

## **Highlights of changes: Summary of revisions in TCPS 2 (2018) New Guidance**

### **Chapter 2, Section B and Article 2.11**

Research involving communities: Supports the application of existing guidance for research involving Indigenous peoples to other distinct communities, where appropriate. New provisions explain how to assess, manage, and review risks to communities, including situations where non-participants might be inadvertently exposed to a research intervention.

### **Article 5.1**

Clarification of institutional responsibilities with respect to supporting researchers faced with an attempt by legal means to compel disclosure of confidential participant information: Incorporates advice from a public interpretation.

### **Chapter 2, Section B and Article 3.7A**

Population and public health research and its distinct requirements are reflected in the addition of relevant examples throughout the TCPS.

### **Chapter 11, Section A and Article 11.6**

Stopping rules: Provides considerations for stopping rules commonly used in sponsored clinical trials.

### **Article 11.1**

Requirement to apply all guidance in other chapters to clinical trials: Clarifies the requirement that researchers and REBs consider general guidance in other chapters (e.g., consent, confidentiality) in the design and review of clinical trials and removes repetition of guidance from other chapters.

### **Article 11.2**

Cluster randomized trials, adaptive design trials, registry-based trials: Describes specialized trial types and particular ethical issues raised by each one.

### **Article 11.3**

Justification of control groups: Provides new requirement for researchers to justify choice of control group to REB.

### **Article 11.6**

Contents of a safety monitoring plan: Clarifies what should be included in the mandatory safety monitoring plan.

## Article 11.7

Establishing a Data Safety Monitoring Board (DSMB): Provides considerations to help researchers and REBs determine whether a DSMB is needed.

## Chapter 11, Section D

Requirement to update clinical trial registry: Calls for the registry of clinical trials to be updated, consistent with current registry requirements.

## Chapter 11, Section A

Definitions: Explain the terms "intervention," "prospective assignment," and "placebo."

## **Topics Moved from Clinical Trials (Chapter 11)**

### Article 2.10

Research-Attributable risk: Identifies the need to distinguish between risks attributable to research from risks to which participants would normally be exposed.

### Article 4.8

Dissemination of research results: Clarifies the requirement to disseminate the analysis of data and interpretation of research results in a timely manner, without undue restriction, through publication or other means.

### Chapter 6, Section E and Article 6.24

Review of sponsor-researcher contracts: Recognizes the review of sponsor-researcher contracts as an institutional responsibility for all types of research. Clarifies that institutions should make such contracts available to research ethics boards if necessary.

### Article 7.4

Institutional responsibilities regarding financial conflicts of interest: Emphasizes the need for institutions to: (i) ensure that budgets and contracts are reviewed to identify conflicts of interest; and (ii) to manage them.

## **Clarifications**

### Articles 2.1 and 6.12

Course-Based research activities: States that course-based research activities require ethics review.

## Articles 2.1 and 6.11

Definition and review of pilot studies: Explains that pilot studies fall within the TCPS definition of research, and require ethics review. Distinguishes pilot studies from the exploratory phase of research.

## Article 2.2

Research involving information that is publicly available through legislation or regulation or that is in the public domain: Stipulates that research is exempt from research ethics board review when it involves information that is: (i) publicly available and protected by law; or (ii) in the public domain with no expectation of privacy.

## Article 3.4

Incidental findings: Indicates that the researcher's obligation to share material incidental findings is conditional on the consent of participants to receive the information. Details how to manage material incidental findings in different circumstances.

## Chapter 11, Section A

Systematic review: Define systematic review in the context of TCPS 2.

## Chapter 11, Section A

Role of principal investigator in multi-jurisdictional research: Distinguishes the role of the principal investigator in the context of multi-jurisdictional research.

## Article 11.4

Use of placebos: Clarifies use of placebos in superiority and non-inferiority studies.

## Article 11.8

Reporting new information: Defines the term "former participant," and specifies that the obligation ends upon the completion of the study.

## **Terminology Changes**

Throughout the Policy

"Aboriginal peoples" - "Indigenous peoples"

Throughout the Policy

"Vulnerable circumstances" - "circumstances that may make participants vulnerable in the context of research."

## Article 11.2

Different trial types: Makes minor clarifications to current guidance for Phase I, Phase II, Phase III, Phase IV, Natural Health, Medical Device, Surgical and Psychotherapy trials.

## **Correction**

Article 5.7 modified to align with guidance in Article 2.2.

Mark the checkbox to indicate you have read the TCSP2 2018 Highlight of Changes . This file will be added to my TCPS2 certificate.

Name: **Click or tap here to enter text.**

Date: **Click or tap to enter a date.**

Signature: