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**Proportionate Approach to  
Research Ethics Review in the TCPS:**

*Proposed Textual Changes for*

**The Concept of Vulnerability in the TCPS**

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*Prepared by the*

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## I. Introduction

In the first consultation document<sup>1</sup> (Dec. 05 – March 06), ProGroup<sup>2</sup>, a working committee of the Interagency Advisory Panel on Research Ethics (PRE) recommended reconsidering the concept of vulnerability as discussed in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS). It proposed replacing “vulnerable” persons by “vulnerability” of persons or research subjects/participants to reflect the reality that vulnerability and resiliency exists along a continuum, and to allow for a more enhanced understanding of the presence or lack of risk to research subjects/participants.

Respondents to the public consultation who were supportive of the proposed change indicated that the term “vulnerability”:

- is more complete and appropriate in a multicultural society
- avoids labeling based on class of persons
- shifts the focus from a group concept to the individual in context
- makes sense and is a concept already used by many REBs

Of those who did not support the change in terminology, there was no overt disagreement with the term. Some questioned the net gain to result from the change. Others offered suggestions of issues that still need to be considered. For example,

- While determination of individual vulnerability is context dependent, the vulnerability of groups such as young children and incapable adults (i.e., permanent incapacity) cannot be ignored.
- Children should be recognized as a separate category and held to a special standard to prevent a disconnect between the law and ethics.
- While vulnerability is a preferred term in certain circumstances to avoid discrimination, its usage must not supersede federal or provincial legislation meant to protect people against discrimination.

## II. Purpose of this Paper

This paper represents a step forward from the previous consultation as it proposes two sets of textual recommendations for changes in the TCPS. ProGroup encourages comments on the specifics of the proposed TCPS textual changes in the following two sets of recommendations on “vulnerability”.

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<sup>1</sup> [http://www.pre.ethics.gc.ca/english/workgroups/progroup/Consultation\\_instructions.cfm](http://www.pre.ethics.gc.ca/english/workgroups/progroup/Consultation_instructions.cfm)

<sup>2</sup> ProGroup was created by PRE in 2003 to provide advice about priorities, methods and mechanisms for identifying gaps and procedural and definitional issues within the TCPS, and to coordinate a response to those issues.

### III. Recommendations

#### Recommendation 1

In reviewing the various sections of the TCPS that address the concept of vulnerability, two related observations were made that influenced ProGroup’s proposal of textual changes.

First, the authors of the TCPS provide a comprehensive consideration of competence where it is stated in the TCPS Section E, page 2.9, that:

Competence refers to the ability of prospective subjects to give informed consent in accord with their own fundamental values. It involves the ability to understand the information presented, to appreciate the potential consequences of a decision, and to provide free and informed consent. This ability may vary according to the choice being made, the circumstances surrounding the decision, or the time in question. Competence to participate in research, then, is not an all-or-nothing condition.

Second, in the section on Guiding Ethical Principles, TCPS page i.5, the authors of the TCPS state:

**Respect for Vulnerable Persons:** Respect for human dignity entails high ethical obligations toward vulnerable persons—to those whose diminished competence and/or decision making capacity make them vulnerable. Children, institutionalized persons or others who are vulnerable are entitled, on grounds of human dignity, caring, solidarity and fairness, to special protection against abuse, exploitation or discrimination. Ethical obligations to vulnerable individuals in the research enterprise will often translate into special procedures to protect their interests.

ProGroup concluded that the description of “competence” in the current version of the TCPS is consistent with its proposed recommendations on the term “vulnerability of persons”. Thus, rather than interfere with the integrity of the TCPS on the issue of vulnerability of persons, given that the term appears throughout the document, ProGroup proposes that the Principle of Respect for Vulnerable Persons be expanded as follows:

ProGroup proposes the following underlined textual changes to the TCPS.

*Concept of Vulnerability - Proposed Textual Changes # 1*

**Section C, Guiding Ethical Principles, TCPS, page i.5**

**Respect for Vulnerable Persons or Groups:** Respect for human dignity entails high special ethical obligations toward vulnerable persons— or groups, such as children, institutionalized persons or others, ~~to those~~ whose situation, diminished competence

and/or decision-making capacity make them vulnerable in the context of the research, and therefore unable to give full, free and voluntary informed consent. Children, institutionalized persons or others who are vulnerable are entitled, on grounds of human dignity, caring, solidarity and fairness, to special protection against abuse, exploitation or discrimination.

Vulnerability is dynamic and needs to be considered within a specific research project, and may change over time and with circumstances. Persons or groups not usually considered vulnerable may become so because of their circumstances at the time of the research. Persons or groups who are vulnerable to abuse, exploitation or discrimination should be provided special protections. While ethical obligations to vulnerable individuals, persons or groups in the research enterprise will often translate into special procedures to protect their interests, these may be subject to applicable laws, regulations and other requirements.

Persons should not automatically be considered vulnerable because of the group with which they may be identified.

## **Recommendation 2**

In the first consultation document, ProGroup made the point that a person may be vulnerable or at elevated risk of exploitation, stigmatization, discrimination, etc. simply because of membership in a group or class that has been previously designated as vulnerable—for example, children or prisoners. Membership in such a group is one factor that must be taken into account when assessing the vulnerability of an individual. In addition, other factors such as age or setting must be considered. Moreover, ProGroup contends that the presumption that vulnerability is a static state is incorrect: a person may be vulnerable in one circumstance, but not vulnerable in another. While ProGroup suggested that REBs and researchers must also avoid a paternalistic attitude when assessing the vulnerability of research subjects/participants or groups, it also notes that in considerations of research involving children, adequate protections must be in place to avoid a conflict between the law and ethics on this issue.

This observation, together with the first recommendation leads ProGroup to recommend that use of the term “vulnerable populations” which appears throughout the TCPS, be reconsidered. Thus, it is recommended that the term “vulnerable persons or groups” replace “vulnerable populations”.

The following underlined text shows the proposed changes.

*Concept of Vulnerability – Proposed Textual Changes # 2*

***TCPS, Section E, page 2.9***

“As indicated in the Ethics Framework of this Policy, the principle of respect for human dignity entails special ~~high~~ ethical obligations to the vulnerable ~~populations~~ persons or groups whose circumstances make them particularly vulnerable to physical or psychological harm, exploitation, abuse, stigmatization, or discrimination. Such obligations often translate into special procedures to promote and protect their interests and dignity.

*Concept of Vulnerability – Proposed Textual Changes # 3*

***TCPS, Section 5, page 5.1***

The important concerns about exploiting vulnerable ~~populations~~ persons or groups and visiting harms on research subjects are also relevant to the sections of this Policy on free and informed consent, privacy and REBs.

*Concept of Vulnerability – Proposed Textual Changes # 4*

***TCPS, Section 5, page 5.4***

Although ethical duties to vulnerable ~~populations~~ persons or groups preclude the exploitation of those who are incompetent to consent for themselves for research purposes, there is nonetheless an obligation to conduct research involving such people because it is unjust to exclude them from the benefits that can be expected from research....