Guidance Document for Completion of Study Form

All studies must complete an end-of-study report for their Research Ethics Boards according to TCPS2 (2014). Article 6.14. The Principle Investigator must fill out a Completion of Study Form after their study is complete and email it to dore@sfu.ca with the study number in square brackets as the first item in the subject line. The ORE will then close your study.

A Completion of Study Form should only be submitted once recruitment, data collection, or other interactions with participants have concluded. Once the Completion of Study Form is reviewed, the REB will issue an Acknowledgement and the study will automatically be listed as “closed”. The ONLY activity available from that point on is a Request for Acknowledgement if needed. The study cannot be amended or reactivated.

Harmonized Studies

A board of record (BoR) is typically the REB representing the institution where the Primary Investigator holds their primary appointment or the institution where the majority of research will take place.

Please click here for more on the BC Ethics Harmonization Initiative (BCEHI).

Section 2

The World Health Organization defines a clinical trial as follows:

*For the purposes of registration, a clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.*

*Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc.*

Section 4

DO NOT submit a completion of study form if participant data collection is ongoing. Once the Completion of Study Form is reviewed, the REB will issue an Acknowledgement and the study will automatically be listed as “closed”. The ONLY activity available from that point on is a Request for Acknowledgement if needed. The study cannot be amended or reactivated.

Section 5

Unanticipated problem

An Unanticipated Problem is any incident, experience, or outcome that meets all of the following criteria:

- Unexpected (in terms of nature, severity, or frequency)
- Related or possibly related to participation in the research;
- Suggests that the research places research participants or others at a greater risk of harm than was previously known or recognized.

For example, the theft of a laptop containing confidential information about participants would constitute an unanticipated problem; an outbreak war or insurrection in the area of the research might constitute an unanticipated problem.

Unanticipated Problems should be reported to the ORE/REB using the Unanticipated Problem Form.
An Adverse Event (AE) is defined as: any untoward medical occurrence in a research participant administered an investigational product and which does not necessarily have a causal relationship with this [product]. An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of an investigational product, whether or not related to the investigational product.

For more information on Unanticipated Problems and Adverse Events please see the Unanticipated Problem Guidance Form

*Please note that an Adverse Event should be reported to the ORE/REB immediately using the Unanticipated Problem Form.