

Title	Communication of REB Decisions
SOP Code	REB SOP 409. 001
N2/CAREB SOP CODE	SOP 601.002
Effective Date	2020-03-20

Status	Name and Title	Date
<i>Author of Harmonized Template</i>	SOPs, Institutional REBs	2019-04-01
<i>Approved</i>	MUHC REB Full Board Meeting	2020-02-13
<i>Acknowledge receipt</i>	MUHC Board of Directors	2020-03-20

Table of Content

1 Purpose..... 1

2 Scope 1

3 Responsibilities..... 2

4 Definitions 2

5 Procedures..... 2

 5.1 Notification of REB Decisions..... 2

6 References..... 3

7 Revision History..... 3

8 Appendices 3

1 PURPOSE

This standard operating procedure (SOP) describes communications between the Research Ethics Board (REB) and the Researcher and his/her research team.

2 SCOPE

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

3 RESPONSIBILITIES

All REB members and designated REB Support Staff are responsible for ensuring that the requirements of this SOP are met.

4 DEFINITIONS

See Glossary of Terms.

5 PROCEDURES

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, Researchers, research staff, and representatives of the institution. This applies not only to communications related to a specific research project, but also to communications related to ethical issues and to REB policies and procedures.

All Researchers participating in an REB-approved research project shall be informed, in writing, of all determinations made by the REB regarding specific research.¹

Feedback from Researchers should be encouraged and should be considered an opportunity to review and improve the functioning of the REB as well as the REB office procedures themselves.

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

The communications between REB members and researchers or other parties involved in a review application will be documented in REB records.²

5.1 Notification of REB Decisions

5.1.1 The REB will notify the Researcher and his/her research staff, in writing and within a reasonable time frame (except under special circumstances, 15 working days or less³ or, in the case of

¹ Operational Guidelines for Ethics Committees that Review Biomedical Research, World Health Organization (WHO), 2000, hereafter "TDR", s. 8; Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2014 (TCPS2), art. 6.13.

² TDR, s. 10.8; *Modèle de règles de fonctionnement d'un comité d'éthique de la recherche*, Ministère de la Santé et des Services sociaux, DGAERA, 2004, hereafter "Modèle", s. 14.

³ *Ministère de la Santé et des Services sociaux, Mesures correctives relatives au mode de fonctionnement des comités d'éthique de la recherche, Rapport d'enquête*, 2007.

multicentre trials, 5 working days or less⁴), of the REB’s decision following a review for ethics approval of new research;

- 5.1.2 The REB will notify the Researcher and his/her research staff, in writing and within a reasonable time frame, of the REB’s decision regarding an application for modifications to approved research, application for continuing review, or reportable events⁵;
- 5.1.3 The document specifying the REB decision will be sent to the Researcher(s)⁶ as an official document on the Nagano web-based platform;
- 5.1.4 All communications regarding a research project will take place on the Nagano platform. In the rare instances where communication takes place outside Nagano (e.g. conflict of interest declarations, if any), the Researcher will be asked to include the REB number or equivalent designation assigned to the research in all subsequent correspondence with the REB. All communications outside Nagano will be uploaded to Nagano, using appropriate security measures to ensure confidentiality, if any;
- 5.1.5 Upon receipt of the Researcher’s response to the REB decision document, the REB will follow-up with the Researcher and/or his/her staff to request any additional clarifications as needed;
- 5.1.6 Once all the REB conditions are satisfied, the REB will issue an approval document,⁷ together with any other attestation required from the REB (e.g. Research Ethics Board Attestation (REBA), Federal Wide Assurance (FWA) number, Cancer Trials Support Unit (CTSU) document, etc.).

6 REFERENCES

See footnotes.

7 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
REB-SOP 409.001	2020-03-20	Original version

8 APPENDICES

⁴ *Ministère de la Santé et des Services sociaux, Cadre de référence pour l’examen éthique des projets de recherche multicentrique*, April 2016.

⁵ TDR, s. 6 and 8; TCPS2, art. 6.13; ICH Harmonised Tripartite Guideline – Guidelines for Good Clinical Practice E6(R1), Health Canada, 1997, hereafter “ICH GCP”, s. 11.4.

⁶ *Modèle*, s. 11.4.2.

⁷ *Modèle*, s. 11.4.