FOR OFFICE USE ONLY
SMU REB #:
DATE RECEIVED:

REPORT OF NEW INFORMATION AND UNANTICIPATED ISSUES

The REB forms are Adobe fillable, savable, PDF forms- they must be opened with Adobe Acrobat Reader to ensure that they look and function correctly.

POLICY AND PROCEDURES

I. Definition of New Information

The continuing duty of researchers is to share new and relevant information about incidents that include any new risks or new benefits that may be relevant to research participant welfare or consent. The report to the REB includes the necessary analysis and evaluation to make the new information interpretable. The incident or issue of concern may have been, on some level, anticipated to occur, for example it may involve a previously foreseeable risk or benefit and the incident or issue is newly discovered.

This new information thus covers a range of matters as it might arise from learning about adverse reactions, it may be discovered during the course of routine evaluation, new elements of data collection procedures may have emerged, or it may be disclosing to the REB that the study has unexpectedly discontinued.

To understand the particular relevance of new information, it should be considered from the perspective of the research participant. New information may present ethical implications and associated changes to risks and benefits of the research.

The obligation to report new information ends with the completion of the study at the time when the End of Study Report, SMU REB Form 5, review request has received REB clearance.

The point of the reporting is to enable the REB and the researcher to better protect research participants.

II. Definition of Unanticipated Issues

Unanticipated issues occur during the conduct of research; may increase the level of risk to participants or have other ethical implications that may affect the welfare; and were not anticipated by the researcher in the research proposal originally submitted for research ethics review or as part of continuing review (Request for Change to Cleared Research, SMU REB Form 2). They may be minor or serious in magnitude, with short or long-term implications.

The TCPS 2, Art. 6.15 recognizes two types of Unanticipated Issues to consider:

UNEXPECTED REACTION (Type 1)

Immediate implication for the health, safety, privacy and confidentiality of a research participant or their willingness to continue in the research, and/or the integrity of the research data.

UNAVOIDABLE SINGLE INCIDENT (Type 2)

No immediate implication for the health, safety, privacy and confidentiality of a research participant or their willingness to continue in the research, and/or integrity of the research data.

Examples of Unexpeted Reactions (Type 1):

- Unintended stimulation of traumatic memories or unforeseen side effects.
- Unanticipated effect on health status (widely referred to as "adverse events"), including negative effects on mental, emotional, psychological, and/or physiologicial aspects of a person related to their participation in the research study. Participants showing signs of emotional upset in conjunction with or following interviews or other tasks associated with participation in behavioural or social science studies.
- Privacy breaches such as any release, even inadvertent, of research participants' identities or personal information.
- Unexpected accidents that occur during the course of a research project (e.g., a participant in an exercise study falling off an exercise bike.)

Researchers must take reasonable steps to monitor unexpected reactions so that they can take action (if appropriate) to minimize the likelihood that other participants in the study will experience the same outcome.

Examples of idiosyncratic, Unavoidable Single Incidents (Type 2):

- Translator not available for a day.
- Calling a participant for an interview in place of a video call because of technical difficulties on an occasion.
- Obtaning informed consent with an outdated version of the consent form/script, etc. on an occasion.
- Failure to provide a participant with a copy of the Informed Consent Form/Script/Feedback letter and following up at a diferent time.
- Learning new features of a data collection platform, or that a participant was not compensated correctly on an occasion.

Upon becoming aware of an issue (incident, experience or outcome) the researcher should assess whether it constitutes an Unanticipated Issue.

III. Procedures for Reporting — Directed to: ethics.continuingreview@smu.ca

1. Researchers submit their report to ethics.continuingreview@smu.ca. For faculty research, the report is submitted directly by the Principal Investigator of the research. For student research, the report is submitted directly by the Faculty Supervisor of the research.

2. Completed reports are allocated to the appropriate REB Chair.

3. The REB Chair decides what immediate action should be taken prior to the next meeting of the Board. Other REB members may be consulted as needed.

4. The REB Chair informs the Principal Investigator/Faculty Supervisor in writing of the necessary immediate actions to take to eliminate or mitigate newly reported risks, equitably distribute benefits, how information should be shared with current participants, contact former participants, and/or what information is required additionally from the research team in order to evaluate the ethical acceptability of the research further.

