

Tips for Filling Out Secondary Use Applications

When filling out the Biomedical Application for the Secondary Use of Health Data, there are certain sections that frequently give applicants trouble. The following is a guide to help you complete these sections correctly.

PART 4: CONSENT/REQUEST FOR WAIVER OF CONSENT

Request to Conduct Research Without Consent

Article 5.5 of the TCPS2 2018:

Researchers who will not obtain consent from participants for secondary use of identifiable information shall only use such information for these purposes if they have satisfied to the REB that:

- 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 to 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;
- f. The researchers have obtained any other necessary permission for secondary use of information for research purposes.

If a researcher satisfies all the conditions in Article 5.5 (a) to (f), (which also complies with Section 29 of the Saskatchewan Health Information Protection Act (HIPA)), the REB may approve the research without requiring consent from the individuals to whom the information relates.

When asking for waiver of consent, please address **all** of the items (a-f) above.

PART 6: DATA COLLECTION, USE AND DISCLOSURE

Describe how the data will be stored.

All research documents must be securely stored in a specified area. It is best practice to store research documents behind 2 locks (e.g., in a locked filing cabinet, located in a locked office). Your application must clearly specify *where* the data will be physically located, including both electronic and paper, and specify *who* will be responsible for the storage (usually this person will be the principal investigator).

A note on computer security:

It is strongly recommended that institutional electronic cloud storage be used instead of utilizing a personal computer. Institutional cloud storage is available to researchers and serves as a standardized level of security. Any electronic devices that will contain data (desktop and laptop computers, smart phones or memory sticks) must be password protected.

The Research Ethics Office strongly recommends that master lists and data collection tools be stored separately. However, if in the course of gathering data, circumstances demand that both be on a laptop or thumb drive that travels out of the study office, the device should be encrypted.

Please note that for electronic data, deleting the file from the computer or device still leaves information that can allow files to be retrieved using sophisticated methods. Free file eraser programs (e.g., Eraser) are available that can overwrite the deleted files on personal computers/laptops and portable media.

Describe the safeguards in place to protect the confidentiality and security of the data. If a coding procedure is being used, describe in detail

To protect participant identity, identifying information must not be recorded in the data set. Identifying information must be kept separate from the data. Creating a master list and a data collection tool is one way to accomplish this.

The master list should include an identifier (e.g., medical record number, health services number) and a unique non-identifying participant ID. The data collection tool should include the same participant ID and the data elements you plan to extract from the participant’s chart. The data collection tool should not contain any names or other identifiers (i.e. full date of birth) with the exception of the study identifier. The master list is the link back to the source document. This is an example:

Master List

Participant ID	Personal Health Number (PHN)
1	
2	

Then, on a separate page:

Data Collection Tool

Participant ID	Age	Date of Dx	Admitting blood glucose level	Discharge blood glucose level
1				
2				

Postal code and date of birth are considered indirect identifiers, as when either is combined with other data points, it increases the likelihood that the participant could be re-identified. If these identifiers are required for your project, collecting the first 3 digits of the postal code and/or the month and year of birth are acceptable. If the variables cannot be altered, justification must be provided to the REB. You should only collect that which is necessary to address your research questions.

Submit your template master list and data collection tool and provide a statement confirming the two document will be stored separate and apart from each other.

The master list must be stored in a secure location (e.g., locked filing cabinet in the locked office of the Principal Investigator), or in an appropriately secure electronic form (e.g., password protection, encryption).

The master list must be stored separately from the study data.

How long will the data be retained?

Research record retention periods will vary depending on the research discipline, research purpose and type of records involved. Research records must be retained for no less than:

- Five (5) years after the end of a research project's records collection and recording period;
- Five (5) years from the submission of a final project report; or,
- Five (5) years from the date of publication of a report of the project research;

The Master List is to be appropriately destroyed when all aspects of the project have been completed, inclusive of the required data storage period (5-years).

In this section you need to indicate your intended data retention period and provide an assurance that any hard copy and electronic data will be permanently and confidentially destroyed (i.e. destroyed beyond recovery) after the retention period.

Key Concepts

The following categories provide guidance for assessing the extent to which information about an individual could be used to identify that individual:

- **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).
- **Coded (or de-identified) 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 individuals (e.g., the principal investigator retains a list that links a participant code (study ID #) to the individual so that re-linkage is possible, if necessary).
- **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.
- **Anonymous information** – the information never had identifiers associated with it (e.g., anonymous surveys) and risk of identification of individuals is low or very low.

McMaster Chart Review and TCSP2 Core Tutorial

Student investigators are required to submit their certificates of completion for the TCPS2 Core tutorial <https://tcps2core.ca/welcome>, and McMaster Chart review tutorial <https://ethics.mcmaster.ca/chart/> (when chart review or data abstraction activities are involved in the project). Certificates must be received for ethical approval to be granted.