
Proposed Amendments for Public Emergencies
in the *Tri-Council Policy Statement:*
Ethical Conduct for Research Involving Humans
(TCPS)

Submitted by

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to the
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The content and views expressed in this document are those of members of this committee, and do not necessarily reflect those of the Interagency Advisory Panel or Secretariat on Research Ethics.

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TABLE OF CONTENTS

1. Introduction.....	1
<i>i. Mandate of the Exploratory Committee on Research Ethics and Public Emergencies.....</i>	<i>1</i>
2. Literature Review and Public Consultations	1
<i>i. Consideration of National & International Perspectives: Substantive and Procedural Issues.....</i>	<i>1</i>
<i>ii. Public and Targeted Consultations</i>	<i>3</i>
<i>iii. Canadian Developments in Public Health Ethics.....</i>	<i>3</i>
3. Review of Relevant TCPS Provisions.....	4
4. Committee’s Proposal for Amending the TCPS Principles and Standards for Public Emergencies	5
A. Respecting Ethics Principles & Standards in Public Emergencies.....	5
<i>i. Compelling Public Necessity: Officially Declared Emergencies</i>	<i>6</i>
<i>ii. Scope: Public Emergencies Apply to Narrow, Limited & Exceptional Circumstances.....</i>	<i>6</i>
<i>iii. Institutional Research Ethics Emergency Preparedness</i>	<i>6</i>
<i>iv. Proportionate Ethics Review</i>	<i>6</i>
<i>v. Requisite Knowledge & Expertise</i>	<i>7</i>
<i>vi. Reasonable & Just Policies, Standards & Implementation.....</i>	<i>7</i>
<i>vii. Respecting Ethics Principles – Limiting Derogations</i>	<i>7</i>
<i>viii. Respecting Vulnerability & Human Dignity.....</i>	<i>8</i>
5. Recommendations to PRE on Proposed Amendments to the TCPS.....	8
<i>Recommendation 1.....</i>	<i>8</i>
<i>Recommendation 2.....</i>	<i>8</i>
<i>Recommendation 3.....</i>	<i>9</i>
6. Conclusion	9
Appendix A	
Sampling of Provisions Relevant to Exemptions or Derogations from General Legal Principles on Grounds of Public Urgency	11

1. Introduction

This report from the Exploratory Committee on Research Ethics and Public Emergencies provides recommendations to the Interagency Advisory Panel and Secretariat on Research Ethics (PRE/SRE) on proposed amendments to the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS) regarding ethical issues concerning research involving humans during public emergencies.

i. Mandate of the Exploratory Committee on Research Ethics and Public Emergencies

Since 2005, several community requests have urged PRE to consider evolving the TCPS to include more explicit attention to issues concerning ethics in public health research, including emergency epidemiology and population health research. A request arising from the organizers during a meeting of the Emerging Infectious Diseases Research Network¹, attended by federal, provincial and local government officials, prompted PRE to consider changes to the TCPS on existing TCPS provisions, such as consent in health emergencies, quorum, and face-to-face meeting requirements, in anticipation of emerging infectious disease outbreaks, such as SARS and pandemic avian influenza. PRE participated in several conferences with Health Canada, the Public Health Agency of Canada, the Canadian Institutes of Health Research and other partners to gather information and to determine whether these public health research ethics issues were relevant to the TCPS and, if so, whether they should be made a priority for TCPS revisions.

In June 2006, in conformity with its process for planning and setting priorities to review such requests, PRE tasked members of an Exploratory Committee on Research Ethics and Public Emergencies to explore these issues in greater detail. The specific mandate of the Exploratory Committee was to 1) identify issues related to public emergency situations such as public health disease outbreak emergencies and REB processes, taking into consideration the goal of the protection of human participants 2) explore whether PRE needs to consider a “force majeure” clause (necessity clause) in the TCPS and 3) prepare recommendations for PRE’s consideration.

2. Literature Review and Public Consultations

i. Consideration of National & International Perspectives: Substantive and Procedural Issues

Upon initial review of the relevant public emergency literature in ethics, public policy and research, the Committee concluded early in the process, that the focus should be on public emergencies in general—natural disasters, pandemic, environmental releases—rather than infectious disease outbreaks alone. This conclusion was informed by discussions with selected experts, a review of major issues and trends in the literature, and an initial review of relevant provincial, national and international documentation on public emergencies, with specific focus on relevant ethical and legal principles.

