# REB Review Procedures and Research Conduct During Publicly Declared Emergencies

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## PURPOSE

1. The purpose of these Standard Operating Procedures (SOP) is to describe the modified research ethics review procedures and practices during a Publicly Declared Emergency. During a Publicly Declared Emergency, the REB membership and staffing levels may be reduced. This will result in delayed or postponed research ethics reviews for non-essential studies involving human participants or human biological materials until membership and staffing levels return to full complement. This SOP is to supplement the University's Emergency Preparedness Plan. Researchers are expected to refer to the University website, as well as trusted and official sources of information related to the emergency for up to date information.

## DEFINITIONS

2. For the purposes of these Procedures the following definitions apply:

   **"Biological Materials"** refers to any human tissues, organs, blood, plasma, serum, DNA, RNA, proteins, cells, skin, hair, nail clippings, urine, saliva and other body fluids, embryos, fetuses, fetal tissues, reproductive materials, and stem cells collected from participants for research purposes.

   **"Publicly Declared Emergency"** referred to as "emergency or emergencies" throughout this SOP, 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.

   **"Research Participants"** describes individuals whose data, or responses to interventions, stimuli or questions by a researcher are gathered or utilized for the purposes of a research project.

**"Minimal Risk"** is defined as research in which the probability and magnitude of possible harm implied by participation in the research is no greater than that encountered by Research Participants in those aspects of their everyday life that relate to the research.

**"Ongoing Research"** refers to research activities that are currently approved and/or active recruitment and/or data collection on Research Participants.

**"Post Approval Events"** are submissions to the REB where the initial approval was granted to the REB and the PI is seeking approval for ongoing research activities. The Post Approval Events include change requests, additional documentation, Unanticipated Event Notification, project completion and renewal requests.

**"Principal Investigator (PI)**" is the head of the research team who has overall responsibility for the ethical conduct of the study and for the actions of any member(s) of the research team. The PI is responsible for communicating any changes to the study, material incidental findings, new information, and/or unanticipated events to their own REB as well as to local site researchers for multi-site studies, who must then inform their respective local REBs.

**"Research"** is defined as the systematic investigation to establish and communicate facts, principles, understandings, or generalizable knowledge. Research involving Research Participants may include, but is not limited to, projects where data are derived through:

a. the collection of information through any interaction or intervention with a living individual;
b. the secondary use of data previously collected from Research Participants;
c. identifiable private information about an individual; and/or
d. human remains, cadavers, human organs, tissues and biological fluids, embryos, or fetuses.

**"REB"** refers to the Research Ethics Board authorized by the University.

**"REB Administration"** includes the Research Ethics Officer and/or REB delegate who provides operational support to the University research ethics framework and REB.

**"Delegate"** is assigned responsibility by the REB Chair for decision-making to provide ethics review support to the University REB.

**"Tri-Council Policy Statement 2: Ethical Conduct for Research Involving Humans (TCPS2)"** is the joint policy of Canada's three federal research agencies – the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC). This policy outlines ethical norms relevant to the conduct of research involving humans.

**"University"** refers to Ontario Tech University.

## SCOPE AND AUTHORITY

3. The REB Chair (or delegate), REB Administration and/or REB delegate are responsible for executing, overseeing the implementation, administration and interpretation of these procedures, as well as to ensure that the research ethics review is compliant with the applicable regulations and guidelines.

## PROCEDURES

4. Research ethics review during emergencies may necessitate the use of innovative and modified 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.
5. Research activities directly related to the emergency and deemed as essential has priority for review over other research submissions.
6. If a request to review research related to an emergency is received, it will be directed to the REB Chair (or delegate) for assessment.
7. The REB Chair (or delegate) will assess the risks associated with the proposed research, as well as aspects of the research that might require enhanced scrutiny or diligence, considering the risk/harm exposure of the emergency on ethics review processes and conduct of research activities involving humans.

### 8. Determination of Essential Work

8.1 Subsequent to an officially Publicly Declared Emergency, the REB Chair (or delegate), in consultation with the University Risk Management and the Executive Director of the Office of Vice-President Research and Innovation (VPRI), if necessary, will assess and prioritize new and ongoing research activities deemed **essential** during the emergency.

8.2 During the emergency**, essential** research activities include:

a. New studies directly related to the emergency,
b. Change requests directly related to the emergency,
c. Change requests that affect the safety of Research Participants for unrelated studies to the emergency.

