Highlights of changes: Summary of revisions in TCPS 2 (2022)

Broad consent for the storage of data and human biological materials for future unspecified research (Chapters 3 & 12)	**Relevant articles in the TCPS**
New article: Introduces the concept of broad consent for the storage of data and human biological materials for future unspecified research, the elements it includes, and how it is consistent with the principles of TCPS.	New Section E in Chapter 3, including new Article 3.13 & Application of Article 12.2
***Evolving capacity & ongoing consent*:** Clarifies an individual's evolving capacity (i.e., developing capacity, diminishing or fluctuating capacity, and only partially developed capacity), including the need to ensure mechanisms to maintain informed and ongoing consent are in place, particularly in the context of evolving capacity.	Application of Article 3.3 & new Application of Article 3.13
***Shared responsibility*:** Specifies that the researcher, the relevant authority of the repository, and future researchers share the responsibility of ensuring that the terms of participant consent are respected, and that privacy and confidentiality are protected.	New Application of Article 3.13
***Creation of a repository*:** Specifies that research ethics board (REB) review is required for the creation of a repository and is subject to continuing review, in accordance with a proportionate approach. Mechanisms should be clearly outlined in the governance of the repository to ensure future use of data and human biological materials aligns with the original terms of participant consent.	New Application of Article 3.13

***Separate consent*:** Clarifies that when seeking consent for a specific research project at the same time as seeking consent for storage of data and human biological materials for future unspecified research, prospective participants must be provided with an option to consent to each separately.	New Application of Article 3.13
***Revised definitions*:** Revises the definition of "biobank" to better align with internationally accepted standard definitions. Revises the definition of "consent" to capture that consent can be provided by an authorized third party, when the prospective participant lacks the decision-making capacity.	Glossary
***New definitions*:** Adds five new definitions to the TCPS: "blanket consent," "broad consent," "repository," "research data repository," and "whole-genome sequencing."	Glossary
Streamlining multi-jurisdictional research ethics review of minimal risk research (Chapter 8)	**Relevant articles in the TCPS**
***Official agreements*:** Emphasizes that official agreements are only required for the adoption of models that streamline an ethics review of more than minimal-risk research.	Application of Article 8.1
***Legislation and policies*:** a) Moves text related to existing provincial legislation or policies that designate one or more REBs for the review of certain types of research earlier in the Application section to indicate that it applies to all models. b) Adds a clear message that where such legislation or policies exist, they supersede the research ethics review models outlined in Article 8.1.	Application of Article 8.1

***REB responsibilities*:** Outlines the responsibilities of the reviewing REB for all alternative research ethics review models.	Application of Article 8.1
***New ethics review model*:** Introduces a new model (becomes #3 in the list of models) that encourages streamlining multi-jurisdictional ethics review of minimal risk research without a requirement for official agreements amongst institutions.	Application of Article 8.1
***Streamlining ethics review*:** Strongly encourages institutions to streamline ethics review and asserts that duplication of ethics review that is not anticipated to provide additional protections for research participants can rarely be justified for research of all risk levels, and particularly for minimal risk multi-jurisdictional research.	Application of Articles 8.1 & 8.2
***Documentation*:** Encourages documentation of the process followed in selecting an alternative research ethics review model.	Application of Article 8.2
***Disagreements in selecting an alternative ethics review model*:** Clarifies the role of the REB in making a final decision where disagreements arise regarding the selection of the appropriate research ethics review model(s).	Application of Article 8.2
***Restructuring existing TCPS text*:** Restructures text within the Application of Article 8.1 such that the least preferred model, which was first in the list of models in TCPS2 (2018), becomes last in TCPS2 (2022). Restructures text for better flow within Article 8.2 itself and to better align with Article 8.1.	Application of Article 8.1 & Application of Article 8.2

Research involving human totipotent stem cells (Chapter 12)	**Relevant articles in the TCPS**
***Research involving human totipotent stem cells*:** Introduces the concept of totipotent stem cells into Chapter 12, Section F to ensure scientific accuracy in light of the evolving science.	Chapter 12, Section F
***Research not permitted under Canadian legislation*:** Clarifies the intention and application of Article 12.10 and the types of stem cell research that cannot be conducted.	Application of Article 12.10 (#2)
***Substantive deviation from original terms of consent*:** Recognizes that researchers may use a more streamlined approach whereby the initial consent for donation would include the option to donate for research purposes (i.e., broad consent). Therefore, subsequent consent will only need to be sought again if future use constitutes a substantive deviation from the original terms of consent.	Article 12.12
***Impossible or impracticable*:** Clarifies that circumstances that make it impossible or impracticable to withdraw a participant's data or biological materials must be clearly articulated to the participant during the consent process.	Article 12.13(b) & its Application
***Revised definitions*:** Revises the definitions of "Human embryonic stem cell (hESC)" and "pluripotent stem cell" to ensure scientific accuracy in light of the evolving science. Revises the definition of "embryonic stem (ES) cell" to refer to the definition of hESC.	Glossary
New definitions: Adds a new definition to the TCPS: "totipotent stem cell."	Glossary

Review of research involving human cell lines (Chapter 12)	**Relevant articles in the TCPS**
***De-identified human biological materials*:** Clarifies that these include both those that have been anonymized or coded.	Chapter 12, Section A
***New article*:** Introduces an exemption from REB review for research that relies exclusively on the re-use of de-identified human somatic cell lines.	New Section G in Chapter 12, including new Article 12.21
***New article*:** Introduces an exemption from REB review for research that relies exclusively on the re-use of identified human somatic cell lines in the public domain (e.g., HeLa cell line).	New Section G in Chapter 12, including new Article 12.22
***HeLa cell line*:** Includes a brief description of what the HeLa cell line is and the fact that it is an example of a cell line in the public domain.	New Application of Article 12.22
New definitions: Adds two new definitions to the TCPS: "cell line" and "re-use."	Glossary