IWK Research Ethics
Standard Operating Procedures

Document # **RE 6.601**	Title: **REB and research office communications to researchers**	Effective Date: **November 19, 2024**
Pages**: 3**	Responsibility of: **Research & Innovation Advancement**	Date Approved: **November 19, 2024**

POLICY

All investigators participating in IWK REB approved research shall be informed, in writing, of all determinations made by the IWK REB for the protocol.

DEFINITIONS

See Glossary of Terms

RESPONSIBLITY

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

PROCEDURES

Investigator Notifications

Initial Submission/Amendment(s)/Study Renewal: Investigators will be notified via an email of the REB's decision as soon as possible after the meeting. Notification may include the REB Review Summary, notification of approval or rejection.

REB Review Summary: Provides specific detail of required clarification, or revisions, once incorporated into the study documentation and procedures, would allow the REB to proceed with finalizing REB review and approval. Written response to the REB review must be provided to the REO and will be circulated for final assessment to the assigned reviewer(s) or the REB Chair (or delegate).

Notification of REB Approval: Investigators will be notified of the REB's decision by the mailed original copy of the Letter of Approval. If the REB approves the study, included in the Letter of Approval letter is the study title, REB study assigned number and name of the Principal Investigator. The document titles, version dates listed in the Letter of Approval correspond to the submitted research documents.

If the REB Rejects the Study: The Principal Investigator will be notified regarding the reasons for rejecting the study. These reasons are listed as part of the Correspondence. For a clinical trial, the Investigator will be reminded that Health Canada must be notified by the Sponsor of the REB's disapproval.

Investigator Appeal of REB Action: An investigator may appeal a rejection by the REB. Requests for appeal are conducted in accordance with the IWK REB Policy: Appeals Process REB SOP 4.411 and meet the requirements set out within TCPS2 Article 6.19.

Non-compliance: Investigator non-compliance may be the result of communication difficulties. Therefore the REB will attempt to resolve apparent instances of non-compliance without interrupting the conduct of the study, especially if the rights and welfare of participants may be jeopardized.

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), 4.2; 6.19
2. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103, 46.109, 46.115

Forms/Records:

Form #	Form/Record Name
SOP 601	REB and research office communications to researchers

Revision History:

Revision	Date	Description of changes
0.0	April 1, 2017	Initial Release
1.0	September 9, 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 & update to responsibility (RIA)