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THE UNIVERSITY OF BRITISH COLUMBIA

SOP 903

TITLE	**903: Non-Compliance**
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, all REB Office Personnel and Researchers
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 Research Ethics Board's (REB) process for responding to reports of non-compliance and the actions that the REB may take as a result of its review of reports of serious and/or continuing non-compliance.

2.0 DEFINITIONS

See the Glossary of Terms.

3.0 RESPONSIBILITIES

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

Researchers are required to comply with all of the applicable guidelines and regulations governing the conduct of human research, as well as with the required conditions of approval of the REB.

The REB Office Personnel and the REB members are responsible for acting on information or reports of non-compliance received from any source.

The REB Chair or designee is responsible for the initial review of allegations of non-compliance.

If intentional, serious or continuing non-compliance is established, the REB Chair or designee, in consultation with the Director, Office of Research Ethics, is responsible for determining the relevant corrective actions.

The REB Chair or designee is responsible for reporting any incidents of serious or continuing non-compliance to the Researcher and to the appropriate Department/Division Head, as well as the Vice-President, Research & Innovation, and has the authority to notify the regulatory authorities (as applicable), and the sponsor[1]. The REB may delegate regulatory authority reporting (as applicable) to the organization.

4.0 PROCEDURE

Reports of non-compliance may come from any source including the REB members, Researchers, research participants, organizational personnel, the media or the public. The rights and welfare of research participants could be at risk if there were serious or repeated non-compliance on the part of a Researcher or any member of the research team. It is, therefore, the duty of the REB to be receptive to these reports and to act on all credible allegations of non-compliance.

4.1 Reports of Non-compliance

4.1.1 Reports of non-compliance in human participant research may come from many sources including, but not limited to, a Researcher (as a self-report), a sponsor representative, a quality assurance or compliance office, a research participant, a member of the research team, or a person not directly involved with the research;

4.1.2 Persons raising such concerns are encouraged to express them in writing. However, the REB office will receive and document oral reports of non-compliance, including those which are received via the Research Participant Complaint Line;

4.1.3 Evidence of serious or repeated non-compliance may also arise from human protection-related Quality Assurance inspections, sponsor audits or inspections, or regulatory agency audits or inspections.

4.2 Evaluating Allegations of Non-compliance

4.2.1 When an allegation of non-compliance is referred to the REB, the REB Office Personnel will document the information and the contact details of the person reporting the allegation, and immediately refer the incident to the REB Chair or designee;

4.2.2 The REB Chair or designee manages all allegations of non-compliance and reports of non-compliance that are determined to be more than minor;

4.2.3 The REB Chair or designee will conduct an initial review of all allegations to determine the veracity of the allegations;

4.2.4 The REB Chair or designee will obtain as much information as possible from the individual reporting the incident;

4.2.5 The REB Chair or designee will obtain as much information as possible, or verification from other sources by one or more of the following means:

- Contacting the Researcher or member of the investigative team directly,
- Consulting with other relevant organizational personnel,
- Collecting relevant documentation,
- Reviewing any written materials,
- Interviewing knowledgeable sources;

4.2.6 If the REB Chair or designee determines that there is evidence of non-compliance, he/she will then assess whether the non-compliance was intentional, serious and/or repeated;

4.2.7 If the REB Chair or designee determines that there is no or insufficient evidence to support the allegations, no further action will be required.

4.3 Managing Non-compliance

4.3.1 The REB Chair or designee will attempt to resolve apparent instances of non-compliance without interrupting the conduct of the research, especially if the rights and welfare of participants may be jeopardized by interrupting the research;

4.3.2 If the REB Chair or designee determines that the non-compliance was not serious or repeated, and the research staff recognized the non-compliance and took appropriate corrective actions, no further action may be required;

4.3.3 If the REB Chair or designee determines that the non-compliance was not serious or repeated, but the research staff did not recognize the non-compliance or take appropriate corrective actions, the REB Chair or designee may discuss the matter

directly with the Researcher, recommend corrective action, request a Quality Assurance evaluation, and/or refer the matter to the REB at a Full Board meeting;

4.3.4 If it appears that a Researcher was intentionally non-compliant, the REB Chair or designee may suspend the conduct of the research immediately. The matter will normally be referred to the next Full Board meeting of the REB. The REB Chair or designee will inform the Department/Division Head and Vice-President, Research & Innovation if necessary;

4.3.5 The REB will review the information at the next Full Board meeting and may recommend appropriate corrective actions;

4.3.6 Corrective actions are based upon the nature and the degree of the non-compliance. In evaluating the non-compliance, the REB, the REB Chair and/or designee may consider one or more of the following actions:

- Request modification of the protocol,
- Request modification of the informed consent document,
- Require that additional information be provided to past participants,
- Require that current participants be notified,
- Require that current participants re-consent to participation,
- Modify the continuing review schedule,
- Require onsite observation of the consent process,
- Suspend the new enrollment of participants,
- Suspend REB approval of the research,
- Suspend Researcher involvement in the research,
- Terminate REB approval of the research,
- Require the Researcher and/or staff to complete a training program,
- Notify organizational entities (e.g., legal counsel, risk management),
- Ensure that all other regulatory reporting requirements are met, as required,
- Any other action deemed appropriate by the REB.

4.4 REB Response to Reports of Non-compliance

4.4.1 The REB Chair or designee will notify the Researcher in writing of the results of the REB review of incidents of non-compliance and any remedial actions required;

4.4.2 The REB Chair or designee will report any serious or continuing non-compliance to the Researcher as well as to the Department/Division Head and Vice-President, Research & Innovation, and has the authority to report to the regulatory authorities (as applicable) and the Sponsor[2]. The REB may delegate regulatory authority reporting to the organization;

4.4.3 The REB Chair or designee may submit an allegation of research misconduct to the Department/Division Head and Vice-President, Research & Innovation as appropriate;

4.4.5 If the non-compliance is determined to be serious and/or continuing, and it is in relation to a study that is funded or supported by the U.S. Federal Government or regulated by the U.S. Food and Drug Administration, the REB Chair or the Director, Office of Research Ethics, will notify the applicable regulatory authorities[3];

4.4.6 The REB will request a time-sensitive response in writing from the Researcher, including the corrective action plan[4];

4.4.7 The Researcher's response may be reviewed using a delegated REB review procedure or the review may be referred to the REB, for a decision from the Full Board;

4.4.8 The REB Chair or designee will follow-up to assess any corrective measures implemented by the Researcher.

4.5 Documenting Non-compliance

4.5.1 The REB Chair or designee will document the findings of reports of non-compliance;

4.5.2 For those incidents of non-compliance referred to the Full Board, the REB Office Personnel will document the following in the REB meeting minutes: a description of the incident and findings, verification of the non-compliance, the REB's decision, the remedial action required by the REB, the Researcher's response and actions implemented and plans for further follow-up.

5.0 REFERENCES

1. *UBC Policy 85*:
https://www.universitycounsel.ubc.ca/files/2015/08/policy85.pdf
Government of Canada, Canadian General Standards Board. CAN/CGSB -191.1-2013 Research ethics oversight of biomedical clinical trials (2013), Section 4.2.3.4:
http://publications.gc.ca/collections/collection_2017/ongc-cgsb/P29-191-001-2013-eng.pdf

2. *Health Canada Guidance for Industry, Good Clinical Practice: Consolidated Guideline*, ICH Topic E6, 1997, Section 5.20:
http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6r2-step4-eng.php#a5.20

3. *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

4. *Government of Canada, Canadian General Standards Board.* CAN/CGSB -191.1-2013 Research ethics oversight of biomedical clinical trials (2013), Sections 4.4.6.6 & 4.4.6.8:
http://publications.gc.ca/collections/collection_2017/ongc-cgsb/P29-191-001-2013-eng.pdf