Research Ethics During Publicly Declared Emergencies

Guidance to support the implementation of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS)

Panel on Research Ethics

www.ethics.gc.ca

Copies of this guidance may be printed or downloaded from the Panel on Research Ethics website.

Government of Canada Gouvernement du Canada

Canada

Secretariat on Responsible Conduct of Research
secretariat@srcr-scrr.gc.ca
www.pre.ethics.gc.ca

On behalf of the:

Canadian Institutes of Health Research: www.cihr-irsc.gc.ca

Natural Sciences and Engineering Research Council of Canada: www.nserc-crsng.gc.ca

Social Sciences and Humanities Research Council of Canada: www.sshrc-crsh.gc.ca

Aussi disponible en français sous le titre : Éthique de la recherche lors d'urgences publiques déclarées

Also available online in PDF and HTML formats

© His Majesty the King in Right of Canada, as represented by the Minister of Health and the Minister of Innovation, Science and Industry, 2026

Catalogue No: MR4-214/2026E-PDF
ISBN: 978-0-662-29740-6

Table of Contents

Part I: Context **2**

1. Introduction 2
2. Purpose 3
3. Scope 3
4. The nature of a publicly declared emergency and its outcomes 4
5. The declaration of a public emergency 5

Part II: Guidance **5**

6. Preparedness plans for publicly declared emergencies 5
   a) Create and sustain adaptive preparedness plans 5
   b) Establish and strengthen collaborations and agreements with other institutions and REBs 7
7. The impacts of a publicly declared emergency 9
   a) Impact on institution and REB operations 10
   b) Impact on researchers and research participants 16
8. Examples of considerations by REBs in the ethics review of research during a publicly declared emergency 20
   a) Risks and benefits of research 20
   b) Conduct of research 21
   c) Requirements, approvals, and permissions 21

Part III: Practical application **22**

Scenario 1: Multi-jurisdictional research during forest fires (wildfires) 22

Scenario 2: Research on a respiratory life-limiting virus 24

Scenario 3: Research involving a Canadian remote community recently exposed to a severe flood 27

Scenario 4: Canadian researchers evaluating the success of emergency response during a hurricane abroad 29

Part I: Context

1. Introduction

Publicly declared emergencies—whether natural hazards, environmental disasters, or major disease outbreaks—require urgent, ethically sound research and are likely to require changes to ongoing research. During publicly declared emergencies, (also referred to as "emergency" and "public emergency" in this document), researchers and research ethics boards (REBs) may face unique challenges shaped by the urgency, unpredictability, and evolving demands of the emergency. Shifting public health directives and rapidly changing requirements can disrupt or halt the usual institutional operations and REB deliberations. Emergencies may severely impact the ethical conduct of research and compromise participant well-being. Conducting ethical research under these conditions requires heightened attention to participant protections.

Since 2010, Chapter 6, Section D of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS) has addressed research ethics review during publicly declared emergencies, emphasizing the importance of the continuity of REB operations to review the ethical acceptability of research. Emergency-specific research studies are vital for generating real-time data to guide response efforts, develop treatments, shape public health policies, and strengthen future preparedness. Meanwhile, certain ongoing critical research activities – unrelated to the emergency – must continue so as to support ongoing research in potentially high impact and life-saving interventions in such areas as medical, surgical and mental health domains. The coronavirus disease 2019 (COVID-19) pandemic underscored the critical need for proactive planning to maintain REB review processes and ensure the safe continuation of research – both new and ongoing – without introducing unnecessary risks or further exacerbating the participants' situation.

This guidance includes examples of ethical considerations for institutions, REBs, and researchers to support the protection of research participants and to uphold public trust in the ethics review and conduct of research during publicly declared emergencies. It concludes with practical application of the guidance through illustrative scenarios drawn from various publicly declared emergency contexts.

This guidance acknowledges the considerable variation in the roles, responsibilities, and organizational structures of REBs, including REB Chairs (and Vice Chairs), and the research ethics administration staff across institutions, especially those with multiple REBs. Unless the guidance is specific to a particular role (e.g., REB Chair), the reference to "REB" is intended to encompass REB members, research ethics administrators, and —where applicable—other members of the institution's research ethics office, whether or not they serve on the REB.

2. Purpose

The Panel on Research Ethics (PRE) developed this guidance as an educational resource to support and expand on the current guidance in Chapter 6, Section D of the TCPS. Drawing from the research community's experience during the COVID-19 pandemic, it integrates PRE's previously issued public interpretations to assist the community during the COVID-19 pandemic and adapts them to a wider spectrum of publicly declared emergencies—such as natural hazards of forest fires and floods.

While some material may be familiar to those well-versed in the topic, this guidance serves as a complementary resource for institutions, REBs, and researchers, reinforcing key concepts and ensuring consistency with the TCPS. It is not meant to override institutions and REBs efforts in developing their own emergency preparedness plans or policies.

3. Scope

This guidance applies to public emergencies that have been declared as such by an authorized official and that meet the following definition and TCPS requirements outlined in Chapter 6, Section D:

> "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 […] 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. They tend to be time limited. They may severely disrupt or may destroy normal functioning of institutions and communities, as well as individual lives."

Although outside the primary scope of this document, the guidance may also inform and be applied proportionately to other types of disruptions, events, or incidents that, while not publicly declared emergencies, can similarly impact an REB's capacity to assess the ethical acceptability of research. Examples of non publicly declared emergencies that may disrupt the orderly ethics review of research include, but are not limited to, labour disruptions at a university, hospital, or other public institution, or hazardous environmental or cyber incidents within an institution. Where relevant and appropriate, institutions may consider this guidance to inform their preparation for such disruptions.