In order to protect the health, safety, privacy, confidentiality and welfare of the research participants, in exceptional cases, the REB may be required to suspend recruitment or suspend all participant involvement in a study, pending further investigation or availability of required information, when relevant.

The immediate response from the REB to researchers may include that the current research ethics clearance is: temporarily, partially, fully, or in no means suspended or revoked depending on the type of issue and whether the REB has sufficient information to understand the appropriateness of research ethics clearance and whether the risks to research participants are still minimized in relation to the anticipated benefits.

5. Copies of the report and all adjusted materials different from from the already cleared proposal (when applicable) are included in the next meeting of the Board.

6. The REB Chair provides the Principal Investigator/Faculty Supervisor with written feedback arising from the REB meeting with any additional actions that need to be taken and an updated REB clearance of the current proposal. (An additional Certificate of Research Ethics Clearance is not issued.)

7. The REB Chair receives written feedback from the Principal Investigator/Faculty Supervisor about the actions taken.

8. When the review of the report has completed, any new future changes to the research proposal will need to be reported via regular continuing research ethics review route, a Request for Change to Cleared Research, SMU REB Form 2 review request process.

9. Minor deviations from the research (e.g., a slight increase or decrease in testing time, a wording adjustment on a question or informed consent form/script such as a version number, inserting REB file number) should not require immediate reporting to the REB, but may be summarized via regular continuing research ethics review route, an Annual Status Report, SMU REB Form 3 review request process.

SECTION A

TYPE OF REPORT

1. ◯ **NEW INFORMATION**

   ◯ **UNEXPECTED REACTION (Type 1)** ◯ **UNAVOIDABLE SINGLE INCIDENT (Type 2)**

2. Title of Research:

3. SMU REB File #:

4. CURRENT REB CLEARANCE PERIOD:

From: dd/mmm/yyyy To: dd/mmm/yyyy

INVESTIGATOR INFORMATION

1. Principal Investigator/Faculty Supervisor name:
2. Principal Investigator/Faculty Supervisor email:
3. Principal Investigator/Faculty Supervisor phone number:

SECTION B

DESCRIPTION OF NEW INFORMATION

To report Unanticipated Issues (Type 1 or Type 2) only, place n/a in 1.b, and proceed to Sections C and D.

1. a. Date investigator became aware of the new information:

b. Detail the new information and how the team became aware of the information.

SECTION C

DESCRIPTION OF UNANTICIPATED ISSUE

Please place "n/a" if the report is for New Information only and not Unanticipated Issues.

1. a. Date of event:

b. Detail how the event represents an unanticipated issue, the affected participants, start and end date of the event, location(s), how the team became aware of the issue.

SECTION D

DESCRIPTION OF RESOLUTION
(Applies when reporting New Information or Unanticipated Issues)

1. Discuss what actions (in any) have been taken, or will be taken and by whom?

SECTION E

DESCRIPTION OF CORRECTIVE ACTIONS
(Applies when reporting New Information or Unanticipated Issues)

1. Describe what action (if any) has been taken or will be taken by the Principal Investigator/Faculty Supervisor in response.

Demonstrate any and all changes to the existing version of the research proposal that the REB has cleared to date. If any changes were a necessary reaction to the issue, it would be reviewed by the REB during this reporting (meaning, a separate/additional Request for Change to Cleared Research, Form 2, would not be required.)

Include any additional plans to eliminate or mitigate any increased risks to participants and/or adjustment to ensure equitable distribution of benefits.

Corrective actions may include changes to: the research methodology, inclusion/exclusion criteria, suspension of a procedure, placement of additional procedures, etc., case-pending.

SECTION F

REVISITNG THE INFORMED CONSENT PROCESS
(Applies when reporting New Information and Unanticipated Issues)

1. Discuss whether the Letter of Information or Informed Consent Form/Script/ Feedback letter, etc. warrant disclosure and have been or will be adjusted? If yes, provide a copy of all draft new materials, highlighting the changes for continuing research ethics review together with this report.

Actions may additionally involve an update to the informed consent process (i.e., TCPS 2, Art. 3.2. d. provision involving providing of all information throughout the course of the research project that is relevant to a participant's decision to continue or withdraw from participation), whether current and/or former participants should be notified to reassess their willingness to continue their participation in the research, etc., case-pending.)