a place of mind
THE UNIVERSITY OF BRITISH COLUMBIA

SOP 601

TITLE	**601: Communication - Researcher**
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 the Researcher and the importance of open communications among REBs, researchers, staff, and university committees and officials.

2.0 DEFINITIONS

See the Glossary of Terms.

3.0 PROCEDURE

In the interest of enhancing human research participant protection, it is important for the REB to foster collaboration and open communication between and among the REB, Researcher, research staff, and organizational representatives. This applies not only to communication related to a specific research project, but also to communication related to ethical issues and REB processes, policies and procedures.

All Researchers participating in REB approved research shall be informed, in writing, of all determinations made by the REB regarding specific research.

Feedback from Researchers should be encouraged and should be considered as an opportunity to review and to improve the function of the REB and of the REB office procedures.

In order to facilitate clear and accurate communication with Researchers and research staff, the REB will follow standardized notification and documentation procedures[1].

3.1 Notifications of REB Decisions

All UBC-affiliated REBs use an electronic secure web-based REB document management system called **R**esearcher **I**nformation **Se**rvices (RISe). Researchers will be notified of the REB's decisions via an email automatically generated by RISe[2].

3.1.1 The RISe system will notify the Researcher and/or his/her research staff of the REB's decision via email following the review[3] (i.e., from the REB meeting or delegated review date) of new research, modifications, or amendments to currently approved research, applications for continuing review or reportable events;

3.1.2 The determinations of the REB will be summarized noting any concerns or requests for clarification including recommended changes to the consent form, and clarifying the reasons for the disapproval of the submission (when appropriate);

3.1.3 If the research does not receive initial approval or is denied re-approval (for continuing review), the REB Chair or designee will notify the Researcher of the REB's decision as soon as possible following the REB meeting. Formal written notification will follow;

3.1.4 The REB Chair or designee will review the draft REB provisos or deferral notice, make revisions as necessary, and will indicate his/her approval;

3.1.5 The REB provisos or deferral notice will be issued to the Researcher(s) via the RISe system;

3.1.6 The Researcher will be asked to include the REB number or equivalent designation assigned to the research in all subsequent correspondence with the REB;

3.1.7 Upon receipt of the Researcher response to the REB provisos or deferral notice, the REB will follow-up with the Researcher and/or his/her staff to request any additional clarifications as needed, or as requested by the REB Chair or designee, or the reviewers;

3.1.8 Once all of the REB conditions are satisfied, the REB will issue a Certificate of Approval. Included in the Certificate of Approval is the study title and REB number, name of the

Principal Investigator and any co-investigator(s), funding agency, study sites, and a list of the approved documents. The document titles, version numbers, and dates listed in the Certificate of Approval correspond to the information entered on page 9 (Documentation) of the RISe application form.

3.2 Researcher Appeal of REB Decision

3.2.1 A Researcher may request a reconsideration or appeal the decision of the REB and/or any of the revisions to the research requested by the REB[4];

3.2.2 Appeals are conducted in accordance with UBC Policy 89[5] and SOP 409;

3.2.3 Only the REB may lift a restriction or re-review previously disapproved research. Delegated review procedures may not be used.

3.3 Communications Concerning Non-compliance

Researcher non-compliance may be the result of communication difficulties. The REB will attempt to resolve apparent instances of non-compliance without interrupting the conduct of the study, especially if the rights and welfare of participants may be jeopardized.

However, if it appears that a Researcher is intentionally non-compliant with the protocol, SOPs, TCPS2, REB, and/or other applicable requirements, the REB, through the REB Chair or his/her designee, will notify the Researcher in writing, detailing the alleged non-compliance, specifying corrective action, and stating the consequences. Such actions may be the result of an onsite audit conducted by the Office of Research Ethics at UBC. When appropriate, copies of such correspondence shall also be sent to the Researcher's supervisor and/or Department Head, study Sponsor, the Director, Office of Research Ethics and the Vice-President, Research & Innovation.

4.0 REFERENCES

1. *Government of Canada, Canadian General Standards Board.* CAN/CGSB -191.1-2013 Research ethics oversight of biomedical clinical trials (2013), Section 4.4.3.1:
http://publications.gc.ca/collections/collection_2017/ongc-cgsb/P29-191-001-2013-eng.pdf
International Conference on Harmonisation Good Clinical Practice Guidelines (ICH-GCP), Section 3.3.9
http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4_2016_1109.pdf

2. *Government of Canada, Canadian General Standards Board.* CAN/CGSB -191.1-2013 Research ethics oversight of biomedical clinical trials (2013), Section 4.4.5:
http://publications.gc.ca/collections/collection_2017/ongc-cgsb/P29-191-001-2013-eng.pdf

3. *U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46.108):*
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.108
U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46.109):
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.109
U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46.115):
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.115
U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56.109(e)):
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.109
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
U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56.115(a)(6)):
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.115

4. *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans,* Article 6.19:
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter6-chapitre6/#ch6_en_a6.19
Government of Canada, Canadian General Standards Board. CAN/CGSB -191.1-2013 Research ethics oversight of biomedical clinical trials (2013), Section 4.4.8:
http://publications.gc.ca/collections/collection_2017/ongc-cgsb/P29-191-001-2013-eng.pdf

5. *UBC Policy 89*:
http://universitycounsel.ubc.ca/files/2012/06/policy89.pdf