TITLE	**601: Communication - Researcher**
SCOPE	All health research submitted to the Health Research Ethics Board (HREB) operating under the direct authority of the Health Research Ethics Authority (HREA)
APPROVAL AUTHORITY	Ethics Director
EFFECTIVE DATE	April 2024

1.0 PURPOSE

This standard operating procedure (SOP) describes the HREB communication with the Researcher and with the research team.

2.0 DEFINITIONS

See the Glossary of Terms.

3.0 RESPONSIBILITIES

HREB members and Research Ethics Office (REO) Personnel are responsible for ensuring that the requirements of this SOP are met.

4.0 PROCEDURE

In the interest of enhancing human research participant protection, it is important for the HREB to foster collaboration and open communication between and among the HREB, Researcher, research staff, and applicable organizational representatives. This applies to communication related to a specific research projects, ethical issues, as well as HREB processes, policies and procedures.

All Researchers participating in HREB-approved research will be informed, either in writing or electronically, of all determinations made by the HREB regarding specific research.

Feedback from Researchers will be encouraged and will be considered an opportunity to review and to improve the function of the HREB and REO procedures.

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

4.1 Notifications of HREB Decisions

4.1.1 The HREB will notify the Researcher and/or the research staff of the HREB decision in a timely manner, following the review of new research applications, amendments to currently approved research, applications for continuing review and reportable events. Decisions made on new applications, as well as amendments that are reviewed at a Full Board meeting, will be communicated in a letter. All other decisions will be communicated by email.

4.1.2 The determinations of the HREB will be summarized, along with any concerns or requests for clarification, including recommended changes to the consent form, as well as reasons for a refusal to approve the submission (when appropriate).

4.1.3 If the research does not receive initial approval or is denied re-approval (for continuing review), the HREB Chairperson or designee will notify the Researcher of the HREB decision as soon as possible following the HREB meeting. Formal written notification will follow.

4.1.4 The HREB Chairperson or designee will review draft HREB review letters, make revisions as necessary, and will indicate their approval.

4.1.5 The HREB review letter will be issued to the Researcher(s).

4.1.6 The Researcher will be asked to include the HREB number or equivalent designation assigned to the research in all subsequent correspondence with the HREB.

4.1.7 Upon receipt of the Researcher response to the HREB review letter, the HREB will follow-up with the Researcher and/or the staff to request any additional clarifications as needed, or as requested by the HREB Chairperson or designee or the reviewers.

4.1.8 Once all of the HREB conditions are satisfied, the HREB will issue an approval letter.

4.1.9 A copy of all formal correspondence from the HREB will be kept in the research file.

4.2 Researcher Reconsideration or Appeal of HREB Decision

4.2.1 A Researcher may request a reconsideration or appeal the decision of the HREB and/or any of the revisions to the research requested by the HREB.

4.2.2 Reconsiderations and appeals are conducted in accordance with Sections 13- 18 of the HREA Act and SOP 409.

5.0 REFERENCES

International Conference on Harmonisation Good Clinical Practice Guidelines (ICH-GCP), Section 3: ICH GCP - 3. INSTITUTIONAL REVIEW BOARD/INDEPENDENT ETHICS COMMITTEE (IRB/IEC) - ICH GCP

The Health Research Ethics Authority Act: SNL2006 CHAPTER H-1.2 - HEALTH RESEARCH ETHICS AUTHORITY ACT (assembly.nl.ca)