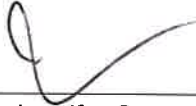




Section 400:	Review of Research
Title:	HSREB Review Decisions
SOP Code:	402.002
Effective Date:	2019APR24

Site Approvals

Signature of Responsible Individual:		
Manager, Research Ethics Compliance		Date 2019APR24
	Name: Jennifer Couture	
Approval Authority:		
Chair, HSREB		Date 2019 APR 24
	Name: Dr. Albert Clark	
Approval Authority:		
Director, Research Ethics Compliance		Date 2019 APR 24
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP describes the decisions that the HSREB may make resulting from its review of proposed research for ethical acceptability.

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 ensuring that a decision is made for every submission that is reviewed by the HSREB, that the decision is clearly understood, and that the delegation of responsibility for considering any further information prior to issuing ethics clearance is agreed.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

As a result of its review, the HSREB has the authority to grant ethics clearance, require modifications/clarifications to submitted research or not grant ethics clearance. If there are questions that must be addressed prior to a determination, the HSREB may defer its decision. When the Full Board review procedure is used, decisions will be made by consensus or a majority vote of the HSREB members who are present at a Full Board meeting at which there is a quorum (See SOP 302 HSREB Meeting Administration for the definition of a quorum).

HSREB members with a conflict of interest in the research under review must not participate in the deliberations or in the vote of the HSREB, in accordance with the HSREB and Queen's University and/or Affiliated Teaching Hospital(s) conflict of interest policies (See SOPs 105A-C).

When the delegated review procedure is used, the HSREB Chair and/or HSREB member(s) who are assigned to the review can decide to ethically clear the research or to request revisions to the research; the decision to not grant ethics clearance of the research must be made by the Full Board.

Researchers have the right to request reconsideration of HSREB decisions and to appeal the decision of the HSREB.

If discrepancies exist among good clinical practices, statutory or regulatory requirements or ethical considerations, the HSREB shall document the rationale for its decisions that attempt to strike a balance between the compliance with applicable regulatory and ethical requirements for ensuring the protection of the rights, safety and well-being of research participants.

5.1 HSREB Decisions

5.1.1 HSREB decisions are made either by consensus or a majority vote of the HSREB members present at a Full Board meeting, with a quorum, with the exception of those who have recused themselves in accordance with the conflict of interest policies;

5.1.2 The HSREB should reach one of the following decisions as a result of its review of research submitted for initial review or for renewal of ethics clearance:

- **Ethics Clearance** (ethically clear the application as submitted, including the consent form):
 - When an acceptable risk/benefit ratio exists and the regulatory criteria required for ethics clearance are

satisfied, the research may be ethically cleared as submitted,

- The ethics clearance date is defined on the ethics clearance letter issued to the researcher,
- The expiry date of the HSREB ethics clearance is calculated from this date,
- A list of all documents and any items ethically cleared for use and distribution are included in the ethics clearance letter,
- A statement that any changes to protocol, consent, etc., must be submitted as an amendment.

- **Ethics Clearance with Modifications/Clarifications:**

- When an acceptable risk/benefit ratio exists, and the regulatory criteria required for ethics clearance are satisfied, but the HSREB members require modification to any aspect of the application or clarification or further information to secure ethical clearance, the HSREB may recommend “Ethics Clearance with Modifications/Clarifications”,
- When the HSREB recommends “Ethics Clearance with Modifications/Clarifications”, the HSREB Chair or designee should ensure that the additional information, modifications, or clarifications required are identified at the HSREB meeting and that the procedures for reviewing the additional information and issuing the ethics clearance are well-defined. The responsibilities for additional review and the decision regarding ethics clearance conditions should be delegated to one of the following:
 - The HSREB Chair alone,
 - The HSREB Chair and one or more named HSREB members that were present at the HSREB meeting or who submitted written comments on the application,
 - A sub-group of the HSREB members designated by the HSREB Chair or designee or by the HSREB,
 - Designated HSREB member(s) with sufficient knowledge and experience regarding the research and the regulations,
- In deciding the procedures to be followed, the HSREB should consider the significance of the requested additional information or modifications and the expertise necessary to assess it. Where the information or

modifications are straightforward, it is acceptable to delegate the consideration of that material to the HSREB Chair or designee alone,

- Where the additional information/modification is technical (e.g., statistical clarifications), the HSREB Chair or designee should review the information with consideration given to involving other HSREB members, such as the lead reviewer(s) or relevant expert member(s),
 - If the Researcher's response is deemed complete and satisfactory, ethics clearance can be issued,
 - If the Researcher's response is incomplete and does not fully address the matters raised, requests for further information, modifications or clarification should be sent to the Researcher,
 - The reviewers may decide upon reviewing the Researcher's response that the decision should be deferred and that the application and the Researcher's response materials should be reviewed at a subsequent Full Board meeting (see 'Deferral' process below),
 - The ethics clearance date is defined on the ethics clearance letter issued to the researcher,
 - The expiry date of the HSREB ethics clearance is calculated from this date.
- **Deferral** (defer decision-making on the application and continue the deliberation of the application at a future Full Board meeting):
 - The HSREB will defer its decision to a subsequent Full Board meeting when significant questions are raised during its review of the research and/or when the criteria required for ethics clearance have not been met,
 - The HSREB Chair or designee should ensure that all additional information, modifications or clarifications that are required are specifically identified at the Full Board meeting,
 - The research and the Researcher's response materials shall be reviewed at a Full Board meeting,
 - Upon consideration of the research along with the response from the Researcher, at the Full Board meeting, the HSREB should issue its final decision (ethics clearance, ethics clearance with modifications, deferral or ethics clearance not granted),