4. The nature of a publicly declared emergency and its outcomes

Publicly declared emergencies vary in type, scope, and impact. For example, natural hazards—such as forest fires, earthquakes, and hurricanes—typically pose acute risks, are time-limited, and affect specific geographic areas. In contrast, health emergencies like outbreaks or pandemics may require extensive public health responses and can spread across borders.

These emergencies may be localized to a region, municipality, or province/territory, or escalate to national or international levels. Some may disproportionately affect specific communities—for instance, Indigenous communities in rural, northern, or remote areas often face heightened exposure to hazards like wildfires or floods. Emergencies may also arise in other countries where Canadian researchers are actively conducting research.

Each context presents distinct ethical and safety considerations, particularly regarding the impact on research participants, the conduct of research, and on the responsibilities of institutions, REBs, and researchers (see section 7 of this guidance document).

5. The declaration of a public emergency

Based on the TCPS, research ethics policies and procedures for emergencies "take effect once an emergency has been publicly declared" (Article 6.22). The delegation of authority to declare a public emergency is based on legislation and/or public policy. Public officials authorized to declare a public emergency will vary based on the jurisdiction and/or country in which the public emergency occurs.

The declaration of a public emergency is normally associated with terms and conditions determined by the declaring authority and informed in part by the nature and magnitude of the emergency. Canada has an *Emergencies Act* that allows the federal government to declare a national emergency, while each province and territory has its own legislation that empowers local authorities and the provincial/territorial government to declare a state of emergency. Other countries, where some Canadian researchers subject to the TCPS conduct their research, may also have their own processes and legislation for declaring a public emergency.

Institutions, REBs, and researchers conducting research during a publicly declared emergency must recognize and follow emergency guidelines and/or relevant disaster emergency laws that apply to their situation or context. Where guidelines/laws differ across research sites or in local jurisdictions in Canada and other countries, the more stringent or protective approach should be followed, and guided by the core principles of the TCPS: Respect for Persons, Concern for Welfare, and Justice.

Part II: Guidance

6. Preparedness plans for publicly declared emergencies

a) Create and sustain adaptive preparedness plans

In anticipation of pressures, time constraints, priorities, and logistical challenges that may arise during public emergencies, and to ensure quality, timely, proportionate and appropriate research ethics review, the TCPS states that "[i]n collaboration with their researchers, institutions and their REBs should develop preparedness plans for emergency research ethics review" (Article 6.21).

Examples of elements that institutions and their REBs may include in preparedness plans are provided in the Application of Article 6.21.

The TCPS also states that "[r]esearch ethics review during publicly declared emergencies may follow modified procedures and practices" that are limited in scope and justified proportionate to the nature, magnitude, and impact of the public emergency (Article 6.21). Section 7a of this guidance document provides examples of such modified procedures and practices.

Table 1 summarizes key criteria for institutions and their REBs to consider in the development of preparedness plans.

Table 1: Key criteria in the design of preparedness plans

Preparedness plans should be	
Dynamic, responsive for temporary activation, and adaptive to nature of the emergency	The design of the preparedness plan allows for temporary activation when necessary. The design of the preparedness plan is flexible and adaptable to the nature of the emergency, acknowledging the diverse contexts of publicly declared emergencies (as mentioned in section 4 of this guidance document), and the varying impacts these may have on research participants, research conduct, and the REB review process.
Fair and reasonable	The implementation of the preparedness plans "should adhere rigorously to a rule of reasonable, fair, and principled design and use during publicly declared emergencies" (Application of Article 6.21). What is deemed "reasonable" or "fair" may evolve as an emergency unfolds and therefore will require periodic reassessment during the emergency.
Assessed for effectiveness and improvement	Institutions, working with their REBs and researchers, are expected to assess the effectiveness of their preparedness plans within a reasonable timeframe following their implementation to identify areas for improvement and make any necessary adjustments.

Reviewed for relevance and applicability	It is important that preparedness plans are reviewed periodically, for example every three years, for current and emerging issues that may impact the relevance and applicability of the plans.
Integrated into training, and awareness-building (REBs/researchers)	Institutions are encouraged to incorporate the requirements and implementation of the plans into ongoing REB training. Institutions and their REBs are expected to: • promote awareness and training for researchers on ethical considerations in research conducted during publicly declared emergencies, whether in Canada or abroad. • proactively remind researchers of their responsibility to seek REB review for any new, unforeseen risks, or significant modifications that may arise due to a public emergency (Articles 6.15 and 6.16).

In addition to developing preparedness plans, other institutional and REB responsibilities include developing a mechanism for announcing their publicly declared emergency procedures.

While not a formal part of their responsibilities, REBs may have concerns about the safety of researchers and the research team (e.g., the availability of personal protective equipment, travel to locations of civil unrest, or inadequate infrastructure). In such situations, REBs should share those concerns with the researchers or refer them to other appropriate bodies within the institutions, such as offices responsible for occupational health and safety, or public health and risk management (Chapter 2, Risks to researchers).

b) Establish and strengthen collaborations and agreements with other institutions and REBs

In preparation for, and during publicly declared emergencies in Canada, REBs are strongly encouraged to collaborate and proactively share information and tools with their counterparts, as well as streamline the ethics review processes of their research, multi-jurisdictional or otherwise (Article 8.1). For example, as

institutional preparedness plans are being developed or updated, it is beneficial for REBs to explore collaborations with REBs at other institutions. This will allow for a shared understanding of how they might assist each other and facilitate the ethics review process during a publicly declared emergency, particularly for research involving multiple jurisdictions. Table 2 summarizes approaches to REB review of multi-jurisdictional research based on risk level of research.

