



SOP Title	REB Review During Publicly Declared Emergencies
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Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
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1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the research ethics review procedures during a publicly declared emergency.

2.0 GENERAL POLICY STATEMENT

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 clinical trials or in new clinical trials initiated as a result of the emergency. 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 REB must have 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, REBs 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 an officially-declared public emergency must be documented and appropriately justified.

3.0 DEFINITIONS

See glossary of terms.

4.0 RESPONSIBILITY

This SOP applies to the Health Sciences Research Ethics Board (HSREB) Chair, Vice-Chair(s), HSREB members and to all Office of Human Research Ethics (OHRE) staff.

5.0 SPECIFIC POLICIES AND PROCEDURES

5.1 Determining the Level of Impact

- 5.1.1 Subsequent to an officially declared public 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 public emergency:
1. **Mild** – little or no impact,
 2. **Moderate** – some impact; decisions to proceed at the discretion of the HSREB Chair or designee, in consultation with the Investigator, as necessary,
 3. **Severe** – extremely debilitating to normal research ethics review procedures;
- 5.1.3 The HSREB Chair or designee will use the level of impact to guide the review of research submissions during the public 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 declared emergency, temporary ethics review processes may be instituted; however, since the OHRE's online system already allows for many of its review activities to be conducted remotely (when appropriate), the HSREB first would attempt to continue with its currently established processes;
- 5.2.2 When the impact on the ethics review processes is deemed to be severe, teleconferences or video conferences may be used to conduct the HSREB meetings;
- 5.2.3 When the impact on the ethics review processes is deemed to be severe, the OHRE staff may conduct their activities remotely (via the online system and remote email and voice mail access), with minimal disruption of services;
- 5.2.4 The HSREB Chair or designee may suspend the currently established meeting quorum of 50% + 1, 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 REB membership requirements and should include at least five members drawn from the existing HSREB membership where possible, including:
- A member knowledgeable in research ethics,
 - A member knowledgeable in relevant law,
 - A nonscientific community member,
 - At least two members with expertise in relevant scientific disciplines, which may include oncology and pharmacology or statistics;
- 5.2.6 The current HSREB Chair or one of the current Vice-Chairs or a 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 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 Where research submissions are deemed to be more than minimal risk, the HSREB Chair or subcommittee Chair or designee will use his/her judgement 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;
- 5.2.9 Any modifications that are made in the application of research ethics policies and procedures during an officially-declared public emergency must be documented and appropriately justified;
- 5.2.10 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;
- 5.2.11 Any modifications that are made in the application of research ethics policies and procedures during an officially-declared public 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;
- 5.2.12 All delegated approvals 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;
- 5.2.13 At the conclusion of the publically declared public emergency, the HSREB Chair, the HSREB Vice-Chairs, and the OHRE staff 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 public 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 postponed until after the emergency is over,
 - The research may continue at the discretion of the HSREB Chair or designee in consultation with the Investigator, as necessary,
 - Investigator responses to HSREB reviews, major amendments, and adverse events will be prioritized for review,
 - Continuing reviews will receive the next priority for review, followed by study completion reports,
 - Other submissions will be reviewed as time allows;
- 5.3.2 When the impact of the public 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;

5.3.3 At the HSREB Chair's or designee's discretion, review procedures may be delayed or temporarily suspended depending upon volume. In such cases, the studies shall be deemed to have continuing approval until such time that HSREB is able to conduct its review.

5.4 Review of New Research NOT Related to or Arising from the Publicly Declared Emergency

5.4.1 When the impact of the public 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 public emergency on ethics review processes is determined to be severe, any new research not related 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 Publicly Declared Emergency

5.5.1 While it is unlikely that HSREB would receive requests to review research related to a publicly declared emergency, in the event that such a submission 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 public emergency on ethics review 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 public emergency on ethics review is determined to be severe, time-sensitive review processes may be followed, such as delegated review, review by an HSREB subcommittee, and/or meetings conducted via teleconference or videoconference.

6. REFERENCES

- 6.1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2010 (TCPS2);
- 6.2. International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines as adopted by Health Canada;
- 6.3. Health Canada Therapeutic Products Directorate Food and Drug Regulations for Clinical Trials, Division 5

7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyyy
502.001	original	04/08/2014
502.002	Minor administrative corrections for clarity	05/10/2016