

## GUIDELINE FOR APPLICANTS – Secondary Use of Data in Research

### Purpose of Guidelines

This document provides guidance for individuals preparing applications for review by the Athabasca University (AU) Research Ethics Board (REB) for ethical review of research studies involving humans that utilizes data contained in records collected for a purpose other than the current research project.

### Research Studies that Require REB REVIEW

All research studies involving humans, with the exception of the exclusions listed in the TCPS2, conducted by members of the university community or by external researchers who use AU resources or recruit participants from AU, must receive prior written approval from the AU Research Ethics Board (REB).

The ‘university community’ comprises all AU faculty, staff, research assistants, graduate students and visiting researchers. Approval is required irrespective of the source of financial support (if any) and irrespective of the location of the research study (in the latter case, as long as the investigator represents the work as AU research).

Research is understood to be “an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation.” “Disciplined inquiry” refers to an inquiry that is conducted with the expectation that the method, results, and conclusions will be able to withstand the scrutiny of the relevant research community.”

**Secondary Use of Information for Research Purposes** refers to “the use in research of information (data) originally collected for a purpose other than the current research purpose.” (TCPS2, Chp 2, Art. 2.4 and Chp 5, Sec. D) Some common examples are health survey datasets, school records, and vital statistics registries). The Tri-Council Policy Statement makes a very clear distinction between secondary data that is *anonymous* vs. that which is *anonymized or coded*.

Chapter 5 of the TCPS2 defines the type of information (data) in these ways:

1. **Anonymous information** – the information never had identifiers associated with it and the risk of identification of individuals is low or very low.
2. **Anonymized information** – the information is irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage and risk of re-identification of individuals from remaining indirect identifiers is low or very low.
3. **Coded information** – direct identifiers are removed from the information and replaced with a code. Depending on access to the code, it may be possible to re-identify specific participants.
4. **Indirectly identifying information** – the information can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g. date of birth, place of residence or unique personal characteristic).
5. **Directly identifying information** – the information identifies a specific individual through direct identifiers (e.g. name, social insurance number, personal health number).

There are two distinct considerations when using secondary information (data) in research:

1. Is ethical review of the research required?
2. If so, must you get consent (re-consent) from participants to use the secondary data in your research?

### How can you determine if ethical review is required if you are intending to access/use secondary data in your research?

Ethical 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.

Ethical review **IS required** for research that relies on secondary use of **anonymized, coded**, direct or indirectly identifying information.

### When do you need to obtain consent (re-consent) from participants to use secondary information (data)?

In Chapter 5, Section D, Article 5.5A, the TCPS2 sets out the criteria that must be met in order for a researcher to be approved to use secondary data without obtaining consent from the participants. The Researcher must satisfy the Research Ethics Board (REB) of ALL of the following:

- a) Identifiable information is *essential* to the research;
- b) The use of identifiable information without the participants' consent is unlikely to adversely affect the welfare of individuals to whom the information relates;
- c) The researchers will take appropriate measures to protect the privacy of individuals, and safeguard the identifiable information;
- d) The researchers will comply with *any known preferences* previously expressed by individuals about any use of their information
- e) It is impossible or impracticable to seek consent from individuals to whom the information relates; and
- f) The researchers have obtained any other necessary permissions for secondary use of information for research purposes.

In Chapter 5, Section D, Article 5.5B, the TCPS2 stipulates that researchers need ethical approval from the REB, but DO NOT have to seek participants' consent for the use of secondary **non-identifiable** information (data). Within the ethics application, it is the researcher's responsibility to establish to the satisfaction of the REB that in the context of the proposed research, the information (data) to be used can be considered non-identifiable for all practical purposes.

### Research Using Publicly available information

There is a clear exemption in the TCPS2 regarding research that relies *exclusively* on publicly available information when that information is:

- a) Legally accessible to the public and appropriately protected by law; or
- b) Publicly accessible and there is no reasonable expectation of privacy.

No distinction is made in this exemption to whether information is identifiable or not. Examples of the types of information that may be considered "publicly available or made accessible through legislation or regulation" include stored documentary material, records or publications, registries of deaths, court judgments or public archives.