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GUIDELINES FOR REPORTING UNANTICIPATED AND ADVERSE ISSUES

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1. Purpose

The purpose of this guideline is to provide researchers with information concerning the nature of unanticipated and adverse events, and Research Ethics Board (REB) requirements related to reporting unanticipated and adverse events. Examples of both types of events are provided below.

2. Background and Examples

The Tri-Council Policy Statement (TCPS 2) 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, TCPS 2, p.83[i])

As defined by the TCPS 2, unanticipated issues are events that "occur during the conduct of research that may increase the level of risk to participants or have other ethical implications that may affect participants' welfare and were not anticipated by the researcher in the research proposal submitted for research ethics review." (TCPS 2, p. 210) Unanticipated issues include complaints that may be made about a research study.

Unanticipated events may be minor or more serious and may have either short- or long-term effects on participants or the conduct of the study.

The following are examples of unanticipated issues or events:

- Any complaint made about the study by research participants or the public.
- During recruitment, many more potential participants identify themselves to the researcher than the researcher aims to enroll. Without a plan in place to manage this, some participants become upset that they cannot participate.
- In an online survey, the link to the page for providing name and email in order to be entered into a draw for an iPad is broken, and this is discovered after multiple participants have tried to submit their name.
- Realizing during the conduct of research new potential risks that require changes to the consent document to capture the newly identified potential risks.
- An unexpected variation in how a study is conducted (e.g., a 3D body scanner fails to work on the day on which research participants were scheduled to be scanned, or a research assistant forgets to administer a particular survey to one group of participants).

Adverse events are defined as occurrences with an undesirable outcome for the participant. These types of events may be unanticipated (e.g., an inadvertent breach in privacy, despite putting measures in place to protect the privacy of participants), under-anticipated (e.g., a set of questions in a validated survey elicits signs of much more distress than anticipated by the researcher), or, in some cases, anticipated (e.g., administration of a drug known to reduce

blood pressure that results in particularly dangerously low blood pressure for a single participant).

The following are examples of adverse events:

- Negative physical or allergic reactions to drugs or interventions administered within the context of a study.
- Physical consequences resulting from dietary manipulations (e.g., fainting from not eating for periods of time).
- Negative physical reactions in volunteers who have already standing chronic diseases (e.g., heart conditions, diabetes).
- Unexpected accidents or injuries that occur during the course of a research project (e.g., a participant in an exercise study falling off an exercise bike or treadmill).
- Equipment failure during an experimental session that results in harm to a participant.
- Participants who show signs of or who report emotional or psychological upset in conjunction with interview or focus group questions, or other tasks associated with participation.
- Participants who report that they were not properly informed, during the informed consent process, of particular aspects of a study that they find objectionable, concerning, or upsetting.
- A participant who discloses information to the researcher that requires mandatory reporting (e.g., child abuse).
- Any public release, even inadvertent, of research participants' identities or personal information.

It is important to note the difference between unanticipated and adverse events, as well as the potential overlap. Unanticipated events are those that even the most well-prepared researcher does not anticipate. Additionally, a well-prepared researcher may have anticipated a number of possible risks but be unprepared for the actual level of magnitude or severity of the potential risk. As an example, consider the case of administering a beta-blocker (a cardiac drug) as part of a research study. The researcher anticipates that participants may experience certain effects or outcomes (e.g., it is known that beta-blockers reduce heart rate) but in this case, a participant experiences this known effect more acutely than others (e.g., the participant receives a beta-blocker, after which her heart rate drops dramatically and she experiences resultant temporary severe side effects requiring additional, immediate support through insertion of an IV and additional medication). This last example would constitute an adverse event – even though the result was, in some way, anticipated – and this should be reported to the REB immediately.

Minor deviations from the research protocol as submitted and approved do not necessarily need to be reported to the REB immediately (e.g., taking out one survey question as a result of participants reporting that the question was not clear; reducing or increasing slightly the number of computer mediated tasks for a study on visual cues). Rather, these can be reported

in the Annual Report process with updated documents (for minor changes). As with many types of research, minor adjustments or changes are made as the study is conducted to adjust to the reality of the research method, environment, and participant population being studied. If you are unsure if your deviation constitutes a minor change, or something that requires submission of an amendment, please consult with the REB.

Example # 1:

Even with well-designed research protocols, things can go wrong, or things may not go as planned. Consider the example of the researcher who is conducting a study of a new online support network. In this example, participants in the study take part in the online network through group discussions or open "chats", seen by all group members or through private one-on-one messaging with online counselors. During the consent process, participants are made aware that if they post in a group discussion, everyone in the group will see their comments, but if they interact with an online counselor, that discussion will be private and only visible to them and the counselor. Participants are also warned, however, that there is always a small (non-zero) risk that information might be shared in a way that might compromise their privacy, although care would be taken to avoid this. Inadvertently, a new counselor posts a response, meant to be part of a private session with an individual participant, in the open group discussion. The participant notices this immediately, becomes very upset at her private information being shared with everyone in error, and notifies the researcher.

This is an example of an adverse event. Even though a research team puts strategies in place to protect the privacy of participants, and informs them of the processes and potential risks, it remains that any research project can involve unintended errors, or a failure of systems.

In this case, this event should be reported to the REB. We would expect that the researcher would be able to describe the event in detail, and to articulate both what was done to try to resolve the immediate situation (e.g., the site was shut down temporarily to ensure that the comment was removed, the participant was referred appropriately and provided with a formal explanation and apology), as well as to address long-term strategies to avoid this happening in future (e.g., better orientation processes for new counselors, and a "failsafe" warning before submission of any comment that notes explicitly alongside the posting button: "You are posting in a group discussion area and your comment will be seen by all the group. Click here to post in the group discussion.")

Example # 2:

A researcher who is studying infants' reactions to hiding desired toys in the lab finds that his intended half hour of research activity is too long for the majority of infants that he studies, and he reduces the required time for participation in activities to 15-20 minutes, for all infants. This does not necessarily change the level of risk and has no other major ethical implications. This

change could be reported through an amendment notice to the REB or in an Annual Report. If, however, the change in timing of research activity resulted from one of the parents of a participating infant becoming upset due to feeling pressured by the researcher for their crying infant to work through the entire half hour, this may need to be reported immediately to the REB.

3. Reporting Unanticipated and Adverse Events

General Guidance

The most important thing to remember is that if, in the conduct of your study, something does not go according to "plan," you should always consult the REB. This includes any complaint made about the study. If you are not sure if an event needs to be reported immediately to the REB, it is always best to consult the REB for clarification and guidance.

To report an Unanticipated Issue or Adverse Event, please first email the Chair of the Research Ethics Board to outline the details of the event. This email should be directed to rebchair@torontomu.ca. This should be followed within 72 hours by the completion and submission of an Adverse/Unanticipated Event Report. You can also, at any time, call the REB Office at (416) 979-5042 if you require more urgent advice or guidance.

How to Report Unanticipated and Adverse Events

Step 1: Log-in 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 on second link entitled "Report Adverse or Unanticipated Event."

Step 6: Carefully answer all of the questions to the best of your ability.

Step 7: Upload all relevant documents as attachments.

Step 8: Review the report ensuring that all questions are answered, and that the report is complete.

Step 9: Once fully reviewed, click "Submit Report."

N.B. You will receive an automatic acknowledgement that the report has been submitted. Once submitted, the report will become a permanent part of the protocol record. The report

will then be reviewed by a member of the Toronto Metropolitan University REB, and you will be notified within one week's time if the REB has any questions or concerns, or if any additional corrective action is required.

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[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*.