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RR0600 – RESEARCH COMPLETION

1.0 PURPOSE

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

2.0 DEFINITIONS

TERM	DEFINITION
Closure	A study is eligible for closure with the REB when there is a no further participant involvement at the site, all new data collection is complete, and the sponsor closeout activities, if applicable, have been completed. If the study is funded or regulated by the US Federal Government it cannot be considered closed until all follow up of participants is final and there is no further data analysis involving individually identifiable information.

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:

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3.2.3 For projects that analyze human tissue, where no additional tissue samples are being withdrawn from or deposited to the tissue bank or being acquired from another research group;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 industry sponsored research where the site has received an official close-out letter from the sponsor.

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

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have finished obtaining data through interaction or intervention with participants or obtaining identifiable private information about the participants which includes the 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 The researcher will submit a Closure Report when there is no further participant involvement at the site, all new data collection is complete, and the sponsor closeout activities, if applicable have been completed.

4.1.2 The researcher must affirm that there will be no further direct or indirect contact with participants for the purpose of data collection. This may be prior to publication or presentation of results.

4.2 Research Ethics Office

1. Receives the Closure Report from the researcher.
2. Requests any outstanding information, clarification or documentation from the researcher, if needed.
3. Sends a notification of Acknowledgment to the researcher that the research project is 'Closed' with the REB.
4. Adds the closure report and related documents to the project file.
5. Updates the Closures Tracking tool on all closure activities and uses the tool to generate a Closures Report for the REB at the next scheduled meeting.
6. Documents project closures and archives project files one year post closure.

5.0 REFERENCES

- Canadian Association of Research Ethics Boards and N2 Network of Networks. (2016). Standard Operating Procedure 406.0012: *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 2014.

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- Island Health Authority. (2013). Research Ethics Standard Operating Procedure 510: *Study Completion,* version 1.
- Office of Human Research Protections. (2010). *Guidance on IRB Continuing Review of Research.*
- UBC Office of Research Ethics. (2013). Standard Operating Procedure 407: *Study Completion*.
- UBC Office of Research Ethics. (2012). Guidance Note: *Notification of Study Closure.*
- 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 which is no longer active:
IH REB Policy: *RE0700 Closures and Terminations* approved February 27, 2008