`	**RESEARCH ETHICS BOARD** **STANDARD OPERATING PROCEDURES**	
	SOP Number	108
	Standard Operating Procedures Maintenance	
	Date of Issue **Date of Revision**	2010 05 12 2018 03 30 2022 07 13

Purpose: The purpose of this standard operating procedure (SOP) is to describe the processes for establishing and maintaining written SOPs. The purpose of having written SOPs is to promote quality and consistency in the ethics review process; ensure compliance with the principles, guidelines and regulations applicable to the ethical review and oversight of research involving humans; and facilitate training of new personnel.

Directive: Fraser Health Policy "Research"

References: 2019 10 08 CAREB SOP 108.003,Tri-Council Policy Statement; Ethical Conduct for Research Involving Humans, International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines as adopted by Health Canada, Health Canada Therapeutic Products Directorate Food and Drug Regulations for Clinical Trials, Division 5, US Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Title 21, Parts 56.108, 56.115, US Department of Health and Human Services (HHS) CFR Title 45 Part 46.103, 46.108.

Responsibility: All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

Procedure

Written standard operating procedures provide the framework to promote ethical standards in the review, oversight and conduct of research involving human participants. SOPs describe the processes that must be followed and documented to ensure that the rights and welfare of human participants of such research are overseen and protected in a uniform manner.

1.0 Development, Review, Revision, and Approval of Policies & Procedures

1.1 The qualified REB Office Personnel will review the SOPs at least biennially. Applicable SOPs will be reviewed sooner if changes to regulations, guidelines, or standard practice warrant revisions of the creation of new SOPs;

1.2 SOPs may be revised for reasons including, but not limited to: changes to regulations or guidelines, new policies, or changes to REB or administrative practices;

1.3 The qualified REB Office Personnel will make the necessary modifications to existing SOPs, or draft a new SOP(s). SOPs are controlled documents and new drafts will be indicated by the addition of "DRAFT version date" and removal of the previous "Final Version Date";

1.4 The revised SOP(s) will be circulated to the REB Office Personnel and REB Chair or designee, as well as REB members (as appropriate) for review. Comments will be incorporated into a new version with an updated version date;

1.5 Once the SOP content is approved, the draft version date will be removed and the date on the approved version will be entered as the "Final Version Date". The history of revisions will be recorded in the 'SOP History' section of each SOP;

1.6 A new final version of the SOP supersedes any previous versions.

2.0 Distribution and Communication

2.1 New or revised SOPs and associated guidance documents will be communicated and disseminated to all individuals identified in the 'Responsibilities' section of each SOP;

2.2 The SOPs will be available to Researchers and researcher sites, Sponsors and Regulatory Authorities as required;

2.3 Qualified REB Office Personnel will train members of the REB and the REB Office Personnel or any new or revised policy and/or relevant procedure, as applicable;

2.4 Each new REB member must review all applicable procedures prior to undertaking their responsibilities as an REB member;

2.5 Each new REB Office Personnel must review all applicable policies and procedures prior to undertaking their responsibilities with the REB office;

2.6 Evidence of training must be documented;

2.7 The REB office shall maintain all documentation of SOP training.

3.0 Forms, Memos and Guidance Documents

3.1 Forms such as checklists and worksheets may be developed to facilitate compliance with the SOPs and to ensure that policies are integrated into daily operations. Forms may be either controlled or non-controlled;

3.2 Memos and guidance documents may be developed to provide guidance for the interpretation and implementation of the SOP;

3.3 Memos and guidance documents will be made available to the Researchers and researcher sites as applicable;

3.4 The qualified REB Office Personnel and/or REB Chair or designee will evaluate the need for new or revised forms, memos or guidance documents.