- Researcher responses must be received and reviewed at a Full Board meeting,
 - The ethics clearance date is defined on the ethics clearance letter issued to the researcher,
 - The expiry date of the HSREB ethics clearance is calculated from this date.
- **Ethics Clearance not granted:**
 - The HSREB may not grant ethics clearance of the research when it fails to meet the ethical standards for clearance and where revision is unlikely to enable the HSREB to reach a positive determination,
 - Denial of ethics clearance cannot be decided through the delegated review mechanism. If the recommendation under delegated review is to not grant ethics clearance for the research, a final decision must be made by the HSREB at a Full Board meeting,
 - The HSREB Chair or designee should ensure that the reasons for not granting ethics clearance are documented in the Full Board meeting minutes for communication to the Researcher,
 - If the research is not granted ethical clearance, the reasons will be communicated to the Researcher in writing and the Researcher will be given an opportunity to respond in person or in writing.

5.1.3 Delegated Reviews

- When the research qualifies for delegated review, the reviewer(s) has the authority to ethically clear the application, to require modifications to any aspect of the application, or to request clarification or further information before considering it eligible for ethics clearance. The reviewer(s) may also refer the applications as submitted for a review at a Full Board meeting,
- When delegated review procedures are followed, the ethics clearance date is defined on the ethics clearance letter issued to the researcher,
- The expiry date of the HSREB ethics clearance is calculated from this date;
- If the research cannot be ethically cleared through the delegated review mechanism, it must be reviewed at a Full Board meeting.

5.2 Reconsideration and Appeal of HSREB Decisions

5.2.1 A Researcher may appeal the decision of the HSREB if the disagreement between the Researcher/applicant and the HSREB cannot be resolved

through a reconsideration process at a Full Board meeting at which the Researcher/ applicant shall have the right to be heard;

- 5.2.2 The Researcher must justify the grounds on which a reconsideration of the decision is requested. An appeal may be launched for procedural or substantive reasons, and a final decision after reconsideration must be issued by the HSREB prior to the initiation of an appeal process;
- 5.2.3 Appeals are conducted in accordance with the established HSREB and Queen's University and Affiliated Teaching Hospital(s) policy(s). The organization at which the appeal will take place will be determined on a case-by-case basis by the HSREB in consultation with the Researcher (and the affiliated organization);
- 5.2.4 The appeal committee shall have the authority to review negative decisions made by the HSREB and in so doing it may grant ethics clearance, request modifications to the research proposal or not grant ethics clearance. Its decision shall be final and shall be communicated to the Researcher and the HSREB in writing.

5.3 Documenting HSREB Decisions

- 5.3.1 The HSREB meetings minutes will satisfy the applicable requirements;
- 5.3.2 The HSREB shall notify the Researcher in writing of its decision to grant ethics clearance, require modifications/clarifications to the proposed research or not grant ethics clearance;
- 5.3.3 The HSREB documentation will include the application number, if the research received Full Board or delegated review and if Full Board review, the date of the Full Board meeting, the decision of the HSREB, a list of all documents cleared for use, the ethics clearance date and expiry date, and a statement that HSREB was compliant with applicable guidelines and regulations;
- 5.3.4 Upon request, the HSREB can provide a detailed copy of the HSREB membership roster in effect on the date of Full Board meeting at which the research was reviewed, including each member's academic qualifications, affiliation(s), gender, citizenship and role on the HSREB. A copy of the general membership roster, which includes name and affiliation(s), is published on the Research Ethics website;
- 5.3.5 For Biomedical Clinical trials, the ethics clearance letter will include a statement that the protocol, informed consent form and conduct of study must not be altered unless ethical clearance has been granted by the HSREB, except in those situations where modification is required to eliminate immediate hazards to participants;
- 5.3.6 If the HSREB defers its decision, the letter to the Researcher should include the issues of concern and what further information is required;
- 5.3.7 The final ethics clearance letter should include standard conditions of ethics clearance to which the Researcher must adhere;

5.3.8 When the decision to grant ethics clearance for a submission is recorded on behalf of the Full Board, or when a delegated reviewer electronically signs off on a decision (under delegated review procedures), the notification or correspondence to the Researcher may be issued by the HSREB Ethics Coordinator or designee.

6.0 REFERENCES

See References.

7.0 APPENDICIES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
HSREB Review Decisions	v.402.001 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.
HSREB Review Decisions	v.402.002 2019APR24	<ol style="list-style-type: none"> 1. Section 5.1.2: Removed the stipulation that the HSREB Chair abstains from voting except to break a tie vote or to meet quorum requirements; 2. Section 5.1: Updated language concerning setting initial ethics clearance dates. 3. Section 5.2: Updated to gender neutral terminology. 4. Section 5.3: References to ROME0 removed as no longer relevant. 5. Section 5.3.5: Added specific reference to protocol and study conduct.

