


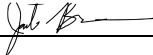


Title	Communication – Researcher
SOP Code	601.004
Effective Date	15-May-2023

Site Approvals

Name and Title (typed or printed)	Signature	Date MM/DD/YYYY
Meera Sidhu, Research Ethics Manager		12/01/2023
Steven Smith, Deputy Vice-Principal Research		12/04/2023
Dean Tripp, Chair HSREB		May 7 2024
Jacob Brower, Chair GREB		May 8 2024

1.0 PURPOSE

This standard operating procedure (SOP) describes the Research Ethics Board’s (REB) communication with the Researcher and with their research team.

2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable regulations and guidelines.

3.0 RESPONSIBILITIES

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

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

To enhance human research participant protection, the REB needs 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 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 improve the function of the REB and the REB Office procedures.

To facilitate clear and accurate communication with Researchers and research staff, the REB will follow standardized notification and documentation procedures.

5.1 Notification of REB Decisions

5.1.1 The REB will notify the Researcher and/or their research staff of the REB's decision in a timely manner 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;

If a study or amendment has been reviewed at the Full Board, communication with the researcher will be completed within 10 business days of the meeting.

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 In the case where 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 decision as soon as possible following the Full 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 their approval;

5.1.5 The REB review letter will be issued to the Researcher(s);

- 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's response to the REB review letter, the REB will follow up with the Researcher and/or their 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 the REB conditions are satisfied, the REB will issue an approval letter.

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.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP601.001	15-Sept-2014	Original version
SOP601.002	08-Mar-2016	No revisions needed
SOP601.003	08-Oct-2019	5.1.1: 'within a time frame specified by the REB' changed to 'in a timely manner.'
SOP601.004	15-May-2023	No revisions needed
SOP601.004	1-Dec-2023	Queen's Specific Revisions/Clarifications added to the N2 SOPs with modifications in bolded text

