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| **Title** | REB Review During Publicly Declared Emergencies |
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# Purpose

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

# Scope

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

# Responsibilities

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

The institution will decide on the volume and nature of research activities and how they will continue to be conducted during a publicly declared emergency situation, in consideration of REB capacities and resources.

# Definitions

See Glossary of Terms.

# 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]](#footnote-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.[[2]](#footnote-2) 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.[[3]](#footnote-3)

During publicly declared emergencies, the REB must have established procedures to continue to provide the necessary research ethics oversight.[[4]](#footnote-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 research emergencies. The occurrence of an emergency must not override the procedures established 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.[[5]](#footnote-5)

## Procedures for Ethics Review in Declared Emergency Situations

### Subject to a publicly declared emergency, temporary ethics review processes may be instituted[[6]](#footnote-6);

### Depending on the circumstances, teleconferencing or videoconferencing may be used to hold REB meetings.

### Depending on the circumstances, REB Support Staff may conduct their activities remotely (remote access to emails and voicemail), thereby minimizing service disruptions.

### The REB Chair or designee may suspend the currently established REB meeting quorum. However, in the case of projects governed by article 21 of the Civil Code of Québec, the quorum must meet the minimum composition required by law;

### In his discretion, the REB Chair or designee may invite persons with expertise in a specific field to collaborate in the review of questions necessitating expertise beyond that available[[7]](#footnote-7); however, ad hoc advisors may not contribute directly to committee decisions and their presence may not be counted towards the quorum.

### 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 Québec Health and Social Services Network (*Réseau de la santé et des services sociaux*, RSSS) or the central research ethics committee,
* Other individuals with the required expertise.

### The REB Chair or designee will rely on his judgment to determine the type of review required (delegated review or full board meeting), in consideration of the gravity of the impact of the emergency and the complexity and urgent character of the request;

### The REB Chair or designee may refer the ethics review of new research and the oversight of ongoing research to another REB of an institution in the Québec Health and Social Services Network (*Réseau de la santé et des services sociaux*, RSSS) or the central research ethics committee;

### 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;

### The REB Chair or designee must periodically review the impact of the emergency on the ethics review process and adjust any temporary ethics review process accordingly;

### Any modifications that are made in the application of research review policies and procedures during a publicly declared emergency will cease as soon as is feasible after the emergency has officially ended as declared by an authorized public official.[[8]](#footnote-8) The REB Chair or designee will determine when research ethics review processes may resume as usual;

### For all reviews conducted in accordance with the delegated review procedure following a publicly declared emergency, members must determine whether 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;

### At the conclusion of the publicly declared emergency, the REB Chair or designee and the REB Support Staff will collaborate to evaluate the effectiveness of the emergency procedures and make recommendations for improvement.

## Order of Priority for Reviews in a Publicly Declared Emergency

### New Research Reviews:

* Any research linked with a publicly declared emergency and with a high impact potential 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;

### 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;

### 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:
* requests for major amendments and reports of adverse events,
* annual review for renewal,
* 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.

# References

See footnotes.

# Revision History

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| **SOP Code** | **Effective Date** | **Summary of Changes** |
| REB-SOP 501-001 | 2019-04-01 | Original version |
| REB-SOP 501-002 | YYYY-MM-DD | Updated in line with regulations in effectNew numberingUpdated references |
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# Appendices

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 2018, hereafter “TCPS2”, c. 6, under D. [↑](#footnote-ref-1)
2. TCPS2, *Ibid.* [↑](#footnote-ref-2)
3. TCPS2, Application under art. 6.23. [↑](#footnote-ref-3)
4. TCPS2, art. 6.21. [↑](#footnote-ref-4)
5. TCPS2, Application under art. 6.21 and 6.23. [↑](#footnote-ref-5)
6. TCPS2, art. 6.22. [↑](#footnote-ref-6)
7. *Avis sur les conditions d’exercice des comités d’éthique de la recherche désignés ou institués par le ministre de la Santé et des Services sociaux en vertu de l’article 21 du Code civil*, *Gazette officielle du Québec*, Part I, vol. 35, 1998, p. 1039; Guidance Document: Good Clinical Practice: Integrated Addendum to E6(R1) ICH Topic E6(R2), Health Canada, April 2019, s. 3.2.6; Operational Guidelines for Ethics Committees that Review Biomedical Research, World Health Organization (WHO), 2000, s. 4.6. [↑](#footnote-ref-7)
8. TCPS2, art. 6.22. [↑](#footnote-ref-8)