

RS0500 – RESEARCH ETHICS BOARD REVIEW DURING PUBLICLY DECLARED EMERGENCIES

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1.0 PURPOSE

To describe the actions of the Interior Health (IH) Research Ethics Board (REB) required for the ethical review of research during a publicly declared emergency.

2.0 DEFINITIONS

TERM	DEFINITION
<i>Publicly declared emergency</i>	<i>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.</i>

3.0 POLICY

The REB must have established procedures to continue to provide necessary research ethics oversight during Publicly Declared Emergencies. Such emergencies may represent significant risks for research participants in ongoing research or in new research initiated because of the emergency. Research ethics review during Publicly Declared Emergencies may necessitate the use of innovative practices. Depending upon the nature of the emergency, for example, delegated review procedures may have to be designed to respond either to urgent opportunities for new research or to current ongoing research.

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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.

The REB must justify and document any modifications made in the application of research ethics policies and procedures during a Publicly Declared Emergency.

REBs and researchers should be aware that individuals, prospective participants, researchers, and institutions not normally considered vulnerable might become so by the very nature of Public Emergencies. Those already vulnerable may become acutely so. REBs and researchers should therefore appropriately evaluate the risks and potential benefits posed by any proposed research, including provisions for greater than normal attention to risk, where applicable.

3.1 Determining the Level of Impact

- 3.1.1 Subsequent to an officially Publicly Declared Emergency, the Chair or Designee will assess the level of impact on the research ethics review processes.
- 3.1.2 There are three levels of impact that may influence how ethics review will be conducted during the Publicly Declared Emergency:
 - 3.1.2.1 Mild – little or no impact;
 - 3.1.2.2 Moderate – some impact, decisions to proceed at the discretion of the Chair or Designee, in consultation with the researcher, as necessary;
 - 3.1.2.3 Severe – extremely debilitating to normal research ethics review procedures.
- 3.1.3 The Chair or Designee will use the level of impact to guide the review of research submissions during the Publicly Declared Emergency.
- 3.1.4 The REB shall follow the currently established ethics review procedures, pending the determination of the level of impact on the review of ongoing or new research.

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- 3.2 Emergency Preparedness Procedures
 - 3.2.1 The REB may institute temporary ethics review processes subsequent to an officially Publicly Declared Emergency.
 - 3.2.2 The Chair or Designee may suspend the currently established REB meeting quorum, in which case the institution, in consultation with the REB, will establish an REB subcommittee for the duration of the Publicly Declared Emergency.
 - 3.2.3 The REB subcommittee composition should be in accordance with the standard REB membership requirements and should include at least five members drawn from the existing REB membership.
 - 3.2.4 The current Chair or Designee should serve as the Chair of the REB subcommittee.
 - 3.2.5 At his/her discretion, the REB subcommittee Chair may invite individuals with expertise in special areas to assist in the review of issues that require expertise beyond that available to the REB subcommittee; however, ad hoc advisors may not contribute directly to the subcommittee’s decision and their presence will not be used in establishing a quorum.
 - 3.2.6 When the impact is severe, the Chair or Subcommittee Chair may refer the ethics review and research oversight of new and ongoing research to another REB, subject to the applicable regulations and agreements.
 - 3.2.7 Where research submissions are deemed to be more than minimal risk and subject to applicable regulations, the Chair or Subcommittee Chair will use his/her judgment in determining the type of review required (delegated or full Board), taking into account the severity of the impact of the emergency and the complexity and urgency of the submission.
 - 3.2.8 The REB will document and appropriately justify any modifications made in the application of research ethics policies and procedures during a Publicly Declared Emergency.
 - 3.2.9 The Chair or Subcommittee Chair should periodically assess the impact of the emergency on the ethics review processes and adjust any temporary ethics review processes accordingly.

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- 3.2.10 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 Chair or Subcommittee Chair will determine when to resume routine ethics review processes.
- 3.2.11 The REB will assess all delegated approvals of research following a Publicly Declared Emergency to determine if subsequent full Board review is required at the first opportunity subsequent to the cessation of the Publicly Declared Emergency.
- 3.2.12 At the conclusion of the Publicly Declared Emergency, the Chair or Subcommittee Chair should work with the REB subcommittee members to evaluate the effectiveness of its declared emergency procedures and to make recommendations for improvements.

4.0 PROCEDURES

- 4.1 Review of Ongoing Research NOT Related to or Arising from the Publicly Declared Emergency
 - 4.1.1 When the impact of the Publicly Declared Emergency on ethics review is mild to moderate, the following will apply to the review of ongoing research:
 - 4.1.1.1 The institution, in consultation with the Chair and researcher, will determine if the research needs to continue, or if it can be postponed until after the emergency is over;
 - 4.1.1.2 The research may continue at the discretion of the institution, in consultation with the Chair or Subcommittee Chair and the researcher, as necessary;
 - 4.1.1.3 Researcher’s response to REB reviews, major amendments, and adverse events will be prioritized for review;
 - 4.1.1.4 Continuing reviews will receive the next priority for review, followed by research completion reports; and
 - 4.1.1.5 The REB will review other submissions as time allows.

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4.1.2 When the impact of the Publicly Declared Emergency on ethics review is severe, the following will apply to the review of ongoing research:

4.1.2.1 Research activities not involving, or no longer involving, recruitment or direct contact with participants may continue;

4.1.2.2 Research activities involving recruitment or direct contact with participants may only continue if ceasing such activity might pose significant risks to participant safety;

4.1.2.3 The REB subcommittee or Subcommittee Chair will review major amendments and adverse events related to these studies, as appropriate.

4.1.3 The Chair or Subcommittee Chair may delay or temporarily suspend review procedures at his/her discretion, subject to applicable regulations, depending upon volume. In such cases, research shall have continuing approval until such time that the REB is able to conduct its review.

4.2 Review of New Research NOT Related to or Arising from the Publicly Declared Emergency

4.2.1 When the impact of the Publicly Declared Emergency on ethics review is mild to moderate, the Chair or Subcommittee Chair will determine whether the REB will continue to review of any new research not related to the Publicly Declared Emergency or postpone these reviews until after the emergency is over.

4.2.2 When the impact of the Publicly Declared Emergency on ethics review processes is severe, the REB will not review any new research not related to the Publicly Declared Emergency until the emergency is declared over.

4.3 Review of Research RELATED to or Arising from the Publicly Declared Emergency

4.3.1 Requests to review research related to a Publicly Declared Emergency will be directed to the Chair or Subcommittee Chair, as applicable.

4.3.2 The Chair or Subcommittee Chair 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.

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- 4.3.3 When the impact of the Publicly Declared Emergency on ethics reviews is mild to moderate, research related to the Publicly Declared Emergency has priority for review.
- 4.3.4 When the impact of the Publicly Declared Emergency on ethics review is severe, time-sensitive review processes may be followed, such as delegated review or review by an REB subcommittee.

5.0 REFERENCES

1. Canadian Association of Research Ethics Boards and N2 Network of Networks (2023). Standard Operating Procedure 501.003: REB Review during Publicly Declared Emergencies.
2. 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 2022.
3. UBC Office of Research Ethics. (2018). Standard Operating Procedure 501: REB Review during Publicly Declared Emergencies.

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