

Title	REB Review During Publicly Declared Emergencies
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1 PURPOSE

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

2 SCOPE

This SOP pertains to Research Ethics Boards (REB) that review human participant research in compliance with applicable regulations and guidelines.

3 RESPONSIBILITIES

All REB members and REB Support Staff are responsible for ensuring that the requirements of this SOP are met.

4 DEFINITIONS

See Glossary of Terms.

5 PROCEDURES

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.¹ 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 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 acutely so.² Special attention and effort should be given to upholding the core principles of Respect for Persons, Concern for Welfare, and Justice.³

During publicly declared emergencies, the REB must have established procedures to continue to provide the necessary research ethics oversight.⁴ 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 urgent opportunities for research. 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.⁵ 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.

¹ Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2014 (TCPS2), p. 87.

² TCPS2, p. 88.

³ TCPS2, p. 88.

⁴ TCPS2, art. 6.21.

⁵ TCPS2, art. 6.23.

5.1 Procedures for Ethics Review in Emergency Situations

- 5.1.1 Subject to a publicly declared emergency, exceptional ethics review processes may be instituted⁶;
- 5.1.2 The REB Chair or designee may suspend the currently established REB meeting quorum, in which case delegated review with the necessary expertise would be established for the duration of the publicly declared emergency;
- 5.1.3 The expertise required for the quorum may be established in the following order of priority:
- REB members from the institution,
 - REB members from another institution in the same network,
 - Other individuals with the required expertise;
- 5.1.4 The current REB Chair or designee, or any other individual appointed as interim, may serve as acting REB Chair;
- 5.1.5 Annual reviews of ongoing research may be done by delegated review or by a Support Staff named by the REB Chair or designee;
- 5.1.6 The REB Chair or designee may refer the ethics review of new research and the oversight of ongoing research to another REB of the Québec Health and Social Services Network (*Réseau de la santé et des services sociaux*, RSSS);
- 5.1.7 Any modifications that are made in the application of research ethics policies and procedures for the review and oversight of research during a publicly declared emergency must be documented and appropriately justified;
- 5.1.8 Any modifications that are made in the application of research ethics policies and procedures for the review and oversight of research 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)⁷;
- 5.1.9 All delegated approvals of research following a publicly declared emergency must be assessed by members to determine whether subsequent Full Board review is required at the first opportunity subsequent to the cessation of the publicly declared emergency, or whether simply informing the Full Board is sufficient;
- 5.1.10 The person mandated by the institution to authorize research may delegate that authority during the emergency period. In the absence of institutional procedures, the REB Chair or designee, an REB member, or an REB Support Staff employed by the institution may authorize research on a temporary basis. As soon as possible, the REB will inform the “person mandated by the institution to authorize

⁶ TCPS2, art. 6.22.

⁷ TCPS2, art. 6.22.

research” of any such research for endorsement;

5.1.11 At the conclusion of the publicly declared emergency, the REB Chair or designee and the REB Support Staff should evaluate the effectiveness of the emergency procedures and make recommendations for improvement.

5.2 Order of Priority for Reviews in a Publicly Declared Emergency

5.2.1 New Research Reviews:

- Any research linked with a publicly declared emergency is a priority item,
- All research linked with a publicly declared emergency should be sent to the REB Chair or designee,
- Research not linked to the publicly declared emergency can be postponed until the necessary resources for review are available;

5.2.2 Reviews in Progress at the Time the Emergency is Declared:

- Research linked with a publicly declared emergency is a priority item,
- Any initial review of research with possible therapeutic value is prioritized according to availability of resources,
- Research not linked to the publicly declared emergency can be postponed until the necessary resources for review are available;

5.2.3 Continuing Review of Ongoing Research:

- The Researcher will advise the REB of any research suspended, if the suspension could impact on the health or safety of participants,
- Reviews will proceed in the following order of priority:
 - annual review for renewal,
 - requests for major amendments and reports of adverse events,
 - all other requests,
 - end-of-study reports;

At the REB Chair or designee’s discretion, and subject to applicable regulations, review procedures may be delayed or temporarily suspended depending upon volume.

6 REFERENCES

See footnotes.

7 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
REB-SOP 501.001	N.A.	Original version (MUHC Board of Directors acknowledged 2020-03-20; approved 2021-03-22)
REB-SOP 501.001-1	2020-03-20	5.1.10: 'mandatee' corrected for "person mandated by the institution to authorize research"

8 APPENDICES