International laws and guidelines rarely permit derogation from their core principles and if so, only in very limited and exceptional circumstances, such as compelling public necessity², or during officially declared emergencies³ (e.g., Siracusa Principles⁴; *Appendix A*). The literature review also revealed

¹ Emerging Infectious Diseases Research Network Summit, April 2006, Toronto, ON, Canada.

² See *Directive 95/46/EC of the European Parliament and Council of 24 October 1995, on the protection of individuals with regards to the processing of personal data and on the free movement of such data* (OJL 281, 23.11.1995, p.31) - Chapter II – General Rules on the Lawfulness of the Processing of Personal Data, Section VI Exemptions and Restrictions, Art. 13, at: <http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/consleg/1995/L/01995L0046-20031120-en.pdf>

several relevant concepts that were considered in greater detail by the Committee, such as “special scrutiny”⁵ in research ethics review, and the “impracticability”⁶ of informed consent in certain research circumstances.

The Committee focused initially on several specific questions to guide its reflection and deliberations:

- What is likely to happen to ethics review in emergencies?
- When does an emergency begin or end?
- What research is most likely to be done before, during or after an emergency?
- Should there be exceptions to research ethics standards during emergencies?
- If there are exceptions, how should they be structured?
- What is the appropriate scope for any exceptions to the TCPS?
- How do, or should, institutions prepare for research ethics review for emergencies?
- What principles are most relevant and applicable to guide the appropriate evolution of the TCPS for research in public emergencies?

Attention to these questions initially led the Committee to consider, and reject, a “necessity” or “*force majeure*” clause, which would permit the suspension of select TCPS provisions during a public emergency. The committee decided that there were no key provisions of the TCPS that could not be accomplished during public emergencies, even if several would require clarification and/or amendment to ensure their applicability during emergencies. The committee also felt that the TCPS would benefit from the inclusion of a number of key principles that would be complementary to the TCPS ethics framework, but provide specific guidance in the case of public emergencies. These principles are presented in detail, in section 4 below.

The Committee also considered the impact of public emergencies on the following principles:

- free and informed consent procedures; impracticability issues of consent procedures during emergencies; voluntariness; infringement of individual liberties (e.g. privacy matters) for societal good (e.g. confine a person in quarantine to protect the community);
- “special scrutiny” and proportionate approaches to risk review;

³ See, World Health Organization: *Draft Project on Addressing Ethical Issues in Pandemic Influenza Planning* at: http://www.who.int/eth/ethics/PI_Ethics_draft_paper_WG2_6_Oct_06.pdf See also, Government of Canada, *Emergencies Act*, (1985, c. 22 (4th Supp.)), Part 1, Art.3 National Emergency; Art. 6 Declaration of a Public Welfare Emergency; Part II, Art. 17 Declaration of a Public Order Emergency at: <http://laws.justice.gc.ca/en/E-4.5/index.html>

⁴ See, e.g., United Nations, Economic and Social Council, *Siracusa Principles on the Limitations and Derogation Provisions in the International Covenant on Civil and Political Rights*, U.N. Doc. E/CN.4/1985/4, Annex (1985). (Part II, Derogations in a Public Emergency; Part II D. para. 58, Non-Derogable Rights - respect of free consent) at: <http://www.law.wits.ac.za/humanrts/instreet/siracusaprinciples.html>

⁵ Levine, C., Faden, R., Grady, C., Hammerschmidt, D., Eckenwiler, L., Sugarman, J., “Special Scrutiny”: A targeted Form of Research Protocol Review. *Ann Intern Med* 2004; 140 (3): 220-223.

⁶ Tu, J.V., Willison, D., Silver, F.L., Fang, J., Richards, J.A., Laupacis, A., Kapral, M.K., Impracticability of Informed Consent in the Registry of the Canadian Stroke Network. *NEJM*, April 1, 2004; 350 (14): 1414-1421.