Table 2: REB review of multi-jurisdictional research during public emergencies

For minimal risk research	For more than minimal risk research
With the support of their institutions, REBs can adopt a single REB review model without entering into an official agreement (Article 8.1). For further guidance, refer to *Applying the Single REB Review Model for Multi-jurisdictional Minimal Risk Research*	REBs should— with the support of their institutions—maintain and renew existing agreements. They should also consider developing new agreements with other institutions that they can implement, as needed.
Where applicable, continuing or reinstating the REB's practices, developed during the COVID-19 pandemic, that facilitated ethics review are also encouraged.	

Agreements for research ethics review can serve multiple purposes. Table 3 highlights purposes and an optional function of institutional agreements for REB review.

Table 3: Purposes and uses of REB review agreements

Primary purposes*	**Enable external REB review during emergencies** Enabling an external REB to assume full responsibility for the ethics review in situations where the responsible REB is unable to operate within the context of a publicly declared emergency – this would also involve providing access to relevant online systems and applications.
	Streamline multi-jurisdictional reviews (more than minimal risk research).

	Streamlining the ethics review process for more than minimal risk multi-jurisdictional research, thereby facilitating the timely conduct of ethically acceptable research during such emergencies.
*Arrangements remain subject to applicable provincial/territorial legislation, as well as any operational or other approvals required by external organizations, such as hospitals and health authorities in the case of clinical studies.	
Optional function	**Function as a contingency for non-emergency disruptions** Possibly serving as a contingency plan for emerging situations beyond the scope of this guidance. For example, in a non-publicly declared emergency such as labour disruptions, maintaining ongoing ethics review ensures the continuity of certain research that if stopped, could adversely affect participants' safety and well-being.

7. The impacts of a publicly declared emergency

Based on the TCPS Article 6.23, REBs and researchers should recognize that prospective participants, researchers, and institutions may not typically be in situations of vulnerability but may find themselves in such circumstances due to the nature of public emergencies. Those already facing such situations may experience heightened impacts. Where the research involves specific communities impacted by the emergency, researchers and REBs shall consider, where relevant and appropriate, guidance specific to that community, including meaningful engagement and guidance from community leadership (Article 2.11 and Chapter 9).

The location and context in which a publicly declared emergency occurs matters, including whether and how the emergency impacts (a) the institution and its REB operations, and (b) researchers and research participants.

Table 4 summarizes the impacts of a publicly declared emergency on the institution, REB operations, researchers, and participants. These impacts are further detailed in the text following the table.

Table 4. Overview: The impacts of a publicly declared emergency

Section	Impact	Key Considerations
7a	Institution and REB operations	Adjustments to REB procedures, continuity planning, and expanded roles. Priority setting and triage factors for REB review during the public emergency.
7b	Researchers and research participants	Researcher responsibilities during emergencies. Potential risks resulting from participation in research during emergencies.

a) Impact on institution and REB operations

Challenges: When no public emergency is declared, institutions remain responsible for fulfilling the requirements of the TCPS. In situations where institutions and their REB(s) are directly impacted by a public emergency (i.e., the emergency occurs within their country, province/territory, city or region), REBs may face challenging circumstances, time pressures to review an increased volume of applications for new research, and amendments to ongoing research. Having the necessary tools and resources to enable the continuity of REB operations will help support REBs in maintaining the quality and rigour of their ethics reviews with a focus on participant protection.

Managing challenges through adjustments: To manage the impact on REB operations, institutions in collaboration with their REBs should consider in their preparedness plans that "REB procedures may warrant reasonable adjustments to address the timing, locale, expertise, form and scope of research ethics review, and the holding of REB meetings during emergency situations" (Article 6.21). The need to modify normal procedures or practices should be justifiable, and proportionate to the need and, "Institutions and REBs must endeavour to return to normal operating procedures as soon as possible after public officials have declared that the emergency is over" (Application of Article 6.22).

Authorization: Typically, where a public emergency affects an REB's operations and necessitates modifications to its procedures and practices, such modifications are only made once the institution's authorized representative has formally acknowledged the declaration made by the public official. The REB may also disseminate this acknowledgement to their researchers.

Even once an end to the emergency is declared, local operational challenges may persist. To maintain the REB's operational efficiency, modified or newly adopted institutional procedures may continue temporarily—provided they are compliant with the TCPS.

Examples of adjustments: The following are examples of possible modifications to normal REB procedures that could facilitate the continuity of the ethics review process during publicly declared emergencies.

(i) Provide REBs with access to alternate modes of communication: Access to virtual communication platforms and technical supports enable REBs to hold their meetings virtually using secure digital platforms, when in-person meetings are not possible (Article 6.2). This includes offering training to REB members on technology requirements and virtual meeting etiquette.

(ii) Prepare for a potential surge in REB review requests, address expertise needs, and manage REB member shortages.

- To manage a possible increase in requests for ethics review of research requiring full board review, REBs may increase their capacity for review. For example, REBs may increase the frequency of their meetings or schedule special ad hoc meetings. With the anticipated increase in requests for REB review of minimal risk research, as well as amendment requests for ongoing research during a publicly declared emergency, streamline REB processes through more robust use of delegation models—particularly involving REB administrative staff (Article 6.12). Consider digital methods such as email and other online processes to support prompt processing of applications.

- A standard practice to maintain REB membership during emergencies is to expand the pool of subject matter experts who can serve as ad hoc advisors. This ensures that REBs can access the necessary expertise, when needed, to evaluate the ethical acceptability of research,

particularly during a public emergency that involves specific communities or is conducted outside Canada (Article 6.5).

