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| **Title** | Communication of REB Decisions |
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| **N2/CAREB SOP CODE** | SOP 601-003 |
| **Effective Date** | YYYY-MM-DD |

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**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

# Purpose

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

# Scope

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

# Responsibilities

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

# Definitions

See Glossary of Terms.

# 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 are informed, in writing, of all decisions made by the REB regarding specific research.[[1]](#footnote-1)

Feedback from Researchers is encouraged and is 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 follows standardized notification and documentation procedures.

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

## Notification of REB Decisions

### The REB notifies the Researcher and his/her research staff, in writing and within a reasonable time frame (except under special circumstances, 15 working days or less[[2]](#footnote-2) or, in the case of multicentre trials, 5 working days or less[[3]](#footnote-3)), of the REB’s decision following a review for ethics approval of new research;

### 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 events[[4]](#footnote-4);

### The document outlining the REB decision (official document in Nagano) is sent to the Researcher(s);

### All communications regarding a research project 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 is asked to include the REB number or equivalent designation assigned to the research in all subsequent correspondence with the REB. All communications outside Nagano are uploaded to Nagano, using appropriate security measures to ensure confidentiality, if any;

### Upon receipt of the Researcher’s response to the REB decision document, the REB follows up with the Researcher and/or his/her staff to request any additional clarifications as needed;

### Once all the REB conditions are satisfied, the REB issues an approval document, together with any other attestation required from the REB (REBA, FWA, CTSU, etc.).

# References

See footnotes.

# Revision History

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| **SOP Code** | **Effective Date** | **Summary of Changes** |
| REB-SOP 409-001 | 2019-04-01 | Original version |
| REB-SOP 601-002 | YYYY-MM-DD | Updated in line with regulations in effectUpdated references |
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# Appendices

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 2018, hereafter “TCPS2”, art. 6.13. [↑](#footnote-ref-1)
2. Within two weeks’ time of the meeting at which the decision was made: TDR, s. 8. [↑](#footnote-ref-2)
3. *Ministère de la Santé et des Services sociaux, Cadre de référence pour l’examen éthique des projets de recherche multicentrique*, April 2016, art. 8.5. [↑](#footnote-ref-3)
4. TDR, s. 6 and 8; TCPS2, art. 6.13; Guidance Document: Good Clinical Practice: Integrated Addendum to E6(R1) ICH Topic E6(R2), Health Canada, April 2019, s. 3.1.2. [↑](#footnote-ref-4)