

Research Ethics Bulletin #3: SECONDARY USE

What is secondary use of information or human biological materials?

TCPS2 (2014) defines secondary use as the use in research of information or human biological materials originally collected for a purpose other than the current research purpose. For example, this could describe accessing information or human biological materials that were originally collected in a clinical setting, and re-using that information or materials to answer a research question (e.g. research using medical charts) or re-analyzing an existing research data set with a different research question.

Does secondary use of information or human biological materials require REB review?

Article 2.4 of TCPS 2 (2014) states that REB review is not required for research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information.

The information or human biological materials must meet the TCPS 2 definition of 'anonymous' (for example, 'anonymous human biological materials' in TCPS 2 is defined as materials that have "never had identifiers attached to them and the risk of identification of individuals is low or very low" (Chapter 12, Section A).

Where a researcher seeks data linkage of two or more anonymous sets of information or human biological materials and there is a reasonable prospect that this could generate identifiable information, then REB review is required.

In Newfoundland and Labrador there is a heightened risk of identification and possible stigmatization where we are a small geographic area and data sets may contain information on or human biological materials about individuals with unique characteristics (e.g. uncommon field of occupational specialization, diagnosis with a rare disease, etc.).

Guidance related to other categories of identifiable and non-identifiable information and human biological materials and their secondary use is provided in Chapters 5 and 12 of TCPS 2 (2014) and will be explored further in tomorrow's bulletin.

Is consent required for secondary use of information or human biological materials?

To determine whether consent is required, the researcher must first assess whether the information or human biological materials are identifiable in the context of the research project. "Identifiable" means the information or human biological materials may reasonably be expected to identify an individual alone or in combination with other available information. For example, human biological materials that have had direct identifiers replaced with a code may identify individuals in research projects where the researcher has access to the key that links participants' codes with their names. However, the same coded human biological materials may be assessed as non-identifiable in research projects where the researcher does not have access to the key.

Researchers are not required to seek participant consent for research involving the secondary use of non-identifiable information or human biological materials.