- REBs may experience a shortage of reviewers and/or administrative staff due to institutional closure or illness. To maintain quorum and preserve the REB membership composition, it is advisable to expand the pool of appropriately trained, substitute REB members who can step in, as needed. It is also worthwhile to consider re-engaging former REB members, including experienced community members, where appropriate (Application of Article 6.4). The substitutes can help ease the workload of existing members and serve as backups when regular members are unavailable due to personal or professional obligations, or to disruptions caused by the public emergency.
- Where applicable, continue implementing the REB's established practices for facilitating ethics review that were developed during the COVID-19 pandemic. Well-developed delegation procedures and pathways may also enable research ethics administrative staff to offset reviewer shortages and availability, helping maintain continuity and responsiveness in ethics review during times of increased demand or limited resources.

(iii) Consider the additional responsibilities of research ethics administration: During a public emergency, research ethics administration staff may undertake additional responsibilities. This includes, but is not limited to:

- Supporting the development of REB review triage processes and their implementation, in consultation with REB Chairs and Vice-Chairs.
- Modifying/aligning research ethics review processes across REBs at their institutions, if their institution has more than one REB, in consultation with REB Chairs.
- Acting as the main point of contact, liaising, and coordinating with external REBs to enable rapid communication and information sharing related to ethics reviews and approvals during public emergencies.
- Supporting the overall implementation of the institutional preparedness plan for ethics review during publicly declared emergencies and its documentation.

- Contributing to the plan's evaluation and recommendations for enhancements post emergency.

(iv) Consider the expanded responsibilities of the REB Chair: During a public emergency, the REB Chair may need to take on expanded responsibilities including triaging and liaising with other institutional REB Chairs. The REB Chair may also contribute to the evaluation of the preparedness plan post emergency. Additional responsibilities of the REB Chair include, but are not limited to:

- In partnership with research ethics administration staff and other relevant bodies of the institution, the REB Chair assesses the scope of the emergency and its impact on research and research ethics review procedures. This will help inform and justify the need to introduce any modified procedures and practices.
- With the support of the research ethics administration staff, the REB Chair takes a more active role in triaging requests for ethics review and determining the appropriate level of review (delegated/full review) required during the emergency.
- In the event that the Chair cannot undertake their responsibilities, designating a substitute REB Chair, likely the Vice-Chair(s) where applicable, is especially important considering the expanded decision-making responsibilities required by the Chair during a public emergency (Article 6.8).

During public emergencies, the REB Chair exercises discretion in applying streamlining processes, including delegating tasks to Vice-Chair(s) and research ethics administration staff when appropriate, to effectively manage the increased demand for ethics reviews.

(v) Setting priorities using a triage process for REB review during the publicly declared emergency: In collaboration with REBs, institutions should consider proactively designing triage processes in their preparedness plans to help prioritize requests for ethics review during a publicly declared emergency. REBs manage the implementation of the triage process, including the following:

- REBs apply the triage process equitably and consistently across research studies within their jurisdiction and ensure transparency in their decision making.
- Subject to available information, the REB periodically assesses the application of the triage process and adjusts it depending on the severity, changing landscape, and local context of the emergency, as well as the availability of REB resources.

The triage process: The following in table 5 outlines key factors that may influence the REB triage process during publicly declared emergencies. Table 6 identifies common types of requests that REBs may need to prioritize for ethics review using the triage process during publicly declared emergencies.

Table 5: Factors that may affect the REB triage process

Factor	Key points
Potential impact on participants	Main guiding factor is the potential impact– including both risks and benefits – of conducting, suddenly suspending, or resuming research on participants and communities affected by the emergency.
Necessity, feasibility	The necessity to conduct the research during the emergency (i.e., whether it is time-sensitive), and the feasibility of beginning or continuing the research: • Research related to public emergencies does not necessarily take priority for ethics review over research that is not related to emergencies. This would be the case if the latter is anticipated to potentially have substantial impact on participant outcomes or survival, or if abrupt cessation of the research is likely to result in harms (e.g., some drugs cannot be safely stopped abruptly). • Some research can be deferred without significant impact to its scientific validity or participant protection, while other ongoing research can continue during the emergency with no changes or need for REB review.

Operational continuity	The need to maintain the REB's operational continuity—including its workload and capacity to fulfill its mandate of reviewing the ethical acceptability of research—while navigating the pressures and context of an emergency.
Contextual constraints	Considering operational context is critical. For example, during the COVID-19 pandemic the closure of university buildings halted most lab-based research, while online studies remained largely unaffected and some ongoing cancer trials continued. Initially, some facilities prohibited all new research activities, but off-site studies in alternative settings later became feasible with adjustments such as physical distancing, masking, and amended consent procedures, in accordance with public health guidelines. When research was deemed operationally infeasible, researchers were advised that ethics reviews would proceed but at a slower pace.
Alignment	Align the triage process with guidance from national bodies, such as the Centre for Research on Pandemic Preparedness and Health Emergencies that calls for research that addresses nationally determined priorities.

Table 6: Examples of requests for REB review during public emergencies

Initial ethics review of time-sensitive research directly related to the emergency. For example, research involving interviews with first responders to understand human response during an earthquake.	**Continuing ethics review of ongoing critical research.** Continuing ethics review of research that may not directly relate to the emergency but has a direct impact on participants' survival or morbidity (e.g., ongoing heart or cancer research trials)
Reviewing amendments due to new risks or unanticipated issues. • Reviewing researchers' requests for amendments resulting from new information or unanticipated issues (e.g., changes to existing research that increase levels of risk to	**Distinguishing research from public health activities.** • Distinguishing between "research" and "public health activities" that increase during public health emergencies but would not be subject to REB review if undertaken under statutory powers during

participants, or implementing new procedures that may affect participants' welfare such as social distancing) (Articles 6.15 and 6.16).	publicly declared health emergencies (Chapter 6, Section D, Preamble).

b) Impact on researchers and research participants

Challenges and their management: In some situations, a public emergency may be declared in the location of participants and/or researchers—whether at the country, province/territory, region or city level. Such emergencies underscore the responsibility of researchers to critically assess and, when necessary, adapt their research engagement and methodologies in response to the specific implications posed by an emergency. Researchers work collaboratively with their REBs to address the necessary ethics issues and considerations around participant protections, as outlined in Section 8 of this guidance document.

