



<b>Policy #</b> REB- POL-01	<b>Annual Renewal</b>		
<b>Approval Date:</b>	2013 February 20	<b>Revision Date:</b>	

**Purpose:** This policy describes the general requirements for the Annual Renewal of research involving human participants at SFU prior to the expiration of the REB approval period.

**Policy:** The SFU REB conducts a continuing review of approved research taking place within its jurisdiction at intervals that are appropriate to the degree of risk to which participants are exposed, but not less than once per year. The SFU REB makes the determination, concerning the duration of the approval period and the interval during which continuing review must occur, at the time of the initial review and approval.

**Annual Review of Research**

Annual Renewals are required from all Principal Investigators (PI) in relation to each study that has REB approval at a frequency determined by the REB at initial approval or as subsequently changed by the Chair as deemed necessary. At a minimum, the REB requires a progress report once per year. The research will be reviewed before the one-year anniversary date of the previous REB approval, even though the research activity may not have begun until sometime after the REB approval. An application for Annual Renewal must be submitted on an ongoing basis until a study is completed.

**Criteria for Determining which Projects Require Review more than Annually**

The SFU REB will require annual renewal reports on at least an annual basis unless it designates otherwise. Studies designated as Greater-Than-Minimal Risk may require review more often than annually. In addition to the designation as Greater-Than-Minimal Risk the REB may consider the following when determining the appropriate interval for renewal:

- The nature of any risks posed by the research project
- The nature of adverse events reported during earlier phases of the study
- The degree of uncertainty regarding the risks involved
- The vulnerability of the participant population
- The experience of the investigators in conducting research



**SIMON FRASER UNIVERSITY**  
ENGAGING THE WORLD

- The SFU REB's previous history with the investigators
- The projected rate of enrollment
- Whether the research project involves novel interventions.

### **Extensions of Approval Period**

There is no grace period extending the conduct of the research beyond the expiration date of approval. Extensions beyond the expiration date will not be granted. If Annual Reports are not submitted as scheduled to the Office of Research Ethics (ORE), the study will be suspended and the Investigator's department head and the Office of Research Services will be advised of the expiration of the study.

### **Criteria for Renewal**

Continuing review must be substantive and meaningful, the rigour of which shall be in accordance with a proportionate approach to ethics assessment. In order for continuation of approval to be granted, the following requirements must be met:

- There have been no changes to the investigators, study protocol, consent form, or consent process since the last progress report unless these have been submitted as amendments and approved\*.
- The risk to participants continues to be minimized and reasonable in relation to the anticipated benefits.
- Where applicable, the reports of the Data Safety Monitoring Boards are favourable for continuation of the study,
- There is no literature/information, which might affect the willingness of study participants to participate or continue to participate.
- There have been no unresolved complaints from study participants.
- There is no conflict of interest that has emerged since approval that might adversely affect the safety or well-being of study participants.

### **Level of Review**

Studies that are approved as Minimal-Risk will normally be delegated to the Director, or Associate Director, ORE or his/her designate. Studies that are approved as Greater-Than-Minimal Risk can be reviewed by the appropriate subcommittee or delegated to the Director, or Associate Director, ORE or his/her designate; this determination will be made by the Chair or Deputy Chair at the time of renewal.

**References:** The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2, Articles 2.8, 2.9, 6.12, 6.14, 6.15 5.3).

---

\* If changes to the approved study have been made these changes must be submitted as amendments prior to or at the same time as the renewal request is submitted.