



Research Ethics Board Standard Operating Policies and Procedures

REB Review During Publicly Declared Emergencies

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SUB-CATEGORY	Section V: Reviews Requiring Special Consideration	Original Issue Date:	March 31, 2014
ISSUED BY:	Research Ethics Office		
APPROVED BY	Vice President, Research		

The WCH REO webpage version of this document is considered the most current.

Please ensure that you have reviewed all linked documents and other reference material within this SOP

1.0 POLICY STATEMENT:

This Standard Operating Procedure (SOP) describes the modified procedures, practices and preparedness plan of the Women's College Hospital (WCH) Research Ethics Board (REB) during official publicly declared emergencies. This SOP is a supplement to the WCH Emergency Preparedness Plan.

For the purpose of this SOP, 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 or public policy. Publicly declared emergencies arise suddenly or unexpectedly, and require urgent responses. Examples include natural disasters, large communicable disease outbreaks, environmental disasters and humanitarian emergencies. Such emergencies may render research participants, researchers and institutions more vulnerable than under normal circumstances.

The WCH REB has established procedures to continue to provide the necessary research ethics oversight during such an event. Research ethics review during publicly declared emergencies may necessitate the use of innovative practices. Depending upon the nature of the emergency, for example, the WCH REB may not be able to meet in person, and delegated review procedures may have to be utilized 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 established WCH research ethics policies and procedures during an officially declared public emergency must be documented and appropriately justified.

2.0 DEFINITION(S):

See Glossary of Terms

3.0 RESPONSIBILITY:

This SOP applies to the REB Chair, Vice-Chair, REB Members and Research Ethics Office (REO) staff.

4.0 PROCEDURES:



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4.1. Determination of Essential Work

The Vice-President, Research at Women's College Hospital in consultation with the Emergency Preparedness Committee Chair, Senior Management, local principal investigators, and the REB Chair (or designate) will identify and prioritize new and ongoing research activities deemed essential or time-sensitive during the emergency.

4.2. 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 is timely, proportionate and appropriate.

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

Priority 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.

4.3. Modification to REB Procedures and Practices

During a publicly declared emergency, the REB may follow a modified review and operations plan. The Research Ethics Office will communicate details of the modified review and the operations plan will be communicated to the WCH Research Community as necessary via email, phone or other suitable means.

4.4. Essential Research Submission Requirements

The WCH REB may allow modifications to the requirements (as described in *WCH REB Submission Requirements and Initial Review of REB Submissions SOP*) for new submissions. In particular, the REB may waive the requirements for formal scientific reviews, a TAHSN ethics application form, departmental letters of support, and signature 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 WCH.

4.5. 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" (where members are contacted individually) will not be considered a full board meeting.

4.6. REB Submissions for Delegated Review



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The REB Chair may modify the delegated review procedures as outlined in (*WCH REB Delegated Review Procedures SOP*) to facilitate the review and approval process for essential new and ongoing research submissions. Specifically, the REB Chair (or delegate) and at least one additional reviewer may review a submission and the REB Chair or delegate may approve submissions involving minimal risk.

4.7. Limited 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 a publicly declared emergency.

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 WCH REB is significantly compromised and where institutional agreements exist.

4.8. 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 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.

5.0 REFERENCES:

1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2), Articles 2.7, 6, 6.21, 6.22, 6.23;
2. The International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines as adopted by Health Canada;
3. Health Canada Therapeutic Products Directorate Food and Drug Regulations For Clinical Trials, Division 5;



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4. Holland Bloorview Research Ethics Board Standard Operating Procedure (REB-410), REB Review During Publicly Declared Emergencies;
5. Women's College Hospital Emergency Preparedness Plan (May 2013)
6. WCH Delegated Review Procedures *SOP: REB-SOP-IV-02.002*.