

**Holland Bloorview Research Ethics Board (REB)  
Standard Operating Procedures**

	<b>REB REVIEW OF RESEARCH</b>		
<b>POLICY: REB-410</b>	<b>REB REVIEW DURING PUBLICLY DECLARED EMERGENCIES</b>		
<b>This policy pertains to:</b>	The activities of the Research Ethics Board (REB) operating under the authority of Holland Bloorview Kids Rehabilitation Hospital		
<b>Responsibility for executing this policy:</b>	Chair, Holland Bloorview REB (or designate)		
<b>Effective date:</b>	September 30, 2014	<b>Supersedes documents dated:</b>	V1 August 2013
<b>Approved:</b>	Chair of the REB  Research, Teaching & Learning Advisory Committee		

**1. PURPOSE:**

The purpose of this SOP is to describe the modified procedures, practices and preparedness plan of the REB during official publicly declared emergencies.

**2. POLICY STATEMENT:**

For the purpose of this policy, a publicly declared emergency is an emergency situation such as a public health outbreak or natural disaster 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.

During such an event, the nature of the emergency may render research participants, researchers, and institutions more vulnerable than under normal circumstances. Consequently, the REB may temporarily follow modified procedures and practices to review new and ongoing research while ensuring that that research is conducted in accordance with the core ethical principles of Respect for Persons, Concern for Welfare and Justice.

**REFERENCES**

Tri-Council Policy Statement on Research Involving Humans 2 (TCPS2) Article 6

CAN/CGSB-191.1-2013 – (4.4.2.1), (4.4.2.3), (4.4.4.2)

**3. SPECIFIC POLICIES**

**3.1 Determination of Essential Work**

The Vice-President of Research at Holland Bloorview in consultation with the Pandemic Planning Committee (or other hospital emergency planning committees), Senior Management, local principal investigators, and the REB Chair (or designate) will identify and prioritize new and ongoing research activities deemed

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essential or time-sensitive during the emergency.

### **3.2 Prioritizing REB review**

The REB Chair (or designate) will consider the pressures, time constraints, priorities and logistical challenges that may arise during the event to ensure that the quality of ethics review is maintained and it is timely, proportionate, and appropriate.

The REB Chair and designated staff will facilitate the ethics review for new and ongoing research submissions during and arising from the emergency.

TCPS2  
Article 6.21

Priority ethics review will be given to any essential new or approved research because new information may become available and require timely action during emergencies. The REB Chair may defer the ethical review of new research unrelated to the emergency.

CAN/CGSB-191.1-2013 –  
(4.4.2.4 (a))

### **3.3 Modifications to REB Procedures and Practices**

During a publicly declared emergency, the REB may follow a modified review and operations plan. REB administration will communicate details of the modified review and operations plan to the BRI research community as necessary via email, phone, or other suitable means.

CAN/CGSB-191.1-2013 –  
(4.4.2.2), (4.5.2.1(p))

#### **3.3.1 Essential Research Submission Requirements**

The REB may allow modifications to the requirements (as described in REB-301) for new research submissions. In particular, the REB may waive the requirements for formal science reviews, a TAHSN ethics application form, departmental letters of support, and signatures of all investigators. However, the review of new submissions shall not proceed unless verbal or written authorization to do so is provided by the Vice-President of Research (or delegate) at Holland Bloorview.

SOP REB-301

#### **3.3.2 REB Submissions Requiring Full Review**

The REB Chair may at his/her discretion convene a meeting for review of submissions requiring full REB review via telephone conference call, web conference, or similar means during a publicly declared emergency. A quorum must participate for the meeting to be convened and this will be recorded in the minutes of the REB meeting. To allow for appropriate discussions to take place – “telephone polling”

TCPS2 article 2.7  
SOP REB-302

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(where members are contacted individually) will not be accepted as a full board meeting.

### 3.3.3 REB Submissions for Delegated Review

The REB Chair may modify the delegated review matrix (REB-402) to facilitate the review and approval process for essential new and ongoing research submissions. Specifically, the REB Chair (or designate) and at least one additional reviewer may review a submission and the REB Chair (or designate) may approve submissions involving minimal risk.

SOP REB-402

### 3.3.4 Limiting Exceptions to Core Ethical Principles

The REB will exercise special care when considering and approving requests from researchers for exceptions to the principles and procedures outlined within the TCPS2. For example, the REB will work with researchers to determine special consent and assent provisions that must be made during the emergency.

TCPS2  
Article 6.23

The REB recognizes that during times of emergency there is a need to be vigilant and exercise due diligence in respecting ethical principles, procedures and laws to preserve the values, purpose and protections of participants, researchers, and institutions. Therefore, researchers requesting exceptions to ethical principles must provide justification for such requests.

When these requests are demonstrably justified, the exceptions to and/or infringements of, ethical principles should be narrowly tailored to address the necessities occasioned by the publicly declared emergency.

Review and oversight of new and ongoing research may be assumed by another qualified REB in the event that the Holland Bloorview REB is significantly compromised and where institutional agreements exist.

CAN/CGSB-191.1-2013 –  
(4.4.2.4 (c))

## 3.4 Onset and Termination of Modified REB Procedures and Practices

Any modifications to the REB procedures and practices will take effect only once an emergency has been publicly declared. The modifications will cease to apply as soon as feasible after the end of the publicly declared emergency. The REB will endeavour to return to its normal standard operating procedures as soon as

TCPS2  
Article 6.22

CAN/CGSB-191.1-2013 –  
(4.4.2.3)

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possible after public officials have declared that the emergency is over. The REB Chair will advise the REB and minute all modifications to standard operating procedures at the first meeting following its return to normal operating procedures.

Revision History

V2/July 2014: CAN/CGSB-191.1-2013 references incorporated to reflect compliance. Changed Research Advisory Committee to Research, Teaching & Learning Advisory Committee.