a place of mind
THE UNIVERSITY OF BRITISH COLUMBIA

SOP 602

TITLE	**602: Communication – Research Participants**
SCOPE	All research submitted to the University of British Columbia's Research Ethics Boards
RESPONSIBILITIES	The Vice-President, Research & Innovation, delegated to the Director, Office of Research Ethics, all Research Ethics Board (REB) Chairs and members and all REB 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 describe the REB actions that must be communicated to various parties involved in the research program.

2.0 DEFINITIONS

See the Glossary of Terms.

3.0 PROCEDURE

The REB is required to communicate certain actions to entities that may have an interest in the status of the research being conducted. Procedures should be in place for prompt reporting to the REB, institutional officials, and, where applicable, funding agencies and Sponsors (including department and agency heads) of:

- Serious Adverse Events and other unanticipated problems;
- Serious or Continuing non-compliance with policies, protocols, or REB requirements; and,

- Suspension or termination of research.

The specific procedures for investigating and making determinations concerning these situations are addressed in SOPs 407 and 408.

3.1 Communication with Research Participants

Research participants should be able to voice their concerns, questions and request information regarding their participation or potential participation in research, in confidence, to an informed individual on the REB or in the REB office.

3.1.1 Research participants are encouraged to contact (by telephone or in writing) the REB office with questions and concerns, using the contact information provided in the informed consent document(s). If requested, the identity of the participant will not be recorded or shared;

3.1.2 Each consent form approved by the REB must contain institutional contact information for participants who wish to discuss their rights as research participants and/or concern about the conduct of the study approved by the REB. Should the expressed concern warrant further consideration, the REB Chair and/or the Director, Office of Research Ethics may request an on-site review of the study;

3.1.3 The REB Office Personnel must document all communication with the research participant;

3.1.4 The REB Office Personnel will communicate participant concerns to the REB Chair or designee;

3.1.5 The REB Chair or designee works to resolve participant issues which may include a follow-up with the Researcher or the Researcher's supervisor or other organizational representative, and with appropriate federal agencies, as applicable;

3.1.6 The REB Chair or designee documents all communication with the research participant and a record of this communication is maintained securely in the Office of Research Ethics file;

3.1.7 If a study is suspended or discontinued for safety reasons or for non-compliance, the REB may require the Researcher to inform study participants in writing of the reasons for study suspension or discontinuation and any actions which should be taken by the participant to ensure safety and health care continuity.

3.2 Communication to Others

3.2.1 Suspension of a study "for cause": The REB will notify the Researcher's Department/Division Head, the Director, Office of Research Ethics and the Vice-President, Research & Innovation.

If it is appropriate or required by contract, policy, or applicable regulations, the REB will also report the suspension to the study sponsor, the REBs at other institutions conducting the same study, and to applicable regulatory agencies[1] (e.g. Health Canada, U.S. Food and Drug Administration (FDA), or the Office for Human Research Protections (OHRP));

3.2.2 Finding of a material conflict of interest: If the REB determines that a material conflict of interest exists which is likely or may be perceived as compromising the safety, well-being or rights of study participants, and if the REB and the Researcher cannot reach agreement on how the conflict of interest will be managed the REB Chair will inform the Researcher's Department/Division Head and, if applicable, the Vice-President, Research & Innovation[2];

3.2.3 Communication to Institutional Official of REB Actions: Minutes of all UBC REB meetings will be prepared and maintained by the REBs and will be made available to appropriately authorized personnel [3];

3.2.4 U.S. Federally Funded Studies: The REB Chair or designee will send notification of disapproval will be sent to both the investigator and sponsor for studies receiving support from the U.S. Federal Government, if the investigation does not meet appropriate regulatory criteria[4]. Similarly, if the REB determines that there is serious and continuing non-compliance that presents significant or increased risk to research participants, the REB shall notify the applicable authorities in accordance with U.S. federal regulations. In accordance with SOP 404, the Principal Investigator is responsible for reporting serious adverse events and other unanticipated problems to the applicable regulatory authorities.

4.0 REFERENCES

1. *U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46.103(b)(5)):*
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.103
U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56.108(b)):
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.108

2. *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans,* Article 13.3:
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter13-chapitre13/#toc13-1b

3. *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, Article 7.3, Application (*REBs and Senior Administrators)*:
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter7-chapitre7/#toc07-1c

4. *U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 50 (21 CFR 50.24):*
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.24