Guidance Document 7:
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 year. Faculty and graduate student investigators must submit a request to the UHREB if their research 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 reporinmust 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.

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.

4.1 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

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” s( )11.kf a ea whathad(f)-17.5a (m)-6 810.6 .7 (e)-6 ()-17..5a (m)-628te (f)

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.