

Secondary Use of Non-identifiable Data

This document provides guidance for completing the Standard Application in MacREM when a study is relying solely on Secondary Use of Non-identifiable Data.

As per the TCPS2, Article 5.5B:

Researchers shall seek REB review, but are not required to seek participant consent, for research that relies exclusively on the secondary use of non-identifiable information.

For REB review purposes, non-identifiable data covers both anonymized and de-identified data. Anonymized data is data that at a previous point in time was identifiable, but the data held by the data custodian has now been stripped of identifiers and any links to identifying information. De-identified data is when the data custodian retains data that is identifiable or linked to identifying information but is providing researchers with a de-identified dataset for secondary use in research.

Secondary use of non-identifiable data is a very straightforward application and normally only goes to one REB reviewer since it is very low risk. The REB is primarily checking to confirm:

- the data qualifies as non-identifiable (per TCPS2 definition) as opposed to identifiable,
- whether there are any necessary data sharing agreements in place,
- that the data security procedures are adequate, and
- that any risks to a specific community, to whom the data pertains, are addressed.

How to complete the Standard Application in MacREM: <https://macrem.mcmaster.ca/>

Sections 1-7: complete as you normally would for any research study. Section 6, research with Indigenous people in Canada, would need to be completed if the dataset pertains to an Indigenous community.

Section 8: complete as normal by providing sufficient background to the project and/or secondary data and the purpose or research question/s.

Section 9: Since the data pertains to a certain population, you still need to complete this section to describe the “participants” – e.g., who is the data about, how many people are included in the data set?

Section 10: There is no recruitment, so you can put “not applicable, secondary use of data” or similar in any mandatory text fields and for the list of recruitment documents check “Not Applicable (e.g., study only involves secondary use of data)”.

Section 11: Complete as normal, but for the first question (11.1) you would need to describe how you are obtaining the data (i.e., requesting or receiving data from...). Other questions may be “not applicable”.

Section 12: The most important part for a secondary use application, as this specially covers the details of the secondary use. You will need to provide a list of the variables you are planning to use. Also, since obtaining the data normally involves a data access agreement (or similar) with the data custodian you should upload that document. Depending on timing of the two processes, you may not have a signed version of the document when submitting the ethics application. That is okay, in that case the ethics clearance would have the condition that you need to submit the signed document to the ethics file before starting the research.

Section 13 and 14: Complete as normal, but it is mostly N/A or No. The Benefits and Experience questions should be answered.

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Section 15: Complete as normal. Questions about how the secondary research data will be collected, stored, transported and retained must be answered. MREB will evaluate the data security procedures. Check to see if there are any data security requirements from the data custodian for using the data (e.g., do you have to keep it encrypted? Is there a certain length of time after which you need to destroy the raw data sent to you?).

Section 16: Since it is non-identifiable data, for 16.1 you can state that additional consent is not required for secondary use of non-identifiable data. It's likely this whole section will be N/A or No (except perhaps the sharing of research results with a specific community, as applicable).