8.3 **Non-essential** research activities include:

a. Other new studies (e.g. delegated, secondary use of data, human tissue, Multi-Jurisdictional Research, course-based research, exemptions) not related to the emergency.
b. Post approval events (e.g. changes requests, additional documentation, Unanticipated Event Notification, project completion and renewal requests) which are not related to the emergency or do not affect the safety of Research Participants.

## 9. Essential Research Submissions

9.1 Review priority will be given to any essential new or approved research because new information may become available and require timely action during emergencies.

9.2 The REB Chair (or delegate) shall use their judgement and the principles of the TCPS2 to assign the review pathway for the studies (e.g. full board review or delegated review).

9.3 For studies that have been deemed as **essential**, the REB Chair (or delegate), in consultation with University Risk Management and the Executive Director of the Office of VPRI, if necessary, will identify the level of risk exposure on the research ethics review processes and research participants.

9.4 There are three levels that may impact the ethics review processes and expose the research participants to foreseeable risks or harm during an emergency. The levels of risk exposure are:

a. **Mild**: No known harm/risk;
b. **Moderate**: some harm/risk where the REB Chair (or delegate), in consultation the University Risk Management and Executive Director of the Office of VPRI, if necessary, will decide at their discretion to proceed with the research;
c. **Severe**: known harm/risk where the REB Chair (or delegate) will advise to suspend the research from moving forward until the imminent harm/risk is removed.

9.5 The determination of the research activities (e.g. essential or non-essential) and the level of risk/harm exposure during the ethics review processes and to the Research Participants for ongoing or new research (e.g. mild, moderation or severe) shall be used to guide the ethics review procedures during an emergency.

## 10. Modifications to REB Review Procedures and Practices

10.1 The REB Chair (or delegate) will consider the pressures, time constraints, priorities and logistical challenges that may arise during the event to ensure that the quality of ethics review is maintained and is timely, proportionate and appropriate.

10.2 Subsequent to an officially Publicly Declared Emergency, temporary and modified ethics review processes may be instituted. The Research Ethics Office will communicate details of the modified review to the Research Community as necessary via email, phone or other suitable means.

10.3 The REB Chair (or delegate) and/or REB Administration will facilitate the ethics review of new and ongoing research for submissions deemed as essential during and arising from the emergency.

10.4 When the ethics review process is deemed to expose the REB Chair (or delegate), REB members, REB Administration and/or REB delegate to a **moderate to severe** level of risk/harm during the emergency, their activities shall be conducted remotely (via remote email, network access and voice mail access), with minimal disruption of services.

10.5 In remote settings, REB Chair (or delegate), REB members, REB Administration and/or REB delegate must ensure meeting discussions are private to respect confidentiality of the discussion.

10.6 The REB Chair (or delegate), and/or REB administration shall periodically assess the impact of the emergency on the ethics review processes and adjust any temporary ethics review processes accordingly.

10.7 Any modifications that are made in the application of research ethics policies and procedures during an emergency must be documented and appropriately justified.

## 11. Essential REB Submissions Requiring Full Board Review

11.1 When the research activities are considered above Minimal Risk as defined by the TCPS2 and the level or risk/harm exposure to the REB Chair (or delegate), REB members, REB Administration and/or REB delegate is deemed as **mild** during the emergency, the established REB review procedures shall be followed as outlined in REB SOP 205 (The Full Review Process).

11.2 When the research activities are considered above Minimal Risk as defined by the TCPS2 and the level or risk/harm exposure to the REB Chair (or delegate), REB members, REB Administration and/or REB delegate is deemed as **moderate to severe** during the emergency, the REB Chair (or delegate) may suspend the currently established REB meeting, in which case a modified REB subcommittee would be established for the duration of the emergency.

- 11.2.1 The REB subcommittee must be organized in a timely manner and will have a composition in accordance with the standard REB membership requirements as outlined in the TCPS2 and must include at least five members drawn from the existing REB membership. A quorum is required for the meeting to be convened and this will be recorded in the REB meeting minutes.
- 11.2.2 The current REB Chair (or delegate) shall serve as the Chair of the REB subcommittee.
- 11.2.3 The REB Subcommittee, REB Administration and/or REB delegate shall use remote methods of communication such as teleconference or videoconference to conduct REB meetings. At their discretion, the REB subcommittee Chair (or delegate) 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.
- 11.2.4 At the discretion of the REB Chair (or delegate) when the risk/harm exposure during the emergency is **severe**, the REB Chair (or delegate) may defer the ethics review and research oversight of new and ongoing research to another REB, subject to the applicable regulations, agreements and acceptance of the ethics review.

