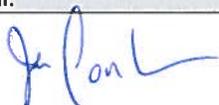


Section 400:	Review of Research
Title:	Delegated Review
SOP Code:	401.001
Effective Date:	2015MAY25

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		2015MAY22 Date
	Name: Jennifer Couture	
Approval Authority:		
Chair, HSREB		May 22, 2015 Date
	Name: Dr. Albert Clark	
Approval Authority:		
Director, Research Ethics Compliance		May 22, 2015 Date
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This standard operating procedure (SOP) describes the processes for determining when research meets the criteria for delegated ethics review and the associated delegated review procedures.

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 research is eligible for delegated review. In some circumstances, the HSREB Chair or designee may delegate this task to qualified HSREB Office Personnel; however, the responsibility for oversight remains with the HSREB Chair or designee.

The HSREB Chair or designee or qualified HSREB member(s) is responsible for conducting the delegated review.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

The HSREB has adopted a proportionate approach to ethics assessment based on the general principle that the more invasive or harmful the proposed and ongoing research, the greater should be the care in assessing the research. Full Board review by the HSREB should be the default requirement for all research involving human participants unless the HSREB decides to authorize delegated review based primarily on the harms that are expected to arise from the research. While all research must be reviewed adequately, requirements for proportionate review allow the HSREB to provide a higher level of scrutiny, and correspondingly more protection, for the most ethically challenging research.

In practice, the proportionate review implies different levels of HSREB review for different research projects. The two levels used by the HSREB are Full Board review or delegated review by one or more experienced HSREB members, as determined by the HSREB Chair or designee.

5.1 Determination of Qualification for Delegated Review

5.1.1 Full Board review is the default for new research projects submitted to the HSREB; however, some research may be eligible for delegated review;

- Submissions that meet the following criteria may be eligible for delegated review:
 - Research projects that involve no more than minimal risk,
 - Minor or minimal risk changes to ethically cleared research,
 - Renewals of ethically cleared minimal risk research,
 - Renewals of research that is more than minimal risk for which enrolment is closed permanently and all research-related interventions for all participants are complete and the only remaining research activities are post-intervention activities or follow-up of participants; or, where the remaining research activities are limited to data analysis; or, where no participants have been enrolled and no additional risks have been identified,

- Renewals of research that is more than minimal risk when there has been little or no modification of the research; and when there has been no increase in risk to or other ethical implications for participants since the initial Full Board review by the HSREB; if permissible under all applicable governing Regulations,
- The submission by the Researcher in response to the HSREB review as a condition of ethics clearance, as authorized by the HSREB,
- Changes to consent documents that do not affect the rights and welfare of research participants or involve increased risk, or affect data integrity, or require significant changes in research procedures,
- Reportable events, including adverse events and safety updates such as reports from Data and Safety Monitoring Boards (DSMB);

5.1.2 The HSREB Chair or designee may use delegated review procedures for the review of other types of minor changes including, but not limited to, the following:

- Participant materials such as: recruitment posters or scripts, diaries, validated questionnaires, clinical trial identification/wallet cards,
- Authorized translations of English versions of documents previously-ethically cleared by the HSREB;

5.1.3 The HSREB Chair or designee may be authorized by the Full Board to use delegated review procedures for the review of miscellaneous items such as changes to meeting minutes that previously received approval with conditions at a Full Board meeting;

5.1.4 When determining if initial review of research or modifications to previously ethically cleared research are eligible for delegated review, the HSREB Chair or designee will take into consideration the methods used to conduct the research, recruitment practices, participant population, rights, safety and well-being of research participants, confidentiality of data, and all regulatory and ethics guidance requirements as applicable.

5.2 Delegated Review Process

5.2.1 The HSREB Ethics Coordinator or qualified designee will perform an initial screening of the submission. Those submissions that meet a pre-defined set of criteria for delegated review as determined by the HSREB may be forwarded for delegated review. For all other submissions, the HSREB Chair or designee will make the determination of whether the submission meets the criteria for delegated review;

- 5.2.2 For research that meets the criteria, delegated review may be conducted by the HSREB Chair, or by one or more qualified HSREB members as designated by the HSREB Chair or designee;
- 5.2.3 The HSREB Chair or designee shall ensure the reviewers assigned delegated reviews have the experience and expertise required;
- 5.2.4 The HSREB Chair or designee reviewing research under delegated review must not have a conflict of interest in the research;
- 5.2.5 In reviewing the research under delegated procedures, the HSREB Chair or designee may exercise all of the authorities of the HSREB, except that he/she may not deny ethics clearance for the research; the research may not be granted ethics clearance only after it has been reviewed by the HSREB at a Full Board meeting;
- 5.2.6 HSREB member(s) conducting a delegated review will contact the HSREB Chair or designee to request the expertise of an ad hoc advisor, if applicable. Ad hoc advisors may not participate in the final decision regarding ethics clearance of the research;
- 5.2.7 If the HSREB Chair or designee subsequently determines that the level of risk for the submission is greater than minimal, the submission will be referred to a Full Board meeting for review;
- 5.2.8 The HSREB Chair or designee will record the decision regarding the designation of the research (i.e., either requiring Full Board or delegated review) and the outcome of the review. The Ethics Coordinator or designee may issue the review or decision letter.

5.3 Notification of the HSREB

- 5.3.1 At its next Full Board meeting the HSREB will be informed of research that was reviewed and ethically cleared using delegated review procedures.

5.4 Documentation

- 5.4.1 The type of HSREB review conducted (i.e., Full Board or delegated) is documented in the HSREB records and noted in the decision letter issued to the Researcher, where appropriate;
- 5.4.2 The HSREB meeting agendas and minutes will include a list of submissions that were reviewed and ethically cleared using delegated review procedures from the time that the agenda for the previous HSREB meeting was issued.

6.0 REFERENCES

See References.

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
Delegated Review	v.401.001 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.