Researcher responsibilities: Researchers' responsibilities during emergencies include but are not limited to those summarized in Table 7. Table 8 presents examples of potential risks that may arise during an emergency—either from participating in research or from changes to the research itself—that researchers should consider. They are in no particular order.

Table 7: Researchers' responsibilities during emergencies

Responsibility	Details
Monitoring & reporting	Monitoring their research and reporting to their REB any unanticipated issues, events, or substantive changes that may increase the level of risk or affect participants' welfare; and that have a higher probability to occur during a public emergency (Articles 6.15 and 6.16).
Understanding of additional requirements or constraints	Demonstrating to their REB an understanding of any additional associated requirements or constraints to the conduct of new or ongoing research during the emergency. This includes how these may impact their research and research participant protections.
Avoiding disruption of	Ensuring the timing and feasibility of research does not disrupt emergency response. For example, whether data

emergency response	collection during the emergency may interfere with local mandatory evacuations, or if potential participants are not ready or willing to participate in the research during the emergency.
Obtaining permissions	Obtaining other relevant institutional permissions resulting from the emergency or approvals beyond that of their REB before their research can proceed.
Jurisdictional awareness	Where the emergency is declared in other jurisdictions outside the province/territory or outside of Canada, in general, the onus is on researchers to inform their REBs about the nature and scope of the emergency. This includes informing their REB whether and how the emergency affects the conduct of their research and demonstrating whether there is a need to pause or stop their research in the other jurisdiction due to the emergency.
Community engagement	The need for community engagement does not change during public emergencies but the nature of the engagement might need to be different. Where research relationships already exist, these will be an important source of guidance for adapting community engagement. Researchers should recognize that where emergencies expose communities to new circumstances of vulnerability, certain communities may be disproportionately impacted, and their priorities and needs may drastically shift. When conducting research during public emergencies that involve specific communities, researchers should make themselves aware of these shifts and engage in respectful collaboration by adapting their approach to align with shifting community priorities and needs within the evolving context of the emergency (Article 2.11). When planning research involving First Nations, Inuit, or Métis communities during public emergencies, researchers must follow community engagement practices and protocols that apply in non-emergency contexts (see Chapter 9), adapted as appropriate with guidance of community

	collaborators, and abide by any additional requirements or limitations imposed by community governing authorities. See also in table 8 below additional risks to particular groups and communities.
Adapt research plans during emergencies	As the emergency evolves, researchers may need to adapt or shift their plans in unexpected directions, responding flexibly to changing circumstances. Such adjustments include recognizing when participation in research could heighten risks for participants, create new situations of vulnerability, or exacerbate existing ones within groups or communities. Researchers can, in some contexts, reduce the risk level to participants during the emergency by modifying their study procedures. For example, attempting to reduce the risk of infection by conducting their research virtually rather than continuing in-person participation.

Table 8: Summary of potential risks arising during emergencies

Potential risk	Details
New risks affecting fairness and equity of participation in research	These risks may arise due to changes in how researchers interact with participants and can limit participation to only those able or with the capacity to interact with researchers under the new circumstances. Researchers may need to alter the recruitment process from in-person to remote mechanisms, or may require changes in data collection methods, such as in the case of an infectious disease requiring physical distancing. Conversely, the research itself may change from remote to in-person recruitment or participation in the context of a natural hazard or environmental emergency, such as a hurricane or a forest fire, where the infrastructure for remote connection may no longer exist.
New risks to privacy and confidentiality	This may include new requirements introduced within the context of a publicly declared emergency. For example, in a publicly declared emergency involving an infectious disease, a public health agency may require that participants'

	personal information be retained for a specified period to support contact tracing and reporting efforts. Greater levels of reporting may inadvertently increase the risk of disclosing sensitive information—for instance, a participant might report having an infectious disease while also indicating that they continue to attend work despite public health guidelines advising otherwise.
Changes in participants' personal circumstances	A publicly declared emergency can limit participants' access to basic resources such as food and shelter, or lead to delays in social or health services, which can affect their overall well-being and ability to participate in research. Participants may experience physical safety risks due to exposure to hazardous conditions or lack of access to healthcare. They may also experience economic burdens resulting from financial losses due to forest fires that can destroy housing, community infrastructure, and public buildings. Psychological burdens of stress and anxiety may also arise from all these situations.
Additional risks to particular groups and communities	This includes, but is not limited to, individuals in vulnerable circumstances, such as individuals with low income, the elderly, those with pre-existing health conditions, those living in remote communities, or those who are precariously housed. The publicly declared emergency may further affect their economic and social circumstances, physical and mental health, and other determinants of health and welfare – such as housing, employment, security, family life, and social participation. These conditions can place additional pressure on individuals or communities, potentially affecting their ability to provide informed consent or their willingness to participate in, or continue with, research.

It should be noted that participants' willingness to accept risks/risk tolerance or their assessment of risk may evolve over time. Some participants may no longer accept risks during public emergencies that they would have otherwise accepted in non-public emergency contexts. Other participants may be willing to accept risks they would not have otherwise accepted. For example, they may be willing to participate in prevention or vaccine trials during a health

outbreak, but not in otherwise normal circumstances. This also affects whether the level of risk of research is considered minimal or more than minimal risk within the context of the emergency (see definition of minimal risk, and balancing risks and potential benefits in the TCPS). See also Section 8a of this guidance document.

