation. The UHREB Chair or Vice-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 by the UHREB.

2.5 Changes to procedures of Course Based or Independent Senior Undergraduate research must be reported to the DEC. At the discretion of the DEC Chair, course instructors and/or undergraduate student researchers may be required to provide the DEC with progress reports and/or may be subject to monitoring of the ongoing approved project.

3.0 Reporting Unanticipated and Adverse Events

3.1 TCPS states that “Researchers shall report to the REB any unanticipated issue or event that may increase the level of risk to participants, or has other ethical implications that may affect participants’ welfare” (Article 6.15). Unanticipated issues or events occur during the conduct of research and were not anticipated by the researcher at the time of their application to the REB. Unanticipated issues or events may be minor or more serious, and they may affect the welfare of participants as well as the integrity of the research itself.

3.2 *Unanticipated issues* can include such things as higher levels of participant interest than the researcher had planned (which might mean needing to turn individuals away or needing to come up with supplementary plans for handling more study participants) or unintended errors in the communication of information to participants. Researchers may encounter issues related to the study design that were not contemplated in the design stage (and the application to the UHREB). Issues may arise when some component of the study has been missed (e.g., not all of the study instruments are used on some or all of the participants). Complaints from study participants are also unanticipated, and may have study design implications.

3.3 *Adverse events* refer to situations that occur in the course of the research that have undesirable consequences for study participants (e.g., breach of privacy of information, negative physical or psychological effects, harms to participants, etc.). Adverse events are, generally speaking, unanticipated. However, in some cases, a researcher may anticipate, for example, that questions might cause distress to participants but not necessarily a level of distress witnessed in practice. Adverse events may be minor or serious.

3.4 Faculty and graduate student researchers are obligated to report to the UHREB all unanticipated issues and adverse events, whether minor or serious. For Course-Based and Independent Senior Undergraduate research, all unanticipated issues and adverse events, whether minor or serious must be reported to the DEC. This reporting should be done expeditiously, normally within 72 hours of the event (completed via Webgrants). Depending on the nature of the issues or events, modifications to the study protocol may be necessary. All such modifications must be approved by the UHREB before the research resumes. In extreme situations, the DEC or UHREB may determine that a protocol should be suspended.

3.5 Annual reports (completed via Webgrants) should reflect any changes that have been made to the protocol as a result of unanticipated issues and adverse events.

4.0 Renewal of a Protocol and the Submission of an Annual Report

4.1 In order to have the approval for a protocol renewed, researchers are expected to provide an annual report (completed via Webgrants) which includes sufficient and relevant information about the study (e.g., number of participants recruited, any unforeseen events, etc.). Renewal requests MUST be submitted **prior to the lapse of an approval by the UHREB.**

4.2 Continuing review, like the original review of a research protocol, is conducted using what the TCPS2 refers to as a “proportionate” approach. The nature of the continuing review will be somewhat different for “minimal risk” studies as compared to “more than minimal risk” studies.

4.3 On the basis of the information provided by the researcher, the Chair will determine if the UHREB should review the project. The Chair may, on behalf of the UHREB, determine that the approval of the protocol should be continued for another year or for a shorter period for studies of a shorter duration. When a researcher submits an annual report, any changes to the protocol (amendments) can be presented at the same time if they have not already been presented to, and approved by, the UHREB. If there have been substantive changes to the research methods, any adverse events affecting participants, and/or major changes to the University’s ethics policy, the UHREB will conduct a review.

5.0 Renewing a Lapsed Protocol

5.1 There may be situations in which a researcher has not renewed a protocol after the 1-year approval period lapses but wishes to continue data collection. When a protocol has lapsed, all participant recruitment and data collection must cease.

6.0 Subsequent Stages of an Approved Research Protocol

6.1 Where a successive stage (or stages) of an already approved protocol is undertaken **within the same research project**, an updated submission must be made to secure ethics approval for the subsequent stage. The *Request Change to Existing Ethics Protocol Form – Subsequent Stage of Research Project* is to be completed and submitted via 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.

7.0 Final Reports

7.1 In accordance with the TCPS, once a study has been finished, the researcher must submit a final report to REB that approved the research (i.e., the DEC for course based and independent senior undergraduate research and the UHREB for faculty and graduate student research).

7.2 Researchers should fill out the online form (completed via Webgrants) and submit it to the DEC or the Ethics Office. A study is considered completed when **all** data collection has been concluded (as per the approved protocol). Research that involves follow-up or the indirect collection of data for follow-up purposes are not considered completed.

7.3 If research has been suspended prematurely or terminated before the expected end date of the approved study, the researcher must still submit a final report and provide reasons for the suspension or termination of the study.