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TCPS 2

HIGHLIGHTS OF CHANGES

December 2014

Chapter 2 - SCOPE AND APPROACH

- Defined disciplined inquiry
- Clarified factors that determine whether an activity is research requiring REB review

Chapter 3 - THE CONSENT PROCESS

- Article 3.7 divided into two articles to clarify:
  - the range of alterations to consent;
  - guidance regarding debriefing in the context of alterations to consent;
- Clarified that the option to withdraw information is required unless adequate justification for limiting or removing this option is provided
- Introduced exceptions to the obligation to disclose material incidental findings
- Clarified that consent is based on decision-making capacity, not chronological age

Chapter 5 - PRIVACY AND CONFIDENTIALITY

- Made explicit that consent is not required for research that relies exclusively on secondary use of non-identifiable information
- Clarified that the assessment of identifiability is context-specific

Chapter 6 - GOVERNANCE OF RESEARCH ETHICS REVIEW

- Added considerations for determining the highest body of an institution for the purposes of establishing an REB
- Clarified that theses and other equivalent student research projects require REB review
- Clarified when annual renewals of more than minimal risk research may be delegated
- Added requirement for institutions to develop criteria for determining when REB involvement is no longer required

Chapter 10 - QUALITATIVE RESEARCH

- Provided clearer examples of public spaces for the purposes of observational research

Chapter 11 - CLINICAL TRIALS

- Clarified requirements associated with registering clinical trials and updating clinical trial registries
- Encouraged researchers to make their data available for further analysis and verification
- Clarified access to data by Principal Investigators and Site Investigators in multi-site clinical trials

Chapter 12 - HUMAN BIOLOGICAL MATERIALS INCLUDING MATERIALS RELATED TO HUMAN REPRODUCTION

- Incorporated CIHR's Guidelines for Human Pluripotent Stem Cell Research, including modifications for consistency with TCPS 2 structure and terminology
- Changes made in Chapter 5 were also made in Chapter 12