

UWO – HSREB & NMREB	GUIDELINE	1-G-002	Page 1 of 1
Effective date: 02-02-12	SECONDARY USE OF DATA		

Background:

The ‘secondary use of data’ refers to the use of information or a biologic sample of body tissue or fluid initially collected for a purpose involving a specified research project or for individual health care or education but subsequently proposed for use in a different research project. Such a use is of ethical concern when the data could be linked to an individual who might then be identified in a published report and/or the subject has objected to their data or sample being used in a second or subsequent studies.

Implications:

The positive aspect of permitting the secondary use of data centres on the unforeseen or serendipitous aspect of future research that has contributed so extensively to scientific discovery and enhanced the current understanding of health and disease. Additionally, the subsequent availability of such data may provide useful information to the study subject and/or family that was not envisioned at the time the data or sample was collected. Conversely, such a process may potentially lead to a loss of the confidentiality of personal information that could be detrimental or unfair to the individual or their family.

The current Tri Council Policy document (Articles 3.3, 3.4 and 3.5):

The TCP document states that if personally identifiable information is accessible through any linkage with the data sample, REB approval shall be sought for the ‘secondary use’ of data. To provide approval in such circumstances, REB must ensure that:

- the potential to derive personally identifiable information is essential to the research-appropriate measures are in place to protect the privacy of the individual by ensuring the confidentiality of the data
- potential harm to subjects is minimized
- subjects have not objected to the secondary use of their data, and
- a ‘proportionate’ approach is taken in addressing the sensitivity of these issues.

Mechanisms to be considered by REB in providing approval for the secondary use of data collected within a research study include assurance of reasonable informed consent as reflected in the Information and consent documentation in the primary protocol. The documentation should outline at least in general terms both the positive and negative implications of the linkage of research data to the study subject personally. Dependent on the proportional risk associated with the data, the REB may require evidence of an appropriate strategy to obtain current consent from or inform the contributing subjects or their representatives or to sample the opinion of a subset of the participating group before initiating the secondary use of their data.

A project in which the secondary use of data is derived from information or a sample for which no direct linkage with an individual study subject is possible would not be subject to REB review. REB recommends however that if information or a biologic sample obtained for research purposes will not be destroyed or all potential linkage deleted immediately following its specific use as documented in the Information/consent documentation, the potential for the secondary use of the subject’s data and the general implications of this possibility to the subject and their family should be outlined in the information/consent documentation.