

SOP Title:	Communication – Investigators and Research Staff		
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Approved By:	Dr. Elizabeth Stephenson		

1.0 PURPOSE

This standard operating procedure (SOP) describes the Research Ethics Board's (REB) communication with the Researcher and with his/her research team.

2.0 POLICY STATEMENT

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.

3.0 DEFINITIONS

See Glossary of Terms

4.0 RESPONSIBILITY

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

5.0 PROCEDURES

5.1 Notification of REB Decisions

- 5.1.1** The REB will notify the Researcher and/or his/her research staff of the REB's decision within a time frame specified by the REB, following the review (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;

- 5.1.2 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);
- 5.1.3 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;
- 5.1.4 The REB Chair or designee will review the draft REB review letter, make revisions as necessary, and will indicate his/her approval;
- 5.1.5 The REB review letter will be issued to the Researcher(s). Alternatively, the REB review may also be communicated to the Researcher(s) via comments on the REB application package;
- 5.1.6 The Researcher will be asked to include the REB number or equivalent designation assigned to the research in all subsequent correspondence with the REB;
- 5.1.7 Upon receipt of the Researcher response to the REB review letter, 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;
- 5.1.8 Once all of the REB conditions are satisfied, the REB will issue an approval letter.
- 5.1.9 The REO personnel will notify the participating investigators in writing of the REB's decision as soon as possible following review of new studies, modifications to currently approved studies, or applications for continuing review.
- 5.1.9.1 *If the REB approves a study/submission* the REB will issue an approval letter that includes the following:
 - The date of approval and the date of expiration date.
 - A list of study documents that have been approved/acknowledged.
 - A list of investigator responsibilities and standard conditions for continued approval:
 - The REB is notified of unanticipated problems within appropriate periods;
 - Changes to the protocol, and deviations from the protocol are reported;
 - Continuing review and request for re-approval reports are submitted to the REB; and
 - Documentation of Health Canada approval prior to study initiation, if required.

5.2 Researcher Appeal of REB Decision

- 5.2.1 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;
- 5.2.2 Appeals are conducted in accordance with established organizational policy at the applicable organization;
- 5.2.3 Only the REB may lift a restriction or re-review previously disapproved research. Delegated review procedures may not be used.

6.0 REFERENCES

See References