IWK Research Ethics
Standard Operating Procedures

Document # **RE 4.404**	Title: **Protocol Amendments, Notifications, and Ongoing Communications**	Effective Date: **November 19, 2024**
Pages**: 3**	Responsibility of: **Research Ethics Board**	Date Approved: **November 19, 2024**

POLICY STATEMENT

Proposed modifications to already-approved research must be submitted to the REB for additional approval. Changes in associated supporting documents (notifications and other communications) must also be communicated to the Board for their information and attention.

Modifications to research protocols or approved documents must not be adopted until REB approval has been obtained.

If urgent protocol changes are necessary to eliminate immediate hazards, the Investigator must notify the Chair immediately and provide justification.

DEFINITIONS

See Glossary of Terms

RESPONSIBILITY

This SOP applies to Investigators, REB Chair, REO Manager, REB members, and Research Ethics Office (REO) staff.

PROCEDURES

Investigators must notify REO promptly of any new information relating to the approved research by submitting the information directly or by using the IWK *Amendment Request Event on the ROMEO Researcher Portal*.

Changes in research staff (e.g. addition of co-investigators, change in research assistants, new investigator covering the principal investigator (PI) during temporary absence, etc.) must be reported using the *IWK Study Personnel Change Notification Event*.

Other study related updates, such as letters/notifications from the study team, sponsor, etc. that require an acknowledgement that the REB has received specific information must be reported using the *IWK Acknowledgement Request Event.*

The Chair will initially assess the submission to determine the appropriate level of REB review required; in many cases where proposed changes are minor or unrelated to participant safety a delegated review will suffice; where more major changes are contemplated, a full board review may be required The results of such review will be conveyed to Investigators in a timely manner.

Documentation and Communication

All REB review activities will be documented and recorded according to the processes described in: Documentation and Document Management REB SOP 3.303.

Note: US regulations will be applied as applicable.

REFERENCES

1. Tri-Council Policy Statement: Ethical conduct for Research Involving Humans, 2018:
(short name: TCPS 2), Chapter 1 Section C; Chapter 2 Section B;
2. The International Conference on Harmonization Good Clinical Practices, Sections 3, 4.4, 4.5, 4.10, 4.11, 4.12;
3. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.109, 46.111, 46.113, 46.115;
4. OHRP Guidance on Continuing Review;
5. US Food and Drug Administration (FDA) CFR Title 21 Part 56.108, 56.109, 56.110, 56.111, 56.115;

Forms/Records:

Form #	Form/Record Name
SOP 404	Protocol Amendments, Notifications, and Ongoing Communications: Submission and Review Procedures

Revision History:

Revision	Date	Description of changes
0.0	April 1, 2017	Initial Release
1.0	September 8, 2022	Additions to comply with TCPS2-2018
1.1	February 1, 2023	Updated logo
1.2	November 19, 2024	Added note regarding compliance with US regulations where applicable