

## Tips for Filling Out Chart Review Applications

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

### **PART 3: DATA ACCESS**

#### **3.5: Waiver of Consent**

Article 5.5 of the TCPS2 2014:

Researchers who have not obtained consent from participants for secondary use of identifiable information shall only use such information for these purposes if they have satisfied 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 who 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 impractical to seek consent from individuals to who 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.

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#### **Section 3.6: How will the confidentiality of participant data be protected?**

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. This is an example:

##### **Master List**

Participant ID	Hospital Chart Number
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				

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 with the exception of the study identifier. The master list is the link back to the source document.

Postal code and date of birth are indirect identifier inasmuch as when either is combined with other data points, it increases the likelihood that the participant could be re-identified. If you need these identifiers for your project, you must provide justification for their inclusion. You should only collect that which is necessary to address your research questions.

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

## **PART 4: DATA SECURITY AND STORAGE**

### **Section 4.2: Describe the storage arrangements and final disposition of the research data collected**

All research documents must be securely stored in a specified area (e.g., in a locked filing cabinet located in the principal investigator's hospital office.). Your application must clearly specify where the data will be physically located, including both electronic and paper. Specify who will be responsible for the storage (usually this person will be the principal investigator).

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.

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

Research record retention periods will vary depending on the research discipline, research purpose and type of records involved. