Toronto Metropolitan University

GUIDELINES FOR CONTINUING REVIEW OF ONGOING RESEARCH

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1. Purpose

The purpose of this guideline is to provide researchers with information about the requirements related to the continuing review of ongoing research studies, and the criteria for assessing ongoing research studies. General information regarding continuing review processes, such as how to submit an amendment and how to submit an annual/final report are included here as well.

2. Background

The Tri-Council Policy Statement (TCPS 2) states that once researchers receive initial Research Ethics Board (REB) approval, they must ensure that their ongoing project is "ethically acceptable [and] in accordance with the principles of this [i.e., the TCPS 2] policy" (p. 20) *[i]. More specifically, the TCPS 2 notes that "researchers' responsibilities include monitoring their research to ensure that it is conducted in an ethical manner, reporting unanticipated issues or changes to the research, supervising all team members in the application of the research procedures, and ensuring that they are properly qualified and versed in the conduct of ethical research" (p. 83).

The TCPS 2 also states that "for research projects lasting longer than one year, researchers shall submit, at minimum, an annual report with sufficient details to enable the REB to make an informed judgment about the continued ethical acceptability of the research. For research lasting less than one year, an end-of-study report may suffice" (p. 82).

3. Ongoing Ethical Responsibilities

Once you receive REB approval to begin conducting your research, you are responsible for ensuring that your project meets the ethical standards laid out in the TCPS 2. This entails that throughout the duration of your project, you monitor your research study and its effects in light of the envisaged ethical implications of your research as noted in your approved ethics protocol. Ongoing review of research activities is necessary to ensure that ethical standards are being upheld. Below are a few examples of parts of a project that typically requires close monitoring:

- (a) Recruitment Posters. At times, recruitment posters (especially those posted in high volume areas) can be defaced or taken down. Thus, it is a good idea to monitor and ensure that recruitment posters are visible and in good condition so that interested potential research participants are able to contact you and find out more information regarding your study.

- (b) Potential Risks. While most research projects involve some potential risks to research participants, whether these risks will be actualized cannot be known beforehand. As

such, it is important that researchers closely monitor the anticipated potential risks so that in the event that a participant suffers some harm, appropriate steps can be taken.

- (c) Participant Involvement. Throughout the course of conducting a study, researchers may realize significant divergence between what they thought participation would entail, and what participation actually entails. For example, a researcher may learn that interviews that were expected to take 30 minutes, are taking (roughly) 60 minutes. Deviations such as this are important to note so that amendments can be made, and that future potential participants can be accurately informed regarding what their participation involves.

If the duration of your study is longer than a year – regardless of whether there have been significant changes to your research project or not – you must (at minimum) complete an Annual Report. The Annual Report provides you with an opportunity to update the REB regarding your research project and enables the REB to reassess the ethical implications of your project. If the duration of your study is less than a year, we ask that you (at minimum) submit a Final Report. This report provides the REB with an opportunity to reassess the ethical implications of your research project as a whole (i.e., from start to finish). The Final Report will also provide you with an opportunity to note any interesting observations or minor changes to your previously approved ethics protocol that you may wish to inform the REB of.

4. Managing Changes in Your Research Project

No matter how carefully planned your research project may have initially been, as you monitor it, you may notice a number of discrepancies between how you originally thought your research project would go, and the way that it is currently unfolding. For example, you may have thought that a particular incentive was sufficient to recruit a certain number of participants, but now realize that such an incentive is not sufficient. Or you may think that many of your research participants will be comfortable answering the majority of the questions in your interview guide, when in fact many of your research participants do not feel comfortable answering the majority of questions in your interview guide.

Depending on the type of changes observed, different actions will be required. In some cases, where, for example, participants report higher emotional or psychological distress as a result of partaking in an interview, an Unanticipated or Adverse Event form may be required. In other cases, where, for example, you would like to slightly change the number of research participants, an amendment will need to be submitted online (See Section 8 below). And, with respect to noteworthy but less significant changes, where, for example, participants are able to complete a questionnaire in, say, 10 to 15 minutes as opposed to 15 to 20 minutes, this may be reported in an Annual Report (see Section 9 below).

The most important thing to remember is that if in the conduct of your study you notice a discrepancy between your initial plan and the way your research is unfolding you make note of

the change. Then, if you are unsure whether to account for this discrepancy by submitting an amendment, an Unanticipated or Adverse Event form, etc., you should consult the REB. It is always the researchers' responsibility to ensure that the ethical principles of the TCPS 2 are being upheld in their work, and it is always best to consult the REB for clarification and guidance on these matters.