8. Examples of considerations by REBs in the ethics review of research during a publicly declared emergency

Below are examples of questions that REBs may consider when evaluating the ethics of research conducted during publicly declared emergencies. Special consideration must be given to the review of research involving particular communities, where the emergency may further exacerbate the vulnerability of the community and its members (Chapter 9).

Assessing the risk level of research during emergencies should be considered on a case-by-case basis. It is important to acknowledge that research conducted during an emergency should not be automatically classified as more than minimal risk.

This list is not exhaustive, and some items may not be applicable to all research.

a) Risks and benefits of research

- Has the researcher considered new risks attributed to the research as a result of the emergency?
- Has the level of previously identified risks of the prior approved research changed?
- What measures has the researcher taken/or plans to take to mitigate any increased levels of risk?
- Are the anticipated benefits of the research still valid given the state of the emergency?
- Do the benefits of conducting the research during the emergency outweigh the additional risks the participants may experience by participating in the research during the emergency?
- Can the researcher maintain a favourable balance between risks and benefits if the study continues during the emergency?

- Would a potential suspension or termination of the research due to the emergency impose additional risks to participants?
- If the public emergency led to a temporary cessation of the research, will resuming the research impose additional burdens on participants to continue participating in the research (e.g., incurring additional costs to connect online for the research, or costs to travel in-person to a research location)?
- Does the researcher expect the circumstances that have created vulnerability of the participants to change as a result of their involvement in the research during the emergency?

b) Conduct of research

- Will the researcher need to modify their consent or recruitment process (e.g., seeking consent virtually rather than in-person or vice-versa; the addition or elimination of interventions; or new data collection)?
- Where the research is ongoing, is the research question still relevant within the context of the emergency?
- Is the information provided to participants, as part of the consent process, still accurate or does the researcher need to update it?
- Where the research has already been initiated, is confirmation of ongoing consent required of participants in the face of new information, ethical or safety concerns?
- Will the emergency impact or alter the representativeness of the research population?
- Has interruption of the research (i.e., the stopping and resumption due to the emergency, or access to research funds) impacted its feasibility, or timelines? This is especially relevant for clinical trials and student research projects that operate within tight timelines.
- If previously approved research is amended, does the change introduce new ethical or safety concerns (e.g., inclusion/exclusion criteria or risks to privacy and confidentiality)?

c) Requirements, approvals, and permissions

- In the case of multi-jurisdictional and international research, what additional ethics approvals are needed? (Article 8.3)

- Are there other community constraints or institutional permissions required to begin recruitment or continue the research during the emergency?
- Is the researcher aware of the laws and regulations in the jurisdiction where their research is being conducted? How may the laws and regulations affect the research recruitment strategy or participation within the context of the emergency?
- How does the researcher plan to inform themselves of the circumstances in other jurisdictions within the context of the emergency?
- Where research is based on community engagement or research agreements, has the researcher considered how to renegotiate or implement required changes (e.g., additional consultation, engagement or permission needed to begin recruitment or continue the research)? (Articles 2.11 and 9.1).

Part III: Practical application

The scenarios below illustrate different types of publicly declared emergencies in varied contexts. They are generalized for broad application and include examples of issues and guiding questions for consideration by REBs and researchers. These scenarios are hypothetical and intended as illustrative to serve as a starting point for reflection and discussion.

Scenario 1: Multi-jurisdictional research during forest fires (wildfires)

Extensive forest fires (wildfires) have erupted in a Canadian province. A team of researchers affiliated with institutions in three provinces wishes to conduct research that informs strategies for improving the overall health and safety of firefighters (the research participants) during extreme conditions of the wildfires.

Researchers will not be present. They will collect data remotely during the wildfires by asking firefighters to wear devices that monitor their oxygen levels and heart rates. After the emergency, researchers will invite firefighters to participate in surveys and interviews about their experiences and the effects on their mental health. Researchers will also ask firefighters to undergo routine non-invasive medical tests to assess their inhalation exposures and the impact on their physical health.

The wildfires have also interrupted the operations of the principal investigator's institution and its REB.

Example of questions and considerations for REBs and researchers

1. **What do the researchers know about the prospective participants and their needs? Is engagement with the community of firefighters needed prior to commencing the research?**

    - Researchers should demonstrate to their REB how they have familiarized themselves with the participant pool (e.g., firefighters). For instance, the research team may have prior experience conducting research with firefighters. Researchers could provide their REB with documentation (e.g., a letter or email) of support from the Chief of the fire department/individual responsible for the organization. Such steps help ensure appropriate engagement with participants and support informed, voluntary consent.

2. **Will the research be feasible and result in an equitable balance of risks and benefits for participants?**

    - REBs and researchers should consider whether there are limitations to the participation of the firefighters in the research. Wearing devices for data collection may interfere with their performance and safety during the emergency.
    - REBs and researchers should assess the research related risk for participants. While the risk of fighting fires is inherent to the participants' daily life and work, it is important to assess whether the use of wearable devices could increase the level of risk attributable to their participation in this research.

3. **What measures should be taken to mitigate the impact of the emergency on REB's operations?**

    - As the research spans multiple jurisdictions, multiple REBs are involved. Collaboration amongst REBs will be instrumental to ensure timely ethics approvals.
    - This situation may require full reliance on other REBs, as the principal investigator's REB is no longer operational. If the research is deemed to involve minimal risk to the participants, a single REB can conduct the

review without the need for formal agreements. However, if the research is classified as more than minimal risk, a formal agreement between institutions is necessary. Having pre-established institutional agreements for ethics review can be especially valuable in such circumstances.
- Alternatively, if the principal investigator's REB can operate, it may require some modified procedures (e.g., need access to virtual communication platforms to allow its members to meet virtually).
- REBs should consider prioritizing this research as some of the data collection for the research is only possible during the public emergency. The onus is on the researchers to justify to their REBs that their research could and should proceed during the public emergency.

