TITLE	**406: Research Completion**
SCOPE	All health research submitted to the Health Research Ethics Board (HREB) operating under the direct authority of the Health Research Ethics Authority (HREA)
APPROVAL AUTHORITY	Ethics Director
EFFECTIVE DATE	April 2024

1.0 PURPOSE

This standard operating procedure (SOP) describes the procedures for the closure of research with the HREB.

2.0 DEFINITIONS

See the Glossary of Terms.

3.0 RESPONSIBILITIES

All HREB members and Research Ethics Office (REO) Personnel are responsible for ensuring that the requirements of this SOP are met.

The HREB Chairperson or designee is responsible for determining if any of the submitted materials should be reviewed by the Full Board.

4.0 PROCEDURE

Completion of research is a change in activity and must be reported to the HREB. A final report allows the HREB to close its files and it provides information that may be used in the evaluation and approval of related studies.

4.1 Determining when Research may be Closed

4.1.1 The Researcher will submit a research closure report to the HREB when there is no further participant involvement at the site, all new data collection is complete and, if applicable, the sponsor closeout activities have been completed.

4.1.2 The responsible REO Personnel will review the research closure application and request any outstanding information, clarification or documentation from the Researcher, if needed.

4.1.3 The HREB Chairperson or designee will review the submission and issue a letter of Acknowledgement to the Researcher. The research state will change to "Closed".

4.1.4 Once a research project is "Closed" with the HREB, no further submissions for that research will be permitted; however, if required, the Researcher may submit relevant documents for acknowledgement and, if applicable, further investigation and/or action may be undertaken by the HREB.

4.1.5 If a study sponsor requests additional data following the closure of the research, a request for approval shall be made to the HREB and the conditions of this request will be determined at the time of the review.

4.1.6 **U.S. Federally Funded Research:** Studies that are funded or supported by the U.S. Federal Government are considered open and subject to annual review until a research project no longer involves human subjects, as defined by the Office of Human Research Protections (OHRP). OHRP only considers a research project to no longer involve human subjects when investigators have finished obtaining data through interaction or intervention with subjects or obtaining identifiable private information about the subjects which includes using, studying, or analyzing identifiable private information (including identifiable tissue).

5.0 REFERENCES

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Chapter 6: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2022) (ethics.gc.ca)

International Conference on Harmonization – Good Clinical Practice (ICH-GCP 4.13): ICH GCP - 4. INVESTIGATOR - ICH GCP

Office for Human Research Protections, Continuing Review Guidance: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-continuing-review-2010/index.html

Health Research Ethics Authority Act: An act to establish a health research ethics authority for the province. (2011). Retrieved from: SNL2006 CHAPTER H-1.2 - HEALTH RESEARCH ETHICS AUTHORITY ACT (assembly.nl.ca)