5. Criteria for Assessing Ongoing Research

The TCPS 2 sets forth the criteria for the continual review of ongoing research. These criteria apply to both initial review and continuing review. The researcher must ensure that all of the following requirements are continually being satisfied:

- Risks to subjects are minimized.
- Risks to subjects are reasonable in relation to anticipated benefits.
- Potential benefits to participants and potential contributions to knowledge are clearly stated and made known.
- Selection of participants is equitable.
- Informed consent is given and maintained, or in cases where informed consent is not possible, appropriate steps are taken, such as receiving informed consent from the prospective participant's legally authorized representative.
- Data collected is being responsibly handled, monitored, and stored.
- Where applicable, provisions have been incorporated to protect the privacy of participants, and the confidentiality of data.
- Appropriate additional safeguards are included to protect vulnerable participants.

N.B. The REB may require modifications to a research activity that does not meet the above criteria.

6. Frequency of Continuing Review

The REB will determine the frequency of continuing review for each study on a case-by- case basis to ensure the continued protection of the rights and welfare of research participants. At minimum, all research projects will undergo continuing review once a year. More frequent reviews (i.e., more frequently than once per year) may be assigned for a number of reasons, such as when the risks to subjects require close monitoring. The REB will consider the factors laid out below when deciding on an appropriate interval for continuing review:

- The nature of risks posed by participation in the study.
- The degree of uncertainty regarding the risks involved.
- The vulnerability of the subject population.
- The experience of the investigator in conducting similar research.

- The REB's previous experience with the investigator (e.g., compliance history, previous problems with the investigator obtaining informed consent, prior complaints from subjects about the investigator, etc.).
- The projected rate of enrollment.
- Whether the study involves novel processes.

At the time of initial approval of the study, the investigator will be notified in writing of the interval at which continuing review must occur. At the time of continuing review, the REB will consider whether the current frequency of continuing review for the study is appropriate or whether it should be adjusted in light of new information.

N.B. Review of an amendment does not extend the date by which continuing review must occur.

7. Suspension and Discontinuation of REB Approval

All REB approvals are subject to researchers fulfilling their ongoing ethical responsibilities. In the event that researchers fail to submit the necessary information/documentation required for continuing review (e.g., failing to submit an annual report by the date it is due), the REB may suspend or discontinue ethics approval. In such circumstances, all research activities must stop.

8. How to Submit an Amendment

Step 1: Log into your MyTorontomu.ca account: https://my.torontomu.ca/

Step 2: Under the "My Links" subheading, click on the "Online Ethics Protocol Submission" link.

Step 3: Click on the second link entitled "All Protocols in Progress and Previously Submitted."

Step 4: Select the relevant protocol.

Step 5: Click the "Request to Reopen Protocol" link.

Step 6: Clearly indicate that you wish to reopen the protocol in order to submit an amendment to your research project. Briefly explain the type of amendment you wish to make.

Step 7: Once carefully reviewed, click the "Request to Reopen Protocol" link. A REB administrator will then review the request to reopen your protocol. Following a review of your rationale, your protocol will be reopened. Typically, you will receive an email within one week, notifying you whether your request has been granted.

Step 8: Once the protocol has been reopened, you will be able to revise your protocol in light of the proposed changes you wish to make. (When resubmitting, please note in the "Comments to Chair" section of the protocol the nature and location of the proposed changes so they may be easily located and reviewed.)

Step 9: After carefully reviewing the proposed changes, you wish to make to your protocol, and attaching any new documents, click on the "submit" button.

N.B. Once submitted, a member of the REB will review your amendment, and follow up with you in a timely manner. Typically, you can expect to hear back regarding your amendment within one week from the day you submit your proposed change(s). In cases where multiple or more complex amendments have been made, REB response time may take longer than one week. In situations where significant revisions are being proposed to your research project, you may be asked to submit a new ethics protocol.

9. How to Submit an Annual Report or Final Report

Step 1: Log into your MyTorontomu.ca account: https://mytorontomu.ca/

Step 2: Under the "My Links" subheading, click on the "Online Ethics Protocol Submission" link.

Step 3: Click on the second link entitled "All Protocols In Progress and Previously Submitted."

Step 4: Select the relevant protocol.

Step 5: Click on "Complete Annual/Final Report".

Step 6: Fill-out the Annual Report/Final Report form, ensuring that all relevant information is provided and accurate.

Step 7: After carefully reviewing your report, click on the "Submit Annual/Final Report" button.

N.B. Once submitted, a member of the REB will review your Annual or Final Report and follow up with you in a timely manner. Typically, you can expect to hear back regarding the status of your Annual or Final Report within one week from the day of your submission.

[i] *All page number references refer to the online version of the TCPS 2 (2014).

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 2014*.