Humber River Health
Study Completion or Termination Research Ethics Board Guidelines

Title:	**Study Completion or Termination**
Original Issue Date:	November 30, 2023
Revised:	
Approved By:	REB Chair

1.0 PURPOSE

The purpose of this guideline is to describe the process to report the closure of a research project and the required notification of the REB.

2.0 POLICY STATEMENT

The completion or termination of the study must be reported to the REB. Although participants will no longer be "at risk" under the study, a final report/notice to the REB allows it to close its files as well as providing information that may be used by the REB in the evaluation and approval of related studies.

3.0 PROCEDURES

3.1 Determining When a Study can be Closed

Once a study is considered completed, an Annual Renewal/Termination Report Form should normally be submitted to the REB within 90 days. The following guidance may be used to determine when a study can be closed:

- Studies that involve direct human participation are complete when no further participant contact is required and all data collection procedures and analyses have been completed as per the approved protocol.
- Studies that do not involve direct human participation (i.e., secondary use of data) will be complete when the acquisition of data is complete (i.e., no new cases are being added to the study dataset) and the data analyses have been completed as per the approved protocol.
- Studies that analyze human tissue will be considered completed when no additional tissue samples are being harvested or being deposited to the tissue bank, and the analysis is completed as per the approved protocol. The REB will be provided with details for end of study handling and destruction.
- For others such as samples being acquired from another research group the terms of the contract and protocol will be adhered to as reported to the REB.
- For industry sponsored studies a copy of the official "close-out letter" will be sent to the REB together with applicable details that address the above.

3.2 US Federally Funded Research

Studies that are funded or supported by the US Federal Government are considered open and participants to annual review requirements even where (i) the research is permanently closed to the enrollment of new participants; and (ii) all participants have completed all research-related interventions. Such studies may not be considered completed until all follow up of participants is final.

3.3 Completion Reports

Final reports (or in its place relevant published or unpublished manuscripts and conference papers) must be submitted with the 'Annual Renewal/Termination Report Form'. The REB Chair (or designate) will review all reports of study completion and, if needed, request further information from the investigator to clarify any questions that may arise.

The final report will contain, but not limited to, the following:

- The Local Principal Investigator's affirmation that participant enrollment is closed and data analysis as per the approved protocol is completed;
- Reason for study termination/closure;
- Number of participants enrolled at Humber River Hospital;
- Number of participants who completed the study;
- Number of participants who dropped out or were withdrawn;
- The number of serious and unexpected adverse events;
- A summary of the results and/or any publication that arose from the study.

3.4 Termination

Once the final report and the Study Closure Form have been reviewed by the REB, the REB will issue an Acknowledgement and the study will automatically be listed as "Closed".

4.0 REFERENCES

1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2022 (TCPS2), Article 2.8 and 6.12.

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.

6. FDA Information Sheets: FAQ Section IV.