Research Ethics Board

Standard Operating Procedure

Document Number	**REB.SOP.601**
Title	Communication - Researchers
Effective Date	September 23, 2021
Next Review	2026
Next Administrative Review	2023

1. **Purpose**
   This standard operating procedure (SOP) describes routine communication procedures between the Research Ethics Board (REB) and the Researcher and their research team.

2. **Definitions**
   See the MSVU **REB Glossary of Terms (REB.INFO.001)**

3. **Scope**
   This SOP pertains to REBs that review human participant research in compliance with applicable policies and guidelines.

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

5. **Procedures and/or Specific Policies**
   For effective human research participant protection, it is important that the REB and Researcher and research team maintain open communication. This applies not only to a specific research project, but also with respect to questions, concerns, ethical issues and REB processes, policies, and procedures. 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. All REB decisions regarding specific research projects shall be documented in writing. Informal communications between the Researcher or research team and REB Chair or REB Office personnel may occur through email, over the phone or in person. Documentation should be created to ensure accurate reflection of discussions for future reference.

5.1 Notification of REB Decisions

5.1.1 The REB will notify the Researcher and/or research staff of the REB's decision in a timely manner, following the review (REB meeting or delegated review) date of new research, modifications, or amendments to currently approved research, applications for continuing review or unanticipated event reports;

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 comments, make revisions as necessary, and will indicate their approval;

5.1.5 The REB review comments will be sent to the Researcher(s);

5.1.6 The Researcher may be asked to identify the protocol by REB number or title in correspondence with the REB regarding the research project;

5.1.7 Upon receipt of the Researcher's response to the REB review comments, the REB or REB Office personnel will follow-up with the Researcher and/or research staff to request any additional clarifications as needed, or as requested by the REB Chair or designee, or the reviewer(s);

5.1.8 Once all of the REB conditions are satisfied, the REB will issue an approval letter or notification of acknowledgement, as determined by submission type.

5.2 Researcher Consultation

5.2.1 A Researcher and/or research team may request advice, guidance or clarification with the REB Chair, designee, or REB Office personnel for current or future research projects. Such consultations may involve communications through email, phone or in person.

5.2.2 REB Chair, designee or REB Office Personnel should document such consultations in writing, including date, who was present and brief description of what the concerns were and how they were addressed. Such documentation should be kept by the REB Office for future reference, if needed.

6. References

See References listed (if applicable)

7. Acknowledgements

The development of this document has benefited directly from similar documents made public by the Tri-Council, as well as several Canadian universities. In some instances, specific formulations drawn from these sources have been incorporated into this document. Specific iterations were drawn from the following:

- Standard Operating Procedures for Observational Health and Non-Clinical Trial Research Ethics Boards - N2/CAREB-ACCER REB SOPs – Canadian Association of Research Ethics Boards (retrieved June 2021)
- N2/CAREB-ACCER REB SOPs - N2 Network of Networks - Resources - N2 Canada (retrieved May 2021)

8. SOP History

SOP Number	Key Changes	Effective Date
REB.SOP.601	Original Version	September 2021

This Page is intentionally left blank.