Terminology Changes

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

Pilot studies
Article 2.1 Application

- Pilot studies require REB review
- Smaller versions of the main study
- Purpose to assess the feasibility and/or inform design of subsequent study
- Previously only referred to in 6.11 under procedures for REB review

Institutional support of researchers Article 5.1

- Shared responsibility for protecting participant confidentiality
- REB approval triggers the requirement for institution to support researchers
- Independent legal advice
- Requires policies and procedures

Principal Investigator role in Multi-Jurisdictional studies - Section A.

- Lead PI is a designated PI who is responsible for the ethical conduct of the study for all sites
- Lead PI is the centre communication point for the study
  - Reports to REB any changes, new info, unanticipated events
  - Reports to sponsor (if any)
  - Reports to local site PIs

Cluster Randomized Trials Article 11.2

- Randomization of clusters takes place before identifying participants and consent
- May directly or indirectly affect individuals who are not the primary focus of the trial by any intervention applied to the cluster
- cluster-level trial interventions may be difficult for individuals to avoid

Adaptive designs
Article 11.2

- Participants joining a later phase might experience fewer risks and greater benefits
- Re-assignment of more participants to an intervention that looks more promising could expose them to side effects that take longer to emerge
- Smaller numbers of participants may reduce the ability to do more focused analyses possibly increasing any false negative or false positive results

Registry Trials
Article 11.2

- May benefit from guidance regarding secondary use of identifiable information for research purpose
- Possible issues related to linkage of records in different registries
- Require coordination with registry administrators as some aspects may overlap with the roles of the researchers

Control Groups
Article 11.3

- Researchers justifies to REB their choice of control group(s) by demonstrating the choice is:
  - relevant to the research question;
  - appropriate for the population of interest; and
  - consistent with the criteria for clinical equipoise.

Stopping Rules
Section A and Article 11.6

Predetermined mechanisms to:

a. **stop all or part of the stud**y due to evidence of greater than expected harms or greater than expected benefits in any of the study conditions;

b. **remove individual participants** from a study for their own safety.

Contents of Safety Monitoring Plan Article 11.6

a. how safety monitored and actions to be taken;

b. how efficacy will be monitored and actions to be taken;

c. the criteria for removing participants for safety reasons;

d. the study-wide stopping rules (if any) due to **evidence of inferior safety, superior efficacy or futility**; and

e. the reporting procedure to the REB

Data Safety Monitoring Board (DSMB) Article 11.7

- the magnitude of foreseeable research-attributable harms to participants;
- whether the circumstances of the participants make them vulnerable in the context of research;
- the feasibility of interim data analysis;
- the complexity of the study; and
- conflicts of interest.

Update Clinical Trial Registry Chapter 11, Section D

- Researchers must update the registry in a timely manner with:
  - new information (Article 11.8);
  - safety and, where feasible, efficacy reports (Article 11.6);
  - reasons for stopping a trial early; and
  - the location of findings.

Clarifications

- Course-Based research activities: States that course-based research activities require ethics review. Articles 2.1 and 6.12
- Systematic review: Define systematic review in the context of TCPS 2. Chapter 11, Section A
- Use of placebos: Clarifies use of placebos in superiority and non-inferiority studies. Article 11.4
- Reporting new information: Defines the term "former participant," and specifies that the obligation ends upon the completion of the study. Article 11.8


Thank you
for listening