IWK Research Ethics
Standard Operating Procedures

Document # **RE 4.410**	Title: **Study Completion**	Effective Date: **November 19, 2024**
Pages**: 3**	Responsibility of: **Research Ethics Board**	Date Approved: **November 19, 2024**

POLICY STATEMENT

A study is considered completed when there is no longer any contact between the investigator and participants, and no more data is being collected from the participants. The completion or termination of the study must be reported to the REB.

DEFINITIONS

See Glossary of Terms

RESPONSIBILITY

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

PROCEDURES

Determining When a Research Study Can be Closed

Studies may be considered completed and an *IWK Study Closure* event should be submitted as follows:

- For studies that involve direct human participation, no further participant contact is contemplated and all data collection procedures in the approved protocol have been completed
- For studies that do not involve direct human participation (i.e., secondary use of data), the acquisition of data is complete (i.e. no new cases are being added to the study dataset)
- For studies that analyze human tissue, no additional tissue samples are being withdrawn from or deposited to the tissue bank or being acquired from another research group
- For an industry sponsored study, the sponsor has completed their specific closure procedures

Study Completion Reports

- When a study is ready to be closed, the investigator should complete and submit the S*tudy Closure Reporting Form* to the REB
- If the research has been prematurely terminated for any reason, the investigator should promptly submit a *IWK Study Closure* event along with a *Premature Study Termination tab* to the REB., which will be reviewed by the Chair for possible other actions related to suspensions and terminations (see REB SOP 4.408)
- On receipt of a termination report, REO staff will perform an administrative review of the report and the files and may request any outstanding information, clarification or documentation from the investigator if needed. Once all outstanding issues have been addressed, the Chair will review the report indicating study closure with the REB. An acknowledgement of formal study closure by the Board will be sent to the Principle Investigator
- After completion of the above steps, REO staff will annotate the REB Study file appropriately and ensure its further management and retention in accordance with the procedures specified in REB SOP 3.303

Note: US regulations will be applied as applicable.

REFERENCES

1. The International Conference on Harmonization Good Clinical Practices, Section 4.13;
2. Tri-Council Policy Statement: Ethical conduct for Research Involving Humans, 2018:
(short name: TCPS 2), Article 6.14;
3. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103, 46.109;
4. US Food and Drug Administration (FDA) CFR Title 21 Part 56.108, 56.109;

Forms/Records:

Form #	Form/Record Name
SOP 410	Study Completion

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