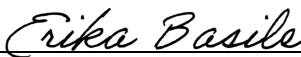



SOP Title	REB Review During Publicly Declared Emergencies
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Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
Erika Basile Director, Research Ethics and Compliance		Mar 4, 2025
Dr. Isha DeCoito Chair, Non-Medical Research Ethics Board		Mar 4, 2025

1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the research ethics review procedures during a publicly declared emergency.

2.0 GENERAL POLICY STATEMENT

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, communicable disease outbreaks, environmental disasters, and humanitarian emergencies. Such emergencies may represent significant risks for research participants. 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 NMREB 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 alternate review procedures may have to be designed to respond to either urgent opportunities for new research related to the emergency or to support the review of 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.

3.0 DEFINITIONS

See glossary of terms.

4.0 RESPONSIBILITY

This SOP applies to the Non-Medical Research Ethics Board (NMREB) Chair, Vice-Chair(s), NMREB members and to all Office of Human Research Ethics (OHRE) staff.

5.0 SPECIFIC POLICIES AND PROCEDURES

5.1 Determining the Level of Impact

5.1.1 Subsequent to a publicly declared emergency, the NMREB Chair or designee will assess the level of impact on the research ethics review processes. The assessment will consider factors including (but not limited to):

- Whether the publicly declared emergency affects some or all of the research reviewed by the NMREB, including:
 - The review of ongoing research that is unrelated to or not arising from the publicly declared emergency,
 - The review of new research that is unrelated to or not arising from the publicly declared emergency, and
 - The review of research that arises from or is related to the publicly declared emergency;
- The nature of the risks imposed by the publicly declared emergency on participants, the REB, and the OHRE staff;
- What research is considered “essential” during the emergency;
- The potential duration of any alterations in review procedures, if predicable.

5.1.2 Based on this assessment, there are three levels of impact that may influence how ethics review will be conducted during the public emergency:

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

5.1.3 The NMREB Chair or designee will use the level of impact to guide the review of research submissions affected by the public emergency;

5.1.4 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.

5.2 Emergency Preparedness Procedures

5.2.1 Subsequent to a publicly declared emergency, temporary ethics review processes may be instituted for some or all research studies; however, since the OHRE’s online system already allows for many of its review activities to be conducted remotely (when appropriate), the NMREB first would attempt to continue with its currently established administrative processes;

5.2.2 When the impact on the ethics review processes for some or all research is deemed to be severe, teleconferences or video conferences may be used to conduct the NMREB meeting(s);

5.2.3 When the impact on the ethics review processes is deemed to be severe, the OHRE staff may conduct their activities remotely (via the online system and remote email and voice mail access), with minimal disruption of services;

5.2.4 The NMREB Chair or designee may call *ad hoc* meeting(s) to support the urgent review of research affected by the publicly declared emergency. In such circumstances, there may also be alterations in the processes for notifying REB members, circulating documents, assignment of reviewers, and other administrative processes;

- 5.2.5 The NMREB Chair or designee may suspend the currently established REB membership and meeting quorum for the review of research affected by the publicly declared emergency;
- 5.2.6 If declared necessary by the REB Chair or designee, the NMREB composition and quorum for review of research affected by a publicly declared emergency will include at least five members drawn from the existing NMREB membership where possible, including:
- At least two (2) members with expertise in relevant scientific disciplines, field and methodologies covered by the REB;
 - At least (1) one member knowledgeable in research ethics;
 - At least one (1) community member who has no affiliation with the institution;
 - At least (1) member who is primarily experienced in non-scientific disciplines;
 - At least (1) one member knowledgeable in considering privacy issues;
 - Additional representation as required by applicable legislation or guidelines.
- 5.2.7 For studies subject to US federal regulations, if the regular membership is suspended for the review of research affected by a publicly emergency, the NMREB will consider the 50%+1 quorum requirement based on the alternate REB membership;
- 5.2.8 The current NMREB Chair or one of the current Vice-Chairs or a designee will normally serve as the Chair of the NMREB for the review of research affected by the publicly declared emergency;
- 5.2.9 At his/her discretion, the NMREB Chair or designee may invite individuals with expertise in special areas to assist in the review of issues that require expertise beyond that available. However, ad hoc advisors may not contribute directly to the NMREB's decision and their presence shall not be used in establishing a quorum;
- 5.2.10 Other modifications to the review procedures may be implemented, in compliance with the applicable guidelines and regulations and as deemed necessary by the REB Chair or designee;
- 5.2.11 Any modifications that are made in the application of research ethics policies and procedures related to a publicly declared emergency must be documented and appropriately justified;
- 5.2.12 The NMREB Chair or designee should periodically assess the impact of the emergency on the ethics review processes and adjust any temporary ethics review processes accordingly;
- 5.2.13 Any modifications that are made in the application of research ethics policies and procedures related to the review of research 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 NMREB Chair or designee will determine when to resume routine ethics review processes;
- 5.2.14 All approvals of research that follow an alternate review procedure must be assessed at the first opportunity to determine if additional review is required. This may be at the next regularly scheduled full board meeting (e.g., if the declared emergency affects only a subset of research) or subsequent to the cessation of the publicly declared emergency;
- 5.2.15 At the conclusion of the publicly declared public emergency, the NMREB and the OHRE staff should evaluate the effectiveness of its declared emergency procedures and make recommendations for improvements.
- 5.3 Review of Ongoing Research NOT Related to or Arising from the Publicly Declared Emergency**
- 5.3.1 When the impact of the public emergency on ethics review of research not related to or arising from the emergency is determined to be mild to moderate, the following principles will apply to the review of ongoing research:

- The NMREB 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 NMREB Chair or designee in consultation with the Investigator, as necessary,
 - Submissions related to participant safety including reportable events and amendments related to safety concerns will be prioritized for review,
 - Continuing reviews will receive the priority for review, followed by investigator responses to NMREB reviews, other amendments, and study completion reports,
 - Other submissions will be reviewed as time allows;
- 5.3.2 When the impact of the public emergency on ethics review of ongoing research unrelated to the emergency is determined to be severe, the following principles 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,
 - The NMREB may require suspension of enrolment of new participants
- 5.3.3 Submissions related to participant's safety, including reportable events and amendments related to safety concerns will be prioritized for review. Continuing reviews will receive the net priority for review, followed by investigator responses to NMREB reviews, non-safety amendments, and study completion reports;
- 5.3.4 The NMREB may implement any/all of the emergency preparedness procedures as deemed appropriate to the research/emergency.
- 5.4 Review of New Research NOT Related to or Arising from the Publicly Declared Emergency**
- 5.4.1 When the impact of the public emergency on ethics review is determined to be mild to moderate, the NMREB 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;
- 5.4.2 When the impact of the public emergency on ethics review processes is determined to be severe, any new research not related the publicly declared emergency will not be reviewed until the emergency is declared to be over.
- 5.5 Review of Research RELATED to or Arising from the Publicly Declared Emergency**
- 5.5.1 Requests to review research related to a publicly declared emergency, will be directed to the NMREB Chair or designee to assess the impact of the research;
- 5.5.2 The NMREB 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;
- 5.5.3 Considerations will be given to the alterations in the ethics review process of new research projects arising from the research and for changes to approved, research related to the emergency;
- 5.5.4 NMREB may implement any/all the emergency preparedness procedures as deemed appropriate to the research/emergency.

6. REFERENCES

6.1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2);

7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyyy
N502.001	Original	07/08/2016
N502.002	Update to NMREB and Administrative revisions	05/11/2018
N502.003	Update to be consistent with HSREB SOP	02/21/2025