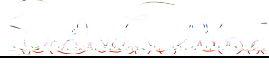


SOP Title	REB Review During Publicly Declared Emergencies
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Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
Erika Basile Director, Research Ethics		
Dr. Randal Graham Chair, Non-Medical Research Ethics Board		

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 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 clinical trials or in new clinical trials initiated as a result of the emergency. Potential research participants who may not normally be considered vulnerable may become so because of 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 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 safety 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 an officially declared public emergency must be documented and properly 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

- 5.2.7 At his/her discretion, the NMREB 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 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;
- 5.2.8 Where research submissions are deemed to be more than minimal risk, the NMREB Chair or subcommittee Chair or designee will use his/her judgement 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
- 5.2.9 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;
- 5.2.10 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;
- 5.2.11 Any modifications that are made in the application of research ethics policies and procedures during an officially declared public 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;
- 5.2.12 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
- 5.2.13 At the conclusion of the publically declared public emergency, the NMREB Chair, the NMREB Vice-Chairs, and the OHRE staff should work with the NMREB subcommittee members to evaluate the effectiveness of its declared emergency procedures and to 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 is determined to be mild to moderate, the following 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,
- Investigator responses, NMREB reviews, major amendments, and adverse events will be prioritized for review,
- Continuing reviews will receive the next priority for review, followed by study completion reports,
- Other submissions will be reviewed as time allows;

- 5.3.2 When the impact of the public 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 NMREB subcommittee or the NMREB subcommittee Chair or designee, as appropriate;

5.3.3 At the NMREB Chair's or designee's discretion, review procedures may be delayed or temporarily