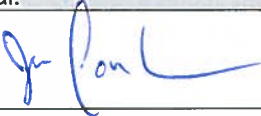




<b>Section 500:</b>	<b>Reviews Requiring Special Consideration</b>
<b>Title:</b>	<b>HSREB Review During Publicly Declared Emergencies</b>
<b>SOP Code:</b>	<b>501.001</b>
<b>Effective Date:</b>	<b>2015MAY25</b>

### 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 SOP describes the research ethics review procedures during a publicly declared emergency.

## 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.

## 4.0 DEFINITIONS

See Glossary of Terms.

## 5.0 PROCEDURES

A publicly declared emergency is an emergency situation that, due to the extraordinary risks it presents, has been proclaimed as such by an authorized public official in accordance with legislation and/or public policy. Publicly declared emergencies arise suddenly or unexpectedly and require urgent or quick responses. Examples include natural disasters, large communicable disease outbreaks, environmental disasters and humanitarian emergencies. Such emergencies may represent significant risks for research participants in ongoing research or in new research initiated as a result of the emergency. Special care should be given to request for exceptions, as potential research participants who may not normally be considered vulnerable may become so by the very nature of the public emergencies, while those already vulnerable may become acutely so.

During publicly declared emergencies, the HSREB follows established procedures to continue to provide the necessary research ethics oversight. Research ethics review during publicly declared emergencies may necessitate the use of innovative practices. Depending upon the nature of the emergency, for example, the HSREB might not be able to meet in person, and delegated review procedures may have to be designed to respond to either urgent opportunities for new research or to current ongoing research. The existence of an emergency does not override established procedures to protect the welfare of research participants. Any relaxation of the usual procedural requirements for review should be proportionate to the complexity and urgency of the emergency, as well as to the risks posed by the research under review. Any modifications that are made in the application of research ethics policies and procedures during a publicly declared emergency must be documented and appropriately justified, and should cease as soon as possible after the emergency ends.

## **5.1 Determining the Level of Impact**

- 5.1.1 Subsequent to an officially publicly declared emergency, the HSREB Chair or designee will assess the level of impact on the research ethics review processes;
- 5.1.2 There are three levels of impact that may influence how ethics review will be conducted during the publicly declared emergency:
  - Mild – little or no impact,
  - Moderate – some impact; decisions to proceed at the discretion of the Chair or designee, in consultation with the Researcher, as necessary,
  - Severe – extremely debilitating to normal research ethics review procedures decisions to proceed at the discretion of the Chair or designee;
- 5.1.3 The HSREB Chair or designee will use the level of impact to guide the review of research submissions during the publicly declared emergency;
- 5.1.4 Pending the determination of the level of impact on the review of ongoing or new research, the currently established ethics review procedures should be followed.

## **5.2 Emergency Preparedness Procedures**

- 5.2.1 Subsequent to an officially publicly declared emergency, temporary ethics review processes may be instituted;
- 5.2.2 When the impact on the ethics review processes is deemed to be severe, teleconferences or videoconferences may be used to conduct HSREB meetings;
- 5.2.3 When the impact on the ethics review processes is deemed to be severe, the HSREB Office Personnel may conduct their activities remotely if possible and practical;
- 5.2.4 The HSREB Chair or designee may suspend the currently established HSREB meeting quorum, in which case an HSREB subcommittee would be established for the duration of the publicly declared emergency;
- 5.2.5 The HSREB subcommittee composition should be in accordance with the standard HSREB membership requirements and should include at least five members drawn from the existing HSREB membership;
- 5.2.6 The current HSREB Chair or designee should serve as the Chair of the HSREB subcommittee;
- 5.2.7 At his/her discretion, the HSREB subcommittee Chair or designee may invite individuals with expertise in special areas to assist in the review of issues that require expertise beyond that available to the HSREB subcommittee; however, ad hoc advisors may not contribute directly to the subcommittee's decision and their presence shall not be used in establishing a quorum;
- 5.2.8 When the impact is deemed to be severe, the HSREB Chair or designee may refer the ethics review and research oversight of new and ongoing research to another REB (at or outside of their institution), subject to the applicable regulations and agreements;
- 5.2.9 Where research submissions are deemed to be more than minimal risk and subject to applicable regulations, the HSREB Chair or subcommittee Chair or designee will use his/her judgment in determining the type of review required (delegated or Full Board), taking into account the severity of the impact of the emergency and the complexity and urgency of the submission;
- 5.2.10 Any modifications that are made in the application of research ethics policies and procedures during a publicly declared emergency must be documented and appropriately justified;
- 5.2.11 The HSREB Chair or designee should periodically assess the impact of the emergency on the ethics review processes and adjust any temporary ethics review processes accordingly;
- 5.2.12 Any modifications that are made in the application of research ethics policies and procedures during a publicly declared