4. **Are there any new or additional requirements to be met, or approvals and permissions to be obtained?**

    - As usual, researchers must obtain permissions from the relevant fire department(s) for the involvement of the firefighters in research.
    - Researchers must follow any other additional requirements (e.g., applicable laws and regulations in the relevant province).

Scenario 2: Research on a respiratory life-limiting virus

There is an emerging global epidemic of a new respiratory virus that, so far, seems highly contagious, although more research is urgently needed on the mechanisms of transmission. New cases are being tracked daily, and to date, they are primarily centered at research/academic hospitals in one large Canadian city. The province's Premier has declared the outbreak to be a public emergency. All patients and hospital staff, including administrators, researchers, and REB members, some of whom were exposed to the infection, have been quarantined and restrictions have been placed on in-person gatherings for those who are not ill or exposed to the virus.

The institutional responsibilities have shifted to the emergency response. The quarantined researchers and REBs continued their work while navigating the challenges of the publicly declared emergency. REBs and researchers quickly implemented new and additional safety and public health measures and requirements. They also adjusted their processes in an environment with rapidly

evolving information. The REBs began to receive requests seeking urgent ethics review of research that included:

- New research on the virus, diagnosis, and treatment.
- New research ethics submissions for which a distinction was required between "research" and "public health activities" undertaken by public health officials operating under statutory powers during publicly declared health emergencies. The latter would not be subject to REB review or the requirements for informed consent (Chapter 6, Section D, Preamble).
- Ongoing approval of research unrelated to the virus, but where timely approvals of changes or renewals are necessary to avoid delays in potentially life-saving interventions.

Example of questions and considerations for REBs and researchers

1. **What do the researchers know about the prospective participants and their needs? Is a community engagement process needed prior to commencing the research?**

    - Consideration should be given to the vulnerability of the patients who are infected by the virus and suddenly become the focus of new research. There should also be considerations for those who are critically ill, and whether they will be able to provide informed consent.
    - Typically, during outbreaks, there may be communities or populations that are disproportionately affected. The researchers should include mention of this in their proposal, and consider this in their recruitment, data collection, analysis, and dissemination strategies.
    - The researchers should describe to their REB how they will interact with participants, and seek their consent, given public health measures, including quarantine measures, and restrictions on gatherings.

2. **Will the research be feasible and result in an equitable balance of risks and benefits for participants?**

    - The researchers should consider whether the quarantined or ill patients are able to participate in research related to the outbreak.
    - The researchers and REBs should consider other relevant practical considerations or constraints given the context of the emergency. This includes whether the research may interfere with or disrupt the public health response to the emergency. Researchers should consider if the research is feasible where equipment or scarce resources are required to

conduct the research (e.g., laboratory space, personal protective and safety equipment).

- The researchers and REBs should consider if there are any new or additional privacy and confidentiality measures needed for the collection and storage of data and human biological materials.
- There is a potential risk of infection for the research team, and researchers should take measures to manage their own safety (Chapter 2, Risks to researchers). Researchers must follow their institutional safety guidelines in response to the emergency.

3. Is there an impact on the REB's operations and procedures in this situation?

- This situation has a major and sudden impact on REB operations.
  - Consider what short-term modifications are needed to mitigate the impact of the emergency on the REB's operations and sustain its work.
  - Consider what kind of arrangements need to be made for substitute members when REB members are ill, to maintain quorum.
  - Consider whether additional provisions should be made for ad hoc advisors to assist when members with the requisite expertise are incapacitated.
- The REB should consider how to manage the triage process for the ethics review of research seeking ethics review, and the criteria that are applied when prioritizing requests for ethics reviews.
- Collaborations between the quarantined REBs and other REBs should be considered. This includes having agreements already in place—where available—to facilitate streamlining the ethics review process of more than minimal risk multi-jurisdictional research, and for external REBs to assume some responsibilities for those REBs who are disproportionately affected by the emergency (see Section 6b of this guidance document).

4. Are there any new or additional requirements to be met, or approvals and permissions to be obtained?

- Both REBs and researchers must adhere to public health acts and directives, and their institutional safety protocols during emergencies. They should also ensure that the ethics review process and the conduct of research are aligned with any requirements introduced as part of the emergency response measures.

- Researchers must also follow their institutional safety guidelines and response to the emergency.

Scenario 3: Research involving a Canadian remote community recently exposed to a severe flood

An out-of-province research team wishes to understand how communities develop resilience measures that can reduce the impact of future disasters and their risks. The researchers propose to conduct research involving residents of a remote community in Canada to analyze the effect of a recent severe flood that destroyed some of the homes and infrastructure in their community. Because of the destruction of the infrastructure as a result of the flood, the aftermath of the emergency continues for some time. This is not the first time that the community has experienced a flood, but this time, an authority within the region declared it a public emergency. The research involves observing and interviewing the affected residents. The researchers are seeking prompt ethics approval from their own out of province institutional REBs. To the REBs knowledge, this marks a new research focus for the research team, and the researchers do not have previous experience with this community.

