

<b>SOP Title</b>	<b>REB Review During Publicly Declared Emergencies</b>
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## Approvals

<b>Name and Title of Signatories</b>	<b>Signature</b>	<b>Date mm/dd/yyyy</b>
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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, 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 alternate review procedures may have to be designed to respond to either urgent opportunities for new research related to the emergency or to support review of 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 public declared 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 a publically declared emergency, the HSREB Chair or designee will assess the level of impact on the research ethics review processes. The assessment will consider factors including (but not limited to):

- Whether the publically declared emergency affects some or all of the research reviewed by the HSREB, including:
  - The review of ongoing research that is unrelated to or not arising from the publically declared emergency
  - The review of new research that is unrelated to or not arising from the publically declared emergency and
  - The review of research that arises from or is related to the publically declared emergency;
- The nature of the risks imposed by the publically declared emergency on participants, the REB, and the OHRE staff;
- What research is considered “essential” during the emergency
- The potential duration of any alterations in review procedures, if predicable

5.1.2 Based on this assessment, there are three levels of impact that may influence how ethics review will be conducted:

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 affected by 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 a publically declared emergency, temporary ethics review processes may be instituted for some or all research studies; 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 administrative processes;

5.2.2 When the impact on the ethics review processes for some or all research is deemed to be severe, teleconferences or video conferences may be used to conduct the HSREB meeting(s);

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 call *ad hoc* meeting(s) to support the urgent review of research affected by the publically declared emergency. In such circumstances, there may also be alternations in the processes for notifying REB members, circulating documents, assignment of reviewers, and other administrative processes;
- 5.2.5 The HSREB Chair or designee may suspend the currently established REB membership and meeting quorum for the review of research affected by the publicly declared emergency;
- 5.2.6 If declared necessary by the REB Chair or designee, the HSREB composition and quorum for review of research affected by a publicly declared emergency will include at least five members, drawn from the existing HSREB membership where possible, including:
- At least two (2) members with expertise in relevant scientific disciplines, field and methodologies covered by the REB (for biomedical clinical trials, this will include at least one member who practices medicine or dentistry and who is in good standing with their regulatory body;
  - At least (1) member who is primarily experienced in non-scientific disciplines;
  - At least (1) one member knowledgeable in research ethics;
  - At least (1) one member knowledgeable in relevant law (but that member should not be the institution's legal counsel or risk manager). This is mandatory for biomedical research and is advisable, but not mandatory, for other areas of research;
  - At least one (1) community member who has no affiliation with the institution;
  - At least (1) one member knowledgeable in considering privacy issues;
  - additional representation as required by applicable legislation or guidelines.
- 5.2.7 For studies subject to US federal regulations, if the regular membership is suspended for the review of research affected by a publically emergency, the HSREB will consider the 50%+1 quorum requirement based on the alternate REB membership;
- 5.2.8 The current HSREB Chair or one of the current Vice-Chairs or a designee will normally serve as the Chair of the HSREB for the review of research affected by a publically declared emergency;
- 5.2.9 At his/her discretion, the HSREB Chair or designee may invite individuals with expertise in special areas to assist in the review of issues that require expertise beyond that available. However, ad hoc advisors may not contribute directly to the HSREB's decision and their presence shall not be used in establishing a quorum;
- 5.2.10 Other modifications to the review procedures may be implemented, in compliance with the applicable guidelines and regulations and as deemed necessary by the REB Chair or designee;
- 5.2.11 Any modifications that are made in the application of research ethics policies and procedures related to a publically declared emergency must be documented and appropriately justified;
- 5.2.12 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;
- 5.2.13 Any modifications that are made in the application of research ethics policies and procedures related to the review of research during a 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;
- 5.2.14 All approvals of research that follow an alternate review procedure must be assessed at the first opportunity to determine if additional review is required. This may be at the next regularly scheduled full board meeting (e.g., if the declared emergency affects only a subset of research) or subsequent to the cessation of the publicly declared emergency;

5.2.15 At the conclusion of the publically declared public emergency, the HSREB and the OHRE staff should 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 of research not related to or arising from the emergency is determined to be mild to moderate, the following principles 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,
- Submissions related to participant safety, including reportable events and amendments related to safety concerns will be prioritized for review
- Continuing reviews will receive the net priority for review, followed by investigator responses to HSREB reviews, other amendments, and study completion reports ,
- Other submissions will be reviewed as time allows;
- The HSREB may implement the emergency preparedness procedures as applicable to the research/emergency.

5.3.2 When the impact of the public emergency on ethics review of ongoing research unrelated to the emergency is determined to be severe, the following principles 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,
- The HSREB may require suspension of enrolment of new participants
- Submissions related to participants safety, including reportable events and amendments related to safety concerns will be prioritized for review
- Continuing reviews will receive the net priority for review, followed by investigator responses to HSREB reviews, non-safety amendments, and study completion reports;
- The HSREB may implement any/all of the emergency preparedness procedures as deemed appropriate to the research/emergency.

### **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 Requests to review research related to a publicly declared emergency will be directed to the HSREB Chair or designee to assess the impact of the research;
- 5.5.2 The HSREB Chair or designee will assess the risks associated with proposed or ongoing 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 Consideration may be given to the alterations in the ethics review process of new research projects arising from the research and for changes to approved research related to the emergency. These alterations may be limited to the review of the research related to the publically declared emergency;
- 5.5.4 HSREB may implement any/all of the emergency preparedness procedures as deemed appropriate to the research/emergency.

**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**

<b>SOP Number.Version</b>	<b>Key Changes</b>	<b>Effective Date mm/dd/yyyy</b>
502.001	original	04/08/2014
502.002	Minor administrative corrections for clarity	05/10/2016
502.003	Accepted major proposed changes	09/10/2018
502.004	Minor administrative corrections for clarity	21/04/2021