## 12. Essential REB Submissions Requiring Delegated Review

12.1 Where research submissions are deemed as **essential** and Minimal Risk according to the principles of the TCPS2, a delegated review will commence according to the REB's established review process as outlined in REB SOP 204 Delegated Review.

12.2 All delegated approvals of research which followed a modified review process shall be assessed following an emergency to determine if subsequent Full Board review is required at the first opportunity subsequent to the cessation of the emergency.

## 13. Non-Essential Research Submissions

### 13.1 New Submissions

13.1.1 When the risk/harm exposure of the Research Participants during an emergency is determined to be **mild to moderate,** the REB Chair (or Delegate) will determine whether review of any new research **not related** to the emergency may proceed or will be postponed until after the emergency is over.

13.1.2 When the risk/harm exposure of the Research Participants during an emergency 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.

### 13.2 Ongoing Research

13.2.1 When the risk exposure of the Research Participants during an emergency is determined to be **mild to moderate,** the following will apply to the review of ongoing research:

a. The REB Chair (or Delegate) will determine if the research needs to continue, or if it can be postponed until after the emergency is over,
b. The research may continue at the discretion of the REB Chair (or Delegate) in consultation with University Risk Management and the Executive Director of the Office of VPRI, if necessary,
c. At the discretion of the REB Chair (or Delegate), and in consultation with the Biosafety Officer if necessary, special considerations must be made on the use of research equipment that are likely to increase the risk of transmission of infectious diseases (e.g. V02 Max), collection and handling of Biological Materials.
d. A PI's response to REB reviews and Post Approval Events will receive the next priority after the essential research studies are reviewed, and
e. Other submissions will be reviewed as time permits.

13.2.2 When the risk exposure of the Research Participants during an emergency is determined to have **severe** risk/harm exposure**,** the following will apply to the review of ongoing research:

a. **All** research activities involving **direct contact** with potential Research Participants must cease,
b. At the discretion of the REB Chair (or Delegate) and in consultation with the University Risk Management and the Executive Director of the Office of VPRI, if necessary, research activities involving direct contact with potential Research Participants may only continue if ceasing such activity might pose significant risks to participant safety,
c. Change requests and Unanticipated Event Notifications related to these studies will be reviewed by the REB subcommittee or the REB subcommittee Chair (or Delegate) as appropriate.

13.2.3 At the REB Chair's (or Delegate'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.

13.3 Risks in research are not limited to research participants as the conduct of research may expose the researchers to risks/harms that may take many forms. Risks to researchers may become a safety concern, especially for student researchers who are at a learning stage regarding the conduct of research in unsafe situations. While it is not a formal part of the REB's responsibilities, the REB may raise concerns about the safety of researchers, including student researchers. Based on the level of risk, the REB may consider referring these concerns for review by the University Risk Management and the Executive Director of the Office of VPRI.

**14. Onset and Termination of Modified REB Review Procedures and Practices**

13.4 Any modifications to the REB procedures and practices will take effect only once an emergency has been declared.

13.5 The modifications will cease to apply after the end of the emergency.

13.6 The REB will endeavour to return to its normal standard operating procedures as soon as possible after public officials have declared that the emergency is over.

13.7 The REB Chair will advise the REB and minute all modifications to standard operating procedures at the first meeting following its return to normal operating procedures.

13.8 At the conclusion of the emergency, the REB Chair (or Delegate), and/or the REB Administration shall work with the REB subcommittee members to evaluate the effectiveness of its declared emergency procedures and to make recommendations for improvements.

## MONITORING AND REVIEW

These Procedures will be reviewed as necessary and at least every three years (unless another timeframe is required for compliance purposes). The REB Chair and REB Administration, or successor thereof, is responsible to monitor and review these Procedures.

## RELATED POLICIES, PROCEDURES & DOCUMENTS

Canadian Association of Research Ethics Board and N2 (Networks of Networks).
Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2, 2018)
REB SOP 204 Delegated Review
REB SOP 205 The Full Review Process