Example of questions and considerations for REBs and researchers

1. **What do the researchers know about the prospective participants and their needs? Is a community engagement process needed prior to commencing the research?**

    - The researchers should demonstrate to their REB how they have informed themselves about the community and its practices/governance structure.
    - As in non-emergency context, if this research involves a First Nations, Inuit, or Métis community, the researchers must follow guidance related to community engagement, and respect community customs and codes of practice (Chapter 9 and Article 2.11). Additionally, the researchers must be aware of any additions or changes regarding community engagement that are required by the community governing authority to protect the interests and wellbeing of community members during the emergency.
    - The researchers should recognize that the impact of a publicly declared emergency on remote communities may differ significantly from its

impact on the general population. These communities may face unique challenges due to geographic isolation, limited infrastructure, or historical vulnerabilities. These challenges may shift the priorities, needs and capacities of communities.

- The researchers should demonstrate to their REB whether and how they have considered the community's readiness and willingness to participate in this research (i.e., consult with the community and its leadership). As the researchers are based out of province, they may encounter added challenges in engaging with the local community.
- The onus is on the researchers – after relevant engagement with the community – to justify to their REB that their research could and should proceed during the public emergency.
- The REBs will need to consider whether this is time-sensitive research that should be prioritized for review.

2. Will the research be feasible and result in an equitable balance of risks and benefits for participants?

- The researchers should consider other relevant practical considerations given the context of the emergency. This includes whether the research may interfere or disrupt response and assistance to the emergency.
- The researchers should consider if they are able to physically access the community. This will affect how the researchers will recruit participants, seek their consent, and collect the data.
- The researchers should develop a plan for how to manage research attributable risks to participants, while maintaining a favourable balance between risks and benefits.
- After engaging meaningfully with the community, researchers are responsible for demonstrating to their REB that their proposed research is both feasible and appropriate during the public emergency—ensuring that it is guided by and responsive to the community's needs and priorities. Where the research involves an Indigenous community, researchers must also consider whether the research aligns with the community's priorities and whether it will benefit the participating community, in accordance with Article 9.13 of the TCPS.
- The researchers should consider that some Indigenous communities in rural, northern, or remote areas often face heightened exposure to natural hazards like floods. Researchers should consider whether the

community's participation in the research may further exacerbate circumstances of vulnerability for the community and its members.

3. **Is there an impact on the REB's operations and procedures in this situation?**

   - Since the researchers are based out of province, the emergency context does not impact the REB of their home institution (i.e., operates as usual following its standard procedures and the TCPS, including Chapter 9). However, where applicable, the context of the emergency is likely to affect the ethics review by a community REB or other responsible body at the research site (Articles 9.9 and 8.3).
   - With the researchers' interest in this community that has a history of exposure to severe floods, advance planning and consultation with the REB on the ethics of this research should have occurred prior to REB submission.
   - The out-of-province REB should ensure that they have the necessary expertise, and consider seeking ad hoc advisors with knowledge of the local community, where the expertise on the REB may be lacking (Article 6.5).

4. **Are there any new or additional requirements to be met, or approvals and permissions to be obtained?**

   - The researchers should be aware that other authorities—such as local governance bodies, Indigenous leadership, or emergency response organizations—may be involved in managing the emergency. These authorities may introduce additional expectations, requirements, permissions, and protocols that researchers must consider and abide by.
   - The researchers should verify whether permissions or additional ethics approvals are needed in the community, for example, research ethics review by a community REB or other responsible body at the research site (Article 9.9), or a research licence.

Scenario 4: Canadian researchers evaluating the success of emergency response during a hurricane abroad

A devastating hurricane struck the coastal region of a country abroad, prompting the declaration of a national emergency. The storm caused widespread damage to infrastructure, displaced thousands, and disrupted

essential services such as electricity, transportation and healthcare. Prior to the emergency, a team of Canadian researchers had secured approval from their Canadian REB to conduct prospective research in collaboration with local emergency management authorities. They also sought approval from the local REB.

The research aimed to evaluate the implementation of new emergency guidelines in response to hurricanes and assess how effectively these guidelines address the community's needs during such events. The ultimate goal was to provide recommendations for future preparedness planning.

The research involves collecting data using mobile tools and devices. Researchers plan to assess how evacuation orders and safety advisories are communicated to the public; conduct surveys and interviews in evacuation shelters to gauge public awareness; observe emergency personnel and evacuation coordinators; and document adherence to the guidelines.

The researchers must revise their research methodology to reflect unfolding events and seek the REBs approval of the proposed changes.

Example of questions and considerations for REBs and researchers

1. **What do the researchers know about the prospective participants and their needs? Is a community engagement process needed prior to commencing the research?**
    - By collaborating with local authorities, the researchers would have gained valuable insight into the community's culture and needs and had time to engage with the community.
    - As the researchers adapt their research to the context of the emergency, they should continue to engage in respectful collaboration with the community (Article 2.11).

2. **Will the research be feasible and result in an equitable balance of risks and benefits for participants?**
    - The research and its amendments are likely of minimal risk. The research in and of itself does not introduce new risks to participants (the evacuees at shelters, and evacuation coordinators being observed). The purpose of the research is to benefit the community.

- The researchers should take into account whether evacuees are willing to participate, considering the impact the hurricane has had on them and their community.
- The researchers' observation of the evacuation coordinators is not likely to interfere or disrupt response to the emergency.

3. Is there an impact on the REB's operations and procedures in this situation?

- The Canadian REB is not impacted by the emergency. It had approved the ethical acceptability of the research.
- During the emergency, the Canadian REB may offer a streamlined process for the review of changes to the research to ensure the research can continue.
- This is multi-jurisdictional research. Local REB review was completed prior to the emergency. However, the researchers must now seek approval for proposed changes to the research and determine whether the local REB—potentially impacted by the emergency—is able to review those amendments (Article 8.3).

4. Are there any new or additional requirements to be met, or approvals and permissions to be obtained?

- The researchers' collaboration with local authorities will facilitate identifying other required approvals or permissions.
- The researchers must follow local emergency requirements and safety guidelines.