RR0600 – RESEARCH COMPLETION

1.0 PURPOSE

To provide direction for the closure of research projects reviewed and approved by the Interior Health (IH) Research Ethics Board (REB).

2.0 DEFINITIONS

3.0 POLICY

3.1 The completion of a project is a change in activity that must be reported to the REB. Although research participants will no longer be at risk under the research, a final report allows the REB to close its file in addition to providing the REB with information that may be used in the evaluation and approval of related projects.

3.2 A project may be considered complete and a REB Closure Report submitted when:

3.2.1 For projects that involve direct human participation, where no further participant contact is contemplated and all data collection procedures as per the approved protocol have been completed;

3.2.2 For projects that do not involve direct human participation (i.e. secondary use of data), where the data collection is complete and no further analysis of individually identifiable data is required;

3.2.3 For projects that analyze human tissue, where no additional tissue samples are being withdrawn from or deposited to the tissue bank or being acquired from another research group;

3.2.4 For sponsored research, where the site has received an official close out letter from the sponsor.

3.2.5 Renewal of ethical approval is not required to analyze data or write a manuscript, other than as noted in section 3.3. If the above conditions are met, the project may be closed with the REB.

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

3.4 Once a research project is 'Closed' with the REB, no further submissions for that research will be permitted; however, if required, the researcher may submit relevant documents for acknowledgment and if, applicable, further investigation and/or action may be undertaken by the REB.

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

4.0 PROCEDURES

4.1 Researcher

4.1.1 Submit a Closure PAA via RISe for studies housed on the RISe platform; or send a completed IH REB Closure Report Form to the REB via email if the study is not housed on RISe. By completing the Closure PAA or IH REB Closure Report Form, the researcher affirms that participant data collection is complete and there will be no further direct or indirect contact with participants.

4.1.2 Confirm that storage of research records adheres to IH policies and/or policies of their primary institution regarding data security. At a minimum, IH researchers will store records on the secure IH server in a limited-access folder for five years post-completion. External researchers will store data for at least the minimum amount of time required by their institution.

4.2 Research Ethics Board Coordinator

4.2.1 Receives the Closure Report from the researcher. Requests any outstanding information, clarification or documentation from the researcher, if needed.

4.2.2 Sends a notification of Acknowledgment to the researcher that the research project is 'Closed' with the REB.

4.2.3 For studies not housed in RISe, adds the closure report and related documents to the project file.

4.2.4 Updates the Closures Tracking tool and uses the tool to generate a Closures Report for the REB at the next scheduled meeting.

4.2.5 Documents project closures in the REB's Master Study list and archives project files.

5.0 REFERENCES

Canadian Association of Research Ethics Boards and N2 Network of Networks. (2019). Standard Operating Procedure 406.003: *Research Completion.*

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, December 2018.

Office of Human Research Protections. (2010). *Guidance on IRB Continuing Review of Research.*

UBC Office of Research Ethics. (2018). Standard Operating Procedure 406: *Research Completion*.

UBC Office of Research Ethics. Guidance Note: *Notification of Study Closure.* Retrieved from https://ethics.research.ubc.ca/clinical-research-ethics/creb-guidance-notes/post-approval-guidance-notes

US Department of Health and Human Services, Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects (45CFR46).

US Food and Drug Administration Code of Federal Regulations, Title 21, Volume 1:

- Part 50, Protection of Human Subjects, (21CFR50).
- Part 56, Institutional Review Boards, (21CFR56).

**This policy replaces the following policy:
IH REB Policy: *RE0700 Closures and Terminations* approved February 27, 2008