emergency will cease as soon as is feasible after the emergency has officially ended (i.e., as declared by an authorized public official). The HSREB Chair or designee will determine when to resume routine ethics review processes;

5.2.13 All delegated ethical clearances of research following a publicly declared emergency must be assessed to determine if subsequent Full Board review is required at the first opportunity subsequent to the cessation of the publicly declared emergency;

5.2.14 At the conclusion of the publically declared emergency, the HSREB Chair or designee and the HSREB Office Personnel should work with the HSREB subcommittee members to evaluate the effectiveness of its declared emergency procedures and to make recommendations for improvements.

5.3 **Review of Ongoing Research NOT Related to or Arising from the Publicly Declared Emergency**

5.3.1 When the impact of the publicly declared emergency on ethics review is determined to be mild to moderate, the following will apply to the review of ongoing research:

- The HSREB Chair or designee will determine if the research needs to continue, or if it can be suspended until after the emergency is over,
- The research may continue at the discretion of the HSREB Chair or designee in consultation with the Researcher, as necessary,
- The Researcher's response to HSREB reviews, major amendments, and adverse events will be prioritized for review,
- Renewals will receive the next priority for review, followed by research completion reports,
- Other submissions will be reviewed as time allows.

5.3.2 When the impact of the publicly declared emergency on ethics review is determined to be severe, the following will apply to the review of ongoing research:

- Research activities not involving, or no longer involving, recruitment or direct contact with participants may continue,
- Research activities involving recruitment or direct contact with participants may only continue if ceasing such activity might pose significant risks to participant safety,
- Major amendments and adverse events related to these studies will be reviewed by the HSREB subcommittee or the HSREB subcommittee Chair or designee, as appropriate;

#### **5.4 Review of NEW Research NOT Related to or Arising from Publically Declared Emergency**

5.4.1 When the impact of the publicly declared emergency on ethics review is determined to be mild to moderate, the HSREB Chair or designee will determine whether review of any new research not related to the publicly declared emergency may proceed or will be postponed until after the emergency is over;

5.4.2 When the impact of the publicly declared emergency on ethics review processes is determined to be severe, any new research not related to the publicly declared emergency will not be reviewed until the emergency is declared to be over.

#### **5.5 Review of Research RELATED to or Arising from the Publically Declared Emergency**

5.5.1 If a request to review research related to a publicly declared emergency is received, it will be directed to the HSREB Chair or HSREB subcommittee Chair or designee, as applicable;

5.5.2 The HSREB Chair or designee will assess the risks associated with the proposed research, as well as aspects of the research that might require enhanced scrutiny or diligence, taking into account the severity of the impact of the emergency on ethics review processes;

5.5.3 When the impact of the publicly declared emergency on ethics reviews is determined to be mild to moderate, research related to the publicly declared emergency has priority for review;

5.5.4 When the impact of the publicly declared emergency on ethics review is determined to be severe, time-sensitive review processes may be followed, such as delegated review as appropriate, review by a HSREB subcommittee, and/or meetings conducted via teleconference or videoconference.

## **6.0 REFERENCES**

See References.

## **7.0 APPENDICES**

None.

## **8.0 REVISION HISTORY**

<b>SOP Title</b>	<b>Version</b>	<b>Updates</b>
HSREB Review During Publicly Declared Emergencies	v.501.001 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.