



## IWK Research Ethics Standard Operating Procedures

Document # <b>RE 5.503</b>	Title: <b>REB review during publicly declared emergencies</b>	Effective Date: <b>November 19, 2024</b>
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### **POLICY STATEMENT**

*For the purpose of this policy, 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.*

*During such an event, the nature of the emergency may render research participants, researchers, and institutions more vulnerable than under normal circumstances. Consequently, the REB may temporarily follow modified procedures and practices to review new and ongoing research while ensuring that that research is conducted in accordance with the core ethical principles of Respect for Persons, Concern for Welfare and Justice. 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.*

### **DEFINITIONS**

See Glossary of Terms

### **RESPONSIBILITY**

This SOP applies to the REB Chair, Manager, REB members, and Research Ethics Office (REO) staff

### **PROCEDURES**

#### **Determination of Essential Work**

Only essential research shall be initiated during a declared public emergency. The IWK Executive Board in consultation with the hospital emergency planning committees, Senior Management, local principal investigators, and the REB Chair (or designate) will identify and prioritize new and ongoing research activities deemed essential or time-sensitive during the emergency.

### **Prioritizing REB review**

The REB Chair will triage all research submissions, allocating priority to time-sensitive or essential research.

The REB Chair will consider the pressures, time constraints, priorities and logistical challenges that may arise during the event to ensure that the quality of ethics review is maintained and it is timely, proportionate, and appropriate.

The REB Chair and designated staff will facilitate the ethics review for new and ongoing research submissions during and arising from the emergency.

Priority ethics review will be given to any essential new or approved research because new information may become available and require timely action during emergencies. The REB Chair may defer the ethical review of new research unrelated to the emergency.

Ongoing review of pre-existing research may be delayed or temporarily suspended.

Review of Annual re-approval applications may be delayed or temporarily suspended. In such a case, the study shall be deemed to have continued approval until such time that the REB is able to conclude its review of the application.

### **Modifications to REB Procedures and Practices**

Subject to applicable regulations, during a publicly declared emergency, the REB may follow a modified review and operations plan. REB administration will communicate details of the modified review and operations plan to the IWK research community as necessary via email, phone, or another suitable means.

Appropriately qualified REB members may be appointed *ad hoc* to provide extraordinary expertise. New REB members may be appointed at the discretion of the Chair.

In the event the IWK REB is unable to form quorum to review an emergency research protocol, Reciprocal Research Ethics Review Agreements for emergency review may be negotiated between peer REB's.

### **Essential Research Submission Requirements**

The REB may allow modifications to the requirements for new research submissions. In particular, the REB may waive the requirements for formal ethics application form and departmental letters of support. However, the review of new submissions shall not proceed unless verbal or written authorization to do so is provided by the IWK Executive Board.

### **REB Submissions Requiring Full Review**

The REB Chair may at his/her discretion convene a meeting for review of submissions requiring full REB review via telephone conference call, web conference, or similar means during a publicly declared emergency. A quorum must participate for the meeting to be convened and

this will be recorded in the minutes of the REB meeting.

### **REB Submissions for Delegated Review**

The REB Chair may modify the delegated review to facilitate the review and approval process for essential new and ongoing research submissions. Specifically, the REB Chair and at least one additional reviewer may review a submission and the REB Chair may approve submissions involving minimal risk.

### **Limiting Exceptions to Core Ethical Principles**

The REB will exercise special care when considering and approving requests from researchers for exceptions to the principles and procedures outlined within the TCPS2. For example, the REB will work with researchers to determine special consent and assent provisions that must be made during the emergency.

The REB recognizes that during times of emergency there is a need to be vigilant and exercise due diligence in respecting ethical principles, procedures and laws to preserve the values, purpose and protections of participants, researchers, and the IWK. Therefore, researchers requesting exceptions to ethical principles must provide justification for such requests.

When these requests are demonstrably justified, the exceptions to and/or infringements of, ethical principles should be narrowly tailored to address the necessities occasioned by the publicly declared emergency.

Review and oversight of new and ongoing research may be assumed by another qualified REB in the event that the IWK REB is significantly compromised and where institutional agreements exist.

### **Onset and Termination of Modified REB Procedures and Practices**

Any modifications to the REB procedures and practices will take effect only once an emergency has been publicly declared. The modifications will cease to apply as soon as feasible after the end of the publicly declared emergency. The REB will return to its normal standard operating procedures as soon as possible after public officials have declared that the emergency is over. The REB Chair will advise the REB and minute all modifications to standard operating procedures at the first meeting following its return to normal operating procedures.

All Expedited approvals of emergency research must be placed before the full-board at its first opportunity, subsequent to the declaration of public emergency.

At the conclusion of the declared public emergency, the REB shall evaluate the effectiveness of its declared emergency procedures and make recommendations for improvements in the future.

**Note:** US regulations will be applied as applicable.

**REFERENCES**

1. Tri-Council Policy Statement: Ethical conduct for Research Involving Humans, 2018: (short name: TCPS 2), Article 6
2. The International Conference on Harmonization (ICH) Guidelines for Good Clinical Practice (GCP)
3. Health Canada Therapeutic Products Directorate Food and Drug Regulations for Clinical Trials, Division 5

**Forms/Records:**

Form #	Form/Record Name
SOP 503	REB Review During a Publicly Declared Emergency

**Revision History:**

Revision	Date	Description of changes
0.0	August 1, 2014	Initial Release
1.0	April 1, 2017	Minor update
1.1	March 21, 2022	Addition of TCPS2-2018 wording
1.2		Addition approved
1.3	February 1, 2023	Updated logo
1.4	November 19, 2024	Added note regarding compliance with US regulations where applicable & update to responsibility (RIA)