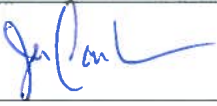




Section 400:	Review of Research
Title:	Research Completion
SOP Code:	406.001
Effective Date:	2015MAY25

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		2015 MAY 22
	Name: Jennifer Couture	
Approval Authority:		
Chair, HSREB		May 22, 2015
	Name: Dr. Albert Clark	
Approval Authority:		
Director, Research Ethics Compliance		May 22, 2015
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP describes the procedures for the closure of research with the HSREB.

2.0 SCOPE

This SOP pertains to the HSREB that reviews human participant research in compliance with applicable regulations, guidelines and current and emerging best practices.

3.0 RESPONSIBILITIES

All HSREB members and HSREB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

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

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

The Completion of research is a change in activity that must be reported to the HSREB. Although research participants will no longer be at risk under the research, a final report allows the HSREB to close its files in addition to providing the HSREB with information that may be used in the evaluation and ethical clearance of related studies.

5.1 Determining when Research can be Closed

- 5.1.1 The Researcher may submit a Renewal Form using ROMEO/TRAQ to 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;
- 5.1.2 THE HSREB recommends that all studies remain open until a manuscript has been accepted for publication (if applicable) in the event that further follow up with respect to data collection is required;
- 5.1.3 The HSREB Ethics Coordinator or designee will review the research Renewal Form and request any outstanding information, clarification or documentation from the Researcher, if needed;
- 5.1.4 The HSREB Chair or designee will review the submission and issue a letter of Acknowledgement (if applicable) to the Researcher. The research state will change to "Closed";
- 5.1.5 Once a research project is "Closed" with the HSREB, no further submissions for that research will be permitted; however, if required, the Researcher still may submit relevant documents for acknowledgement and, if applicable, further investigation and/or action may be undertaken by the HSREB;
- 5.1.6 If the sponsor requests additional data following the closure of the research, a request to re-open the research file shall be made to the HSREB and the conditions of this request will be determined at the time of the review; however; the HSREB recommends that the studies remain open until publication.

6.0 REFERENCES

See References.

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
Research Completion	v.406.001 2015MAY25	Original: Adoption of standardized SOPs developed by CAREB/N2 with an effective date of 2014SEP15. Minor modifications were made to the CAREB/N2 SOPs to reflect institutional policies.

