Annual Renewal Form Guidance

All approved and continuing human research ethics applications must submit a report summarizing the research activities that have taken place that year according to TCPS2 (2014) Article 6.14. At SFU ORE, this report is called an Annual Renewal Report and was formally referred to as a Progress Report.

Section 4

New information or changes in scientific knowledge

Since your Initial Ethics Approval, has there been any new information or changes in scientific knowledge that might affect the ethics basis of the research design?

It may be appropriate in some cases to change the design of a study in response to new scientific information. In this case, it would be necessary to submit an Amendment Request using the corresponding form to ORE.

In other situations, it might also be advisable to inform past, present, or future study participants of this new information. We encourage you to contact ORE for assistance and guidance in these matters.

Institutional Approvals/Permissions

Some studies involving health authorities, schools, or other universities may require Approvals/Permissions from these organizations before this research can be initiated. As your study’s Board of Record,* it is important that these documents are submitted to ORE so that they can be included with your application. If ORE does not receive this documentation, your Annual Renewal will NOT be approved and your study will be suspended and/or terminated.

*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.

Conflict of Interest

Please read below for a brief explanation of SFU’s Conflict of Interest Policy (GP 37)

Simon Fraser University is committed to academic freedom and to excellence in teaching and research. As a place of learning, the University encourages its faculty, staff and students to be broadly involved in professional interests and activities compatible with the University’s mission, values and commitments. Occasionally, the best interests of the University and the personal interests of its Members may conflict, or may be perceived to conflict.

To maintain public and professional trust and confidence, the University must deal with real or perceived conflicts of interest (COIs) in a fair, open, consistent and practical way. Rather than taking a rigid approach, the University prefers to assess COIs on an individual basis and to manage conflict, where appropriate.

To that end, this Policy sets out a mechanism for identifying and addressing conflicts of interest, whether real or perceived, so that the University and its external constituencies can be confident decisions and actions are not inappropriately influenced by private interests. At the heart of this Policy is the duty of each Member to assess his or her own activities and to report any real or potential conflicts of interest as prescribed in this Policy and its accompanying procedures.

Assessing conflict requires the collection, use, disclosure and retention of personal information as defined in BC’s Freedom of Information and Protection of Privacy Act. The University will conduct this and other conflict-related activities in compliance with the Act.
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.