



TITLE: Standard Operating Procedure (SOP) Review During Publicly Declared Emergencies	NUMBER: NSHA REB-SOP-5-003
Effective Date: April 2014	Revision: September 29, 2017
Applies To: Executive Chair, Co-Chairs, NSHA REB members, REB Office Personnel and Researchers.	

1. PURPOSE:

The purpose of this standard operating procedure (SOP) describes the modified procedures, practices and preparedness plan of the Nova Scotia Health Authority Research Ethics Board (NSHA REB) during official publicly declared emergencies.

2. POLICY:

For the purpose of this SOP, 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 public policy and/or legislation. Publicly declared emergencies arise suddenly or unexpectedly, and require urgent responses (e.g. natural disasters, public health outbreaks, etc.). Such emergencies may render research participants, researchers and institutions more vulnerable than under normal circumstances.

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 a publicly declared emergency does not overrule established procedures to protect the welfare of research participants. Any modifications to 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. DEFINITIONS:

- 1) Emergency preparedness plan: Plans that detail an institution's policies and procedures for addressing research ethics review during public health outbreaks, natural disasters, and other publicly declared emergencies.
- 2) Publicly declared emergency: An emergency situation which, due to the extraordinary risks it presents has been proclaimed as such by an authorized public office (in accordance with legislation and/or public policy). Publicly declared emergencies are extraordinary events that arise suddenly or unexpectedly, and require urgent or quick responses to minimize devastation. Examples include hurricanes and other natural disasters, large communicable disease outbreaks, catastrophic civil disorders, bio-hazardous releases, environmental disasters, and humanitarian emergencies.

4. PROCEDURES:

4.1. Determining the Level of Impact

- 4.1.1. Subsequent to an officially publicly declared emergency, the REB Executive Chair or designee will assess the level of impact on the research ethics review processes;
- 4.1.2. 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;
- 4.1.3. The REB Executive Chair or designee will use the level of impact to guide the review of research submissions during the publicly declared emergency;
- 4.1.4. The REB Executive Chair or designee in consultation with the Executive Committee will identify and prioritize new and ongoing research activities deemed essential or time sensitive during the emergency;
- 4.1.5. 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.

4.2. Emergency Preparedness Procedures

- 4.2.1. Subsequent to an officially publicly declared emergency, temporary ethics review processes may be instituted. The REB may follow a modified review and operations plan which may include reasonable adjustments to

address the timing, locale, expertise, form and scope of research ethics review, and the holding of REB meetings during emergency situations;

- 4.2.2. In such cases, the research ethics office will communicate details of the modified review and the operations plan to the research community as necessary via email, phone or other suitable means.
- 4.2.3. When the impact on the ethics review processes is deemed to be severe, teleconferences or videoconferences may be used to conduct REB meetings;
- 4.2.4. 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;
- 4.2.5. The Executive 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;
- 4.2.6. 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;
- 4.2.7. The Executive Chair or designee should serve as the Chair of the REB subcommittee;
- 4.2.8. At his/her 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 (they cannot vote) and their presence shall not be used in establishing a quorum;
- 4.2.9. When the impact is deemed to be severe, the Executive 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;
- 4.2.10. Where research submissions are deemed to be more than minimal risk and subject to applicable regulations, the Executive 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;
- 4.2.11. 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;

- 4.2.12. The Executive Chair or designee should periodically assess the impact of the emergency on the ethics review processes and adjust any temporary ethics review processes accordingly;
- 4.2.13. 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 Executive Chair or designee will determine when to resume routine ethics review processes;
- 4.2.14. 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;
- 4.2.15. At the conclusion of the publically declared emergency, the Executive 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.

4.3. Review of Ongoing Research NOT Related to or Arising from the Publicly Declared Emergency

- 4.3.1. 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 Executive 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 Executive 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;
- 4.3.2. 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, as appropriate;

4.3.2. At the Executive 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.

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

4.4.1. When the impact of the publicly declared emergency on ethics review is determined to be mild to moderate, the Executive 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;

4.4.2. 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.

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

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

4.5.2. The Executive 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;

4.5.3. 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;

4.5.4. 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.

5 REFERENCES

- I. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2010 (TCPS2), Articles 2.7, 6, 6.21,6.22, 6.23;
- II. The International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines as adopted by Health Canada;
- III. Health Canada Therapeutic Products Directorate Food and Drug Regulations For Clinical Trials, Division 5.

6 RELATED DOCUMENTS: n/a

Version History

Effective Date	Major Revisions (e.g. Standard 4 year review)	Minor Revisions (e.g. spelling correction, wording changes, etc.)
June 3, 2016		Reflect the change from nine DHA's to one
September 29, 2017		Harmonize with CAREB/N2 SOP's