

TITLE	501: REB Review During Publicly Declared Emergencies
SCOPE	All health research submitted to the Health Research Ethics Board (HREB) operating under the direct authority of the Health Research Ethics Authority (HREA)
APPROVAL AUTHORITY	Ethics Director
EFFECTIVE DATE	April 2021

1.0 PURPOSE

This standard operating procedure (SOP) describes the research ethics review procedures during a publicly declared emergency.

2.0 DEFINITIONS

See the Glossary of Terms.

3.0 RESPONSIBILITIES

All HREB members and Research Ethics Office (REO) Personnel are responsible for ensuring that the requirements of this SOP are met.

4.0 PROCEDURE

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 increased risks for research participants in ongoing research or in new research 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 increasingly so.

During publicly declared emergencies, the HREB 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, delegated review procedures may have to be designed to respond to either urgent opportunities for new research or to facilitate 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.

4.1 Determining the Level of Impact

4.1.1 Subsequent to a publicly declared emergency, the HREB Chairperson or designee, in consultation with the Ethics Director, will assess the potential effect on the research ethics review processes.

4.1.2 There are three levels of potential effect that will influence how ethics review will be conducted during the publicly declared emergency:

- **Mild** –no measurable effect;
- **Moderate** – measurable effect falling within a tolerable range – at this level, decisions to proceed will be made at the discretion of the Chairperson or designee, and in consultation with the Researcher, as necessary; and
- **Severe** – severe effect that would be debilitating to normal research ethics review procedures

4.1.3 The HREB Chairperson or designee and the Ethics Director will use the level of effect to guide the review of research submissions during the publicly declared emergency.

4.1.4 Pending the determination of the level of potential effect on the review of ongoing or new research, the currently established ethics review procedures will be followed.

4.2 Emergency Preparedness Procedures

4.2.1 Subsequent to an officially publicly declared emergency, temporary ethics review processes will be instituted.

4.2.2 When the potential effect on the ethics review processes is deemed severe, the usual processes for review may need to be altered.

4.2.3 The HREB Chairperson or designee may establish an HREB subcommittee for the duration of the publicly declared emergency.

4.2.4 The HREB subcommittee composition will be in accordance with the standard HREB membership requirements and will include at least five members drawn from the existing HREB membership.

4.2.5 The current HREB Chairperson or designee will serve as the Chairperson of the HREB subcommittee.

4.2.6 At their discretion, the HREB subcommittee Chairperson 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 HREB 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.

- 4.2.7** Where research submissions are deemed to be at more than minimal risk the HREB Chairperson or subcommittee Chairperson or designee will, subject to applicable regulations, use their judgment in determining the type of review required (delegated or Full Board), taking into account the severity of the potential effect of the emergency and the complexity and urgency of the submission.
- 4.2.8** 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.
- 4.2.9** The HREB Chairperson or designee and the Ethics Director will periodically assess the effect of the emergency on the ethics review processes and adjust any temporary ethics review processes accordingly.
- 4.2.10** 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 HREB Chairperson or designee and the Ethics Director will determine when to resume routine ethics review processes.
- 4.2.11** All delegated approvals of research following a publicly declared emergency must be assessed by the HREB Chairperson or designee to determine if subsequent Full Board review is required at the first opportunity subsequent to the cessation of the publicly declared emergency.
- 4.2.12** At the conclusion of the publicly declared emergency, the HREB Chairperson or designee and the REO Personnel will work with the HREB members to evaluate the effectiveness of its declared emergency procedures and to make recommendations for improvements.

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

- 4.3.1** When the potential effect 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 HREB Chairperson 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 HREB Chairperson or designee in consultation with the Researcher, as necessary;
 - the researcher's response to HREB reviews, major amendments, and adverse events will be prioritized for review;
 - continuing reviews will receive the next priority for review, followed by research completion reports; and
 - other submissions will be reviewed as time allows.

4.3.2 When the potential effect 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, in keeping with the public emergency guidance and organizational policies, as applicable;
- research activities involving recruitment or direct contact with participants may continue if ceasing such activity might pose significant risks to participant safety, and in keeping with the public emergency guidance and organizational policies, as applicable; and
- as required, major amendments and adverse events related to these studies will be reviewed by the HREB subcommittee or the HREB subcommittee Chairperson or designee, as appropriate.

4.3.3 At the HREB Chairperson or designee's discretion, and subject to applicable regulations, review procedures may be delayed or temporarily suspended depending upon volume. In such cases, research shall be deemed to have continuing approval until such time that the HREB is able to conduct its review.

4.4 Review of New Research during a Publicly Declared Emergency

4.4.1 Review of new health research during a publicly declared emergency will proceed as per public emergency guidelines and in compliance with the HREA Act.

4.4.2 The HREB or the HREB Chairperson 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.

4.4.3 When the potential effect of the publicly declared emergency is determined to be mild to moderate, research related to the publicly declared emergency will have priority for review.

4.4.4 When the potential effect 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 an HREB subcommittee, and/or an alteration in the usual processes for conducting meetings.

5.0 REFERENCES

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Chapter 6:
<http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter6-chapitre6/#toc06-1d>

Health Research Ethics Authority Act: An Act to Establish A Health Research Ethics Authority For The Province (2011). Retrieved from: [SNL2006 CHAPTER H-1.2 - HEALTH RESEARCH ETHICS AUTHORITY ACT](http://www.assembly.nl.ca/SNL2006/CHAPTER%20H-1.2%20-%20HEALTH%20RESEARCH%20ETHICS%20AUTHORITY%20ACT)
[assembly.nl.ca](http://www.assembly.nl.ca)