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THE UNIVERSITY OF BRITISH COLUMBIA

SOP 103

TITLE	**103: Policies and Procedures Maintenance**
SCOPE	The Research Ethics Boards operating under the direct authority of the University of British Columbia that review human participant research in compliance with applicable regulations and guidelines
RESPONSIBILITIES	The Chairs and members of the Research Ethics Boards, Director, Research Ethics, and Research Ethics Board Office Personnel
APPROVAL AUTHORITY	The Vice-President, Research & Innovation
EFFECTIVE DATE	May 2018
Supersedes documents dated	May 2011, April 2009; July 2003

1.0 PURPOSE

The purpose of this standard operating procedure (SOP) is to state the REB's commitment to maintain and follow up-to-date policies and procedures that adhere to regulatory mandates and ethical principles regarding the conduct of research with human participants.

2.0 DEFINITIONS

See Glossary of Terms.

3.0 PROCEDURE

Following the regulations and guidance of Health Canada's Food and Drugs Act[1], ICH-GCP[2], (where applicable) U.S. Federal Regulations[3], and the Tri-Council Policy Statement, supported by institutional policies, assures that the rights and welfare of human research participants will be overseen and protected in a uniform manner, regardless of changes in personnel. Written

procedures must be in place to ensure that the review, oversight, and documentation of research involving human participants is of the highest quality and integrity.

Standard operating policies (SOPs or Policies) and procedures provide the framework for the ethical and scientifically sound conduct of research involving human participants.

4.0 SPECIFIC POLICIES

4.1 Development, Review, Revision and Approval of Policies and Procedures

4.1.1 Policies will be reviewed by the appropriate Institutional Official(s) at intervals established by the Director, Office of Research Ethics in consultation with the Chairs of the REBs. The qualified REB Office Personnel will review the SOPs at least once every two years. Applicable SOPs will be reviewed sooner if changes to regulations, guidelines, or standard practice warrant revisions or the creation of new SOPs;

4.1.2 Changes to regulations, federal or international ethical guidelines, or research practice as well as changes to REB or administrative policies and procedures of the University of British Columbia may require a new policy or a revision to a previously issued policy;

4.1.3 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”;

4.1.4 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;

4.1.5 Once the SOP content is approved, the draft version date will be removed and the date of 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;

4.1.6 Signatures on the SOP as determined by organizational policy will denote SOP approval. A new final version of the SOP supersedes any previous versions.

4.2 Policy Dissemination and Training

4.2.1 When new or revised SOPs and associated guidance documents are approved, they will be disseminated to the appropriate individuals and departments identified in the “Responsibilities” section of each SOP;

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

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

4.2.4 Each new REB member must review all applicable policies and procedures prior to undertaking any responsibilities as an REB member;

4.2.5 Each new REB Office Personnel must review all applicable policies and procedures prior to undertaking any responsibilities within the REB office;

4.2.6 Evidence of training must be documented;

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

4.3. Forms, Memos and Guidance Documents

Forms are used to:

- ensure that policies are integrated into the daily operations of research and review throughout the UBC system; and
- enable REB Office Personnel to manage review, tracking, and notification functions consistently.

Standardized online RISe (Research Information Services) forms used by all of the UBC-affiliated REBs include the REB application forms, and all post-approval activity forms including notices of completion, renewals, amendments, requests for information and requests for acknowledgement. Changes to these forms are reviewed and approved by the Director, Research Ethics, in consultation with the UBC REB Chairs and/or REB Office Personnel where appropriate.

4.3.1 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;

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

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

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

5.0 REFERENCES

1. *Health Canada Food and Drug Regulations, Part C, Division 5, Drugs for Clinical Trials Involving Human Subjects* (Schedule 1024):
http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/clini/cta_documents-eng.php

2. *Health Canada Guidance for Industry, Good Clinical Practice: Consolidated Guideline*, ICH Topic E6, 1997:
https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/efficacy/guidance-document-good-clinical-practice-integrated-addendum-e6-r1-topic-e6-r2.html

3. *U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46* (45 CFR 46.103(4):
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/#46.103
U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56.108(a)):
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.108