- limited derogation from ethical principles in the face of compelling “public necessity” and during an “officially declared emergency”; distinction between “emergency” and “urgency”;
- potential for increased vulnerability of those bearing the burdens and effects of the emergency, i.e., research participants, institutional staff, REB members and researchers;
- developing institutional and REB emergency research ethics preparedness plans and procedures for review processes (e.g. quorum; face-to face requirement of REB meeting; full, accelerated or expedited reviews, multi-centered review, etc.).

ii. *Public and Targeted Consultations*

In fall 2006, following the initial review of the literature, the Committee drafted a list of principles for the TCPS to guide REBs, institutions and investigators in public emergencies. The Committee received feedback on these draft principles during presentations at several conferences, e.g., the National Council on Ethics in Human Research, and the Canadian Association of Research Ethics Boards, and from targeted consultations with federal government agencies, e.g., the Canadian Institutes of Health Research, Health Canada, and the Public Health Agency of Canada.

In addition, similar questions were included in PRE’s Social Sciences and Humanities Special Working Committee (SSHWC) public consultation on its working document on qualitative research ethics⁷ in spring 2007. SSHWC provided the Committee with results of the consultation on the two questions related to REB procedural matters on the conduct of research during emergencies⁸.

In general, the draft principles and standards were well received in the community and there seemed to be general agreement that institutions and REBs should consider putting in place, before an emergency occurs, a detailed plan and procedures for research ethics review during public emergencies. Most respondents to the SSHWC consultation questions on public emergencies thought that REBs should be provided with some mechanism that would permit “immediate” or accelerated/expedited review and approval of some research during emergencies. A few respondents indicated that in social sciences and humanities disciplines, some research should be permitted to proceed without REB approval and then be reviewed in detail by the REB *post priori*. However, there was also confusion about the circumstances under which ‘emergency’ provisions would be applied, in particular the distinction between research during a publicly declared emergency, as opposed to research where there is a perceived “urgency” to do the research, but where there may not be agreement that the situation constitutes an “emergency”. Very few respondents seemed to appreciate the idea that more care, or “special scrutiny”⁹, might be needed in emergency situations given that the victims of the emergency may be more vulnerable. For example, during SARS, some of the proposed clinical treatment trials exacerbated, rather than alleviated, the harms arising from the disease outbreak.

iii. *Canadian Developments in Public Health Ethics*

In January 2008, a public consultation was undertaken by the Canadian Institutes of Health Research, Health Canada and the Public Health Agency of Canada to examine the ethical distinctions between

⁷ Qualitative Research in the Context of the TCPS, Spring 2007, SSHWC.

⁸ See, Note 7: Question 7: Should institutions develop special review procedures for such unexpected and immediate “emergency or disaster” research? What would they look like in the context of qualitative research? Question 8: Should researchers be able to submit general research intentions and procedures in anticipation of such unique research environments, while working within appropriate ethics guidelines? Could institutions consider accelerated review procedures?

⁹ See, Levine et al., in Note 5.

public health activities requiring REB review and those for which other mechanisms of review or accountability would be more appropriate. Based on the SARS experience, the potential for other pandemic outbreaks (e.g., avian influenza), and the public health research challenges encountered during other emergencies, this initiative recently produced a “triage” instrument¹⁰ to help investigators, institutions and REBs to navigate these issues. Results from this consultation may prove useful for PRE in its final deliberations about the second edition of the TCPS.

3. Review of Relevant TCPS Provisions

The current TCPS does not address research in public emergencies explicitly, although several of its provisions are relevant to public emergencies. For example, Article 1.6 addresses the proportionate review principle, which would provide the basis for appropriate latitude and judgement in emergency situations, both in the sense of identifying research that presents minimal risks for which expedited review may be appropriate and research that might require heightened attention by a full REB review. Article 1.9 introduces the requirement that REBs must hold face-to-face meetings, an issue that PRE has already responded to in an interpretation¹¹ of the TCPS.

Article 2.8, on research in emergency health situations, provides a narrow exception to the normal TCPS consent procedures, subject to applicable legislative and regulatory requirements, allowing REBs to approve deferred or waived consent under strict criteria if the research “addresses the emergency needs of individuals involved, and then only in accordance with criteria established in advance of such research by the REB”¹². All of the six criteria must be met: 1) research will be done in a serious life threatening situation in which immediate intervention is required, 2) the research either holds the potential for direct benefit to the research participants compared to the standard of care or no standard of care exists, 3) the risk of harm is not greater than standard care interventions and 4) where the potential research participant is unable to provide consent (e.g., unconscious or decreased capacity) and 5) where it is impossible to obtain third-party authorization for consent despite diligent and documented efforts, 6) no relevant prior directive on the individual’s wishes to participate in the research are known. This deferred or waived consent provision in the TCPS was intended for a limited class of research for emergency health situations which would not be expected to be widely applicable in other types of public emergencies, and implies special ethical obligations and protections to research participants, commensurate with the level of harms.

The Committee found most of the TCPS principles and procedures to be adequate for the purposes of guidance in public emergencies and concluded that there was no need to adopt a “necessity” or “*force majeure*” clause to suspend any specific provisions of the TCPS to facilitate appropriate research ethics review in a public emergency. The Committee recommended that the TCPS principles and standards should be applied during officially declared public emergencies by institutions, researchers and REBs, with the following added provisions:

- special attention should be given during any public emergency to ensure appropriate evaluation of the risks and potential benefits posed by any proposed research, including provisions for greater-than-normal attention to risk, where applicable,
- REBs and investigators should pay special attention to how the emergency circumstances may increase the vulnerability of prospective research participants to research-related risks,

¹⁰ See, Canadian Institutes of Health Research, Health Canada and the Public Health Agency of Canada: *First Public Consultation Draft: Triage Instrument for the Ethical Review of Public Health Activities*, January 2008.

¹¹ See <http://pre.ethics.gc.ca/english/policyinitiatives/interpretations/interpretation021.cfm>

¹² See, TCPS Article 2.8 at: <http://pre.ethics.gc.ca/english/policystatement/section2.cfm#2F>

- Institutional and REB emergency research ethics review preparedness plans and procedures should be put in place, anticipating any potentially relevant jurisdictional issues with respect to mandates of other public authorities (e.g., provincial public health departments; federal legislation related to management of emergencies), that may conflict with, or require special coordination with proposed emergency review procedures,
- in rare cases of compelling public necessity, usually supported by relevant legislation, derogations from certain TCPS principles or standards of conducting research could be justified, such as in the case of application of the Quarantine Act¹³, or when exceptional or exigent circumstances significantly disrupt or limit the feasibility of face-to-face REB meetings, such as during a public health emergency. However, this does not imply that REB review is not required for research, but rather, that being responsive to contextual issues during officially declared public emergencies is consistent with the TCPS Ethics Framework, which encourages non-formulaic, context-sensitive implementation of the principles and standards of the TCPS.

4. Committee’s Proposal for Amending the TCPS Principles and Standards for Public Emergencies

Based on the above considerations, the Committee recommends adding the following ethical principles and standards for public emergencies in a new proposed insert in the TCPS. It consists of two parts: a short introduction and overview of the emergency context, followed by a listing of points and principles.

Proposed text for the TCPS:

A. Respecting Ethics Principles & Standards in Public Emergencies

Public emergencies are extraordinary events that arise suddenly or unexpectedly and require urgent or quick responses to minimize devastation such as in the case of hurricanes and other natural disasters, large communicable disease outbreaks, catastrophic civil disorders, biohazardous releases, environmental disasters, and humanitarian emergencies. They tend to be temporal or time-limited. They may severely disrupt or may destroy normal institutional, community and individual life. Because emergencies present extraordinary public risks that warrant special responses, legislation or public policies usually require that they be officially proclaimed or declared. The official declaration of a public emergency, such as a public health outbreak, initiates emergency procedures, and provides special responsibilities and powers. The exercise of those responsibilities may temporarily modify normal procedures or practices. In extreme instances, public emergencies might warrant the suspension of some civil liberties. The ethical rationale behind such powers and duties is beneficence-based public necessity: that the exceptions to, and infringements of, principles like informed consent may prove necessary to preserve or protect human life or public health, safety, order and welfare. An important concern regarding such powers is that they not be used beyond the scope of the emergency, nor used arbitrarily, unreasonably or otherwise abused. For such reasons, they are circumscribed.

Research ethics review involving or during declared public emergencies should, accordingly, respect basic principles.

¹³ See, e.g., Canadian *Quarantine Act* (R.S., 1985, c. Q-1) at: <http://laws.justice.gc.ca/en/showtdm/cs/Q-1>

i. Compelling Public Necessity: Officially Declared Emergencies: To ensure their limited application, research ethics policy and procedures for emergencies should apply only to the compelling public necessities occasioned by a public emergency. Public emergencies must be officially declared by an authorized official.¹⁴ Exceptional research ethics policy and procedures for emergencies should cease immediately after such declaration is withdrawn.

ii. Scope: Public Emergencies Apply to Narrow, Limited & Exceptional Circumstances: To preserve the values, purpose and protection that TCPS principles advance, the onus for demonstrating a reasonable public emergency exception to an ethical principle or standard should fall on those claiming the exception.

iii. Institutional Research Ethics Emergency Preparedness: Institutions and their REBs should develop emergency research ethics preparedness plans in concert with their affected communities. These plans should outline policies and procedures for addressing research ethics review during and concerning public health outbreaks, natural disasters, and other public emergencies. Such policies should try to anticipate the extraordinary circumstances or demands occasioned by emergencies, and set priorities, for example, through the use of a “triage” instrument for the kinds of research that should be designed before (cf. article 2.8), undertaken during,¹⁵ or conducted after¹⁶ officially declared public emergencies. For example, a plan to help prioritize REB reviews during emergencies should consider 1) what constitutes “essential” research during the emergency; 2) the review process of new research projects developed from the opportunity that arises from the emergency (e.g., research involving interviews with first responders and victims to understand human response during a disaster, such as a tornado or earthquake) and 3) regular ongoing reviews of research undertaken prior to the occurrence of the emergency. Special focus could be given to REB procedures to review and approve research (e.g., full or accelerated reviews; quorum rules; special agreements with other institutions for sharing REB reviews, etc.) while considering the impact of the emergency on research participants, researchers, REB members, institutional staff and others. The plan and its policies should proactively address basic operational questions: e.g.,: how may emergencies affect research and ethics review in institutions/REBs; how does the REB conduct business or meet; what research needs should be planned in advance of or done after an emergency; what research, if any, needs to be done during an emergency; what qualifies as time-sensitive or “essential” research, what procedures govern, and what evaluation methods need to be developed.

iv. Proportionate Ethics Review: Research ethics review during or regarding public emergencies remains even more important and may require even greater scrutiny since everyone (research participants, researchers and REB members themselves) may be rendered more vulnerable by the nature of the emergency, than they would have been under normal circumstances. Ethics review should be contoured to the necessities occasioned by the emergency, because of the critical interplay between public urgencies, essential research, and a

¹⁴ See, e.g., Government of Canada: *Department of Public Safety and Emergency Preparedness Act* (2005, c. 10) at: <http://laws.justice.gc.ca/en/showtdm/cs/P-31.55>; *Emergency Management Act* (2007, c. 15) at: <http://laws.justice.gc.ca/en/showtdm/cs/E-4.56>; *Emergency Preparedness Act* (1985, c. 6 (4th Supp.)) at: <http://laws.justice.gc.ca/en/showtdm/cs/E-4.6>

¹⁵ For brief considerations for and against research during complex humanitarian emergencies, see National Research Council, *Research Ethics in Complex Humanitarian Emergencies: Summary of a Workshop*. National Academy of Sciences: Washington, DC, 2002.

¹⁶ Collogan LK, Tuma F, Dolan-Sewell R et al. Ethical Issues Pertaining to Research in the Aftermath of Disaster. *J Traumatic Stress* 2004; 17:363-372; Knoppers BM, Sainure M, Cash H. Ethical Issues in Secondary Uses of Human Biological Materials from Mass Disasters. *J Law Med Ethics* 2006 (summer):352-365.

continuing commitment to fundamental ethics principles even in the face of acute public necessity. REB procedures may warrant reasonable adjustments to address the timing, locale, expertise, form and scope of review, and ways of meeting. REB adherence to proportionate ethics review, under TCPS article 1.6, may need special considerations in public emergencies, calibrated to the level of risk under the circumstances. Through their emergency preparedness plans, institutions, researchers and their REBs need to anticipate the pressures, time constraints and logistical challenges that may arise to ensure quality, timely, proportionate and appropriate ethics review.

v. *Requisite Knowledge & Expertise:* Both the TCPS Ethics Framework and REB standards underline the importance of relevant knowledge as part of the multidisciplinary analysis of research ethics issues. Research ethics policy and review for emergencies warrant special expertise. For instance, public health and legal knowledge would be extremely valuable to institutions developing preparedness plans for research ethics review during public emergencies and they will prove particularly relevant to understanding and managing the public health concerns, legal issues and responsibilities in declared public health emergencies under applicable legislation or public policy.¹⁷ However, in the context of an officially declared public emergency, REB members may become unavailable (e.g., due to illness or quarantine by public authorities or inability to be reached as they are relocated in a hurricane disaster) and institutions and REBs should explore the nomination of *ad hoc* members with relevant expertise and substitute REB members, negotiate reciprocity agreements with other institutions for REB reviews, and revisit how scholarly review would be applied in such instances.

vi. *Reasonable & Just Policies, Standards & Implementation:* Ethics policies, procedures and their implementation should adhere rigorously to a rule of reasonable, fair and principled design and use for emergency purposes. Respect for the principle of justice means that reasonable policies and procedures shall be designed and used in a manner that is not discriminatory or arbitrary. The commitment to justice advances a fair and balanced distribution of burdens and benefits even in the face of public emergencies.

vii. *Respecting Ethics Principles – Limiting Derogations:* Especially during times of emergency, researchers, REBs and institutions need to be vigilant and exercise due diligence in respecting ethical principles and standards. To guide fair and reasonable implementation for emergency circumstances, any derogations from or infringement of ethics principles and standards need to be demonstrably justified by those urging the infringement. Sometimes a proposed infringement or derogation will not be justified for research purposes.¹⁸ Justified derogations from or infringement of ethics principles and standards should correspond directly

¹⁷ See, e.g., Canadian *Quarantine Act* (R.S., 1985, c. Q-1) at: <http://laws.justice.gc.ca/en/showtdm/cs/Q-1>

¹⁸ The balance and proportionality between potential societal benefits from an initiative and the risks to, or invasion of, the individual and his/her rights may determine whether the intervention is ethical or legal. Thus, compulsory isolation of contagious individuals during a communicable disease outbreak may be acceptable, while non-consensual public health research in cases of public urgencies may not. Current Canadian reflection in public health suggests that if the intent of a communicable disease outbreak study is to control the current outbreak by public health authorities with a legal mandate, REB review would not be necessary, however, if the purpose of the study during an outbreak is to generate knowledge that is not used to control the current outbreak but as a generalizable knowledge for the future, then that particular study would need to go to a REB. However, these reflections are still under consideration and should be applied with caution. See, Note 10 on Consultation Document on the Draft Triage Instrument in Public Health.. See also Note 4, on Siracusa Principles. See also, e.g., Council of Europe, *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, Oviedo, 4.IV.1997, Chapter 5, Article 16 and Chapter 9, Articles 26 at: <http://conventions.coe.int/Treaty/EN/Treaties/Html/164.htm>;

and be calibrated to the benefit targeted by the goal of the policy. Derogations should be narrowly tailored to address the necessities occasioned by the public emergency, such that the least restrictive or least intrusive means necessary to achieve the policy goal are relied on. This approach – consistent with international bioethics¹⁹ and human rights norms²⁰ – maximizes respect of ethical principles and helps to ensure that exceptions or infringements and their implementing means are not unduly broad, over-reaching or unjustifiably invasive.

viii. Respecting Vulnerability & Human Dignity: Individuals, potential participants, researchers, institutions that may not normally be considered vulnerable²¹, may become so by the very nature of public emergencies. Those already vulnerable may become acutely so. The increased public risks and devastation on which public emergencies are declared threaten autonomy, physical, emotional, institutional and social well-being or safety. They also bring inherent tensions and pressures that may impact deliberative decision-making. Research ethics policy and review for public emergencies should recognize that in such situations the affected population, as individuals or as a body, may become more vulnerable and the need for promoting, protecting and respecting human dignity must be accordingly addressed.

5. Recommendations to PRE on Proposed Amendments to the TCPS

The Committee outlined areas for potential amendments to the TCPS concerning substantive and procedural issues, and had originally chosen to integrate these draft principles into the TCPS ethics framework section to help the research ethics community understand the underlying substantive and ethical – and some legal - implications of conducting research in the context of public emergencies. However, informed by a PRE decision in early 2008 to develop a 2nd edition of the TCPS, which will include modifications to its basic structure, the Committee recommends, instead, a specific TCPS section on research ethics review during public emergencies.

This section might present a discussion of extraordinary circumstances that public emergencies may present for research ethics review and could be supplemented by a stand-alone companion document that could elaborate on the basic principles and practical implications presented in the TCPS.

The Exploratory Committee on Research Ethics and Public Emergencies proposes the following recommendations to PRE:

Recommendation 1: To approve the inclusion of the *TCPS Principles and Standards for Public Emergencies* as a new section in the TCPS.

Recommendation 2: That the *TCPS Principles and Standards for Public Emergencies* should:

- (i) **be introduced in the general context of the TCPS (e.g., “ethics framework”), as follows: “The growing awareness of the need for planning in anticipation of public emergencies has provided the occasion to consider the potential challenges posed by public emergencies for research ethics review. The reader is referred to the section on *TCPS Principles and Standards for Public Emergencies* for guidance in Chapter XX”.**

¹⁹ See, United Nations Educational, Scientific and Cultural Organization (UNESCO), *Universal Declaration on Bioethics and Human Rights*, 2005, Art. 6.2 Consent, Art. 9 Privacy and confidentiality, Art. 27 Limitations on the application of the principles at: <http://unesdoc.unesco.org/images/0014/001461/146180E.pdf>

²⁰ See, Note 4, on Siracusa Principles.

²¹ For an exploration of the meaning of vulnerability, see Levine, C. The Concept of Vulnerability in Disaster Research. *J Traumatic Stress* 2004 17(5):395-402.

- (ii) **not be located in the “free and informed consent” section of the TCPS (e.g., Article 2.8), so as to minimize confusion between emergency health situations and public emergencies;**
- (iii) **be considered in a separate section under the current TCPS chapter on “Process of Ethics Review”. This section presents general principles about the governance of research ethics and the REB review process under special circumstances (e.g., multi-centred research, ongoing research, etc.)**

Recommendation 3: To make these recommendations public (e.g., by posting on PRE’s website)

6. Conclusion

PRE’s Exploratory Committee on Research Ethics and Public Emergencies was created to examine questions pertaining to the application of principles and standards of the TCPS in the context of public emergencies. Through its review of literature, ethics, legislation and from feedback from public and targeted consultations, the Committee concluded that the basic TCPS principles and standards were adequate to guide research ethics review during officially declared public emergencies, with some minor clarifications and amendments. The Committee also recommended that institutions and REBs develop emergency preparedness plans for research ethics review during public emergencies.

Appendix A - Sampling of Provisions Relevant to Exemptions or Derogations from General Legal Principles on Grounds of Public Urgency

Government of Canada, *Emergencies Act*, (1985, c. 22 (4th Supp.)), Part 1, Art.3 National Emergency; Art. 6 Declaration of a Public Welfare Emergency; Part II, Art. 17 Declaration of a Public Order Emergency at: <http://laws.justice.gc.ca/en/E-4.5/index.html>

Part 1, Article 3 National Emergency

3. For the purposes of this Act, a “national emergency” is an urgent and critical situation of a temporary nature that [*emphasis added*]

(a) seriously endangers the lives, health or safety of Canadians and is of such proportions or nature as to exceed the capacity or authority of a province to deal with it, or

(b) seriously threatens the ability of the Government of Canada to preserve the sovereignty, security and territorial integrity of Canada

and that cannot be effectively dealt with under any other law of Canada.

Article 6 Declaration of a Public Welfare Emergency

6. (1) When the Governor in Council believes, on reasonable grounds, that a public welfare emergency exists and necessitates the taking of special temporary measures for dealing with the emergency, the Governor in Council, after such consultation as is required by section 14, may, by proclamation, so declare.

(2) A declaration of a public welfare emergency shall specify

(a) concisely the state of affairs constituting the emergency;

(b) the special temporary measures that the Governor in Council anticipates may be necessary for dealing with the emergency; and

(c) if the direct effects of the emergency do not extend to the whole of Canada, the area of Canada to which the direct effects of the emergency extend.

Part II, Article 17 Declaration of a Public Order Emergency

17. (1) When the Governor in Council believes, on reasonable grounds, that a public order emergency exists and necessitates the taking of special temporary measures for dealing with the emergency, the Governor in Council, after such consultation as is required by section 25, may, by proclamation, so declare.

(2) A declaration of a public order emergency shall specify

(a) concisely the state of affairs constituting the emergency;

(b) the special temporary measures that the Governor in Council anticipates may be necessary for dealing with the emergency; and

(c) if the effects of the emergency do not extend to the whole of Canada, the area of Canada to which the effects of the emergency extend.

International Declarations & Covenants

United Nations Educational, Scientific and Cultural Organization (UNESCO), *Universal Declaration on Bioethics and Human Rights*, 2005, Art. 6.2 Consent, Art. 9 Privacy and confidentiality, Art. 27 Limitations on the application of the principles at:

<http://unesdoc.unesco.org/images/0014/001461/146180E.pdf>

Article 6.2. Consent

Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form and should include modalities for withdrawal of consent. Consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or prejudice. Exceptions to this principle should be made only in accordance with ethical and legal standards adopted by States, consistent with the principles and provisions set out in this Declaration, in particular in Article 27, and international human rights law. [emphasis added]

Article 9 Privacy and Confidentiality

The privacy of the persons concerned and the confidentiality of their personal information should be respected. To the greatest extent possible, such information should not be used or disclosed for purposes other than those for which it was collected or consented to, consistent with international law, in particular international human rights law.

Article 27 – Limitations on the application of the principles

If the application of the principles of this Declaration is to be limited, it should be by law, including laws in the interests of public safety, for the investigation, detection and prosecution of criminal offences, for the protection of public health or for the protection of the rights and freedoms of others. Any such law needs to be consistent with international human rights law. [emphasis added]

Council of Europe, *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, Oviedo, 4.IV.1997, Chapter 5, Article 16 and Chapter 9, Articles 26 at: <http://conventions.coe.int/Treaty/EN/Treaties/Html/164.htm>;

Chapter IX- Relation between this Convention and other provisions

Article 26 – Restrictions on the exercise of the rights

- 1 No restrictions shall be placed on the exercise of the rights and protective provisions contained in this Convention other than such as are prescribed by law and are necessary in a democratic society in the interest of public safety, for the prevention of crime, for the protection of public health or for the protection of the rights and freedoms of others. [emphasis added]
- 2 The restrictions contemplated in the preceding paragraph may not be placed on Articles 11, 13, 14, 16, 17, 19, 20 and 21.

Nota: Article 11 Non-discrimination; Article 13 Interventions on the human genome; Article 14 Non-selection of sex; Article 19: General rule (Organ and tissue removal from living donors for transplantation purposes); Article 20 Protection of persons not able to consent to organ removal; Article 21 Prohibition of financial gain.

Chapter V- Scientific Research

Article 16 – Protection of persons undergoing research

Research on a person may only be undertaken if all the following conditions are met:

- i there is no alternative of comparable effectiveness to research on humans;
- ii the risks which may be incurred by that person are not disproportionate to the potential benefits of the research;
- iii the research project has been approved by the competent body after independent examination of its scientific merit, including assessment of the importance of the aim of the research, and multidisciplinary review of its ethical acceptability,
- iv the persons undergoing research have been informed of their rights and the safeguards prescribed by law for their protection;
- v the necessary consent as provided for under Article 5 has been given expressly, specifically and is documented. Such consent may be freely withdrawn at any time.

Directive 95/46/EC of the European Parliament and Council of 24 October 1995, on the protection of individuals with regards to the processing of personal data and on the free movement of such data (OJL 281, 23.11.1995, p.31), Chapter II – General Rules on the Lawfulness of the Processing of Personal Data, Section VI Exemptions and Restrictions, Art. 13, at:
<http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/consleg/1995/L/01995L0046-20031120-en.pdf>
or <http://www.dataprotection.ie/viewdoc.asp?DocID=93>

Chapter II – General Rules on the Lawfulness of the Processing of Personal Data,
Section VI Exemptions and Restrictions, Article 13,
Exemptions and restrictions

1. Member States may adopt legislative measures to restrict the scope of the obligations and rights provided for in Articles 6 (1), 10, 11 (1), 12 and 21 when such a restriction constitutes a necessary measures to safeguard: [emphasis added]

- (a) national security;
- (b) defence;
- (c) public security;
- (d) the prevention, investigation, detection and prosecution of criminal offences, or of breaches of ethics for regulated professions;
- (e) an important economic or financial interest of a Member State or of the European Union, including monetary, budgetary and taxation matters;
- (f) a monitoring, inspection or regulatory function connected, even occasionally, with the exercise of official authority in cases referred to in (c), (d) and (e);
- (g) the protection of the data subject or of the rights and freedoms of others.