Purpose:	To provide the Research Ethics Board (REB) a standardized approach for the research ethics review procedures during a publicly declared emergency as outlined by the Government of Canada, Canadian Standards Board and the Tri Council Policy Statement (TCPS2 (2018).
Scope:	• Affected Roles o REB Office Personnel o Manager, Research Ethics & Compliance o REB Chairs and Members • Environment o Island Health Wide • Research Environment
Outcomes:	• Procedures that facilitate quality, completeness, adequate documentation, and regulatory compliance in the conduct of research.

1 RESPONSIBILITY

1.1 All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

2 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 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.

During publicly declared emergencies, the REB 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, for example, REBs might not be able to meet in person, and delegated review procedures may have to be designed to respond to either urgent opportunities for new research or to 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.

3 Determining the Level of Impact

3.1 Subsequent to an officially publicly declared emergency, the REB Chair or designee will assess the level of impact on the research ethics review processes.

3.2 There are three levels of impact that may influence how ethics review will be conducted during the publicly declared emergency:

- **Mild** – little or no impact,
- **Moderate** – some impact; decisions to proceed at the discretion of the Chair or designee, in consultation with the Researcher, as necessary,
- **Severe** – extremely debilitating to normal research ethics review procedures

3.3 The REB Chair or designee will use the level of impact to guide the review of research submissions during the publicly declared emergency.

3.4 Pending the determination of the level of impact on the review of ongoing or new research, the currently established ethics review procedures should be followed.

4 EMERGENCY PREPAREDNESS PROCEDURES

4.1 Subsequent to an officially publicly declared emergency, alternative ethics review processes may be instituted.

4.2 When the impact on the ethics review processes is deemed to be severe, teleconferences or videoconferences may be used to conduct REB meetings.

4.3 When the impact on the ethics review processes is deemed to be severe, the REB Office Personnel may conduct their activities remotely (via remote email and voice mail access), with minimal disruption of services.

4.4 The REB Chair or designee may suspend the currently established REB meeting quorum, in which case an REB subcommittee would be established for the duration of the publicly declared emergency.

4.5 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.

4.6 The current REB Chair or designee should serve as the Chair of the REB subcommittee.

4.7 At their discretion, the REB subcommittee Chair 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 REB 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.

4.8 When the impact is deemed to be severe, the REB Chair or designee may refer the ethics review and research oversight of new and ongoing research to another REB, subject to the applicable regulations and agreements.

4.9 Where research submissions are deemed to be more than minimal risk and subject to applicable regulations, the REB Chair or subcommittee Chair or designee 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.

4.10 The REB Chair or designee should periodically assess the impact of the emergency on the ethics review processes and adjust any temporary ethics review processes accordingly.

4.11 Any alterations to usual REB practice 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 (e.g., as declared by an authorized public official). The REB Chair or designee will determine when to resume routine ethics review processes.

4.12 At the conclusion of the publically declared emergency, the REB Chair or designee and the REB Office Personnel should work with the REB subcommittee members to evaluate the effectiveness of its declared emergency procedures and to make recommendations for improvements.

4.13 All delegated approvals of research following a publicly declared emergency must be assessed to determine if subsequent Full Board review is required at the first opportunity subsequent to the cessation of the publicly declared emergency.

4.14 At the conclusion of the publicly declared emergency, the REB Chair or designee and the REB Office Personnel should work with the REB subcommittee members to evaluate the effectiveness of its declared emergency procedures and to make recommendations for improvements.

5 REVIEW OF ONGOING RESEARCH NOT RELATED TO OR ARISING FROM THE PUBLICLY DECLARED EMERGENCY

5.1 When the impact 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 REB Chair 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 REB Chair or designee in consultation with the Researcher, as necessary.
- Researcher's response to REB 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.
- Other submissions will be reviewed as time allows.

5.2 When the impact 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,
- Research activities involving recruitment or direct contact with participants may only continue if ceasing such activity might pose significant risks to participant safety,

- Major amendments and adverse events related to these studies will be reviewed by the REB subcommittee or the REB subcommittee Chair or designee, in accordance with regulatory agency requirements, as appropriate.

5.3 At the REB Chair 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 REB is able to conduct its review.

6 REVIEW OF NEW RESEARCH NOT RELATED TO OR ARISING FROM THE PUBLICLY DECLARED EMERGENCY

6.1 When the impact of the publicly declared emergency on ethics review is determined to be mild to moderate, the REB Chair or designee will determine whether review of any new research not related to the publicly declared emergency may proceed or will be postponed until after the emergency is over.

6.2 When the impact of the publicly declared emergency on ethics review processes is determined to be severe, any new research not related to the publicly declared emergency will not be reviewed until the emergency is declared to be over.

7 REVIEW OF RESEARCH RELATED TO OR ARISING FROM THE PUBLICLY DECLARED EMERGENCY

7.1 If a request to review research related to a publicly declared emergency is received, it will be directed to the REB Chair or REB subcommittee Chair or designee, as applicable.

7.2 The REB Chair 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.

7.3 When the impact of the publicly declared emergency on ethics reviews is determined to be mild to moderate, research related to the publicly declared emergency has priority for review.

7.4 When the impact 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 REB subcommittee, and/or meetings conducted via teleconference or videoconference.

8 TRAINING

8.1 Applicable roles related to the REB review of research will be trained on this SOP as appropriate.

9 COMPLIANCE MONITORING

9.1 The Island Health Manager, Research Compliance and Ethics or their delegate is responsible for ongoing monitoring of Island Health operations to verify compliance with this SOP.

9.2 The Island Health Manager, Research Compliance and Ethics or their delegate is responsible for communicating any changes to this SOP to all relevant personnel.

9.3 Deviations from this SOP will be addressed through corrective and preventative action implementation.

10 DEFINITIONS

10.1 **Publicly declared emergency:** 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 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

11 REFERENCES

Government of Canada, Canadian General Standards Board. CAN/CGSB -191.1-2013 Research ethics oversight of biomedical clinical trials (2013), Section 4.4.2.1: http://publications.gc.ca/collections/collection_2017/ongc-cgsb/P29-191-001-2013-eng.pdf

Government of Canada, Canadian General Standards Board. CAN/CGSB -191.1-2013 Research ethics oversight of biomedical clinical trials (2013), Section 4.4.2.2: http://publications.gc.ca/collections/collection_2017/ongc-cgsb/P29-191-001-2013-eng.pdf

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The TriCouncil Policy Statement: Ethical Conduct for Research Involving Humans, Article 6.21: http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter6-chapitre6/#toc06-1d

The TriCouncil Policy Statement: Ethical Conduct for Research Involving Humans, Article 6.22: http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter6-chapitre6/#toc06-1d

The TriCouncil Policy Statement: Ethical Conduct for Research Involving Humans, Article 6.23: http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter6-chapitre6/#toc06-1d

12 SUMMARY OF CHANGES

Version	Effective Date	Change Description
1.0	30 Mar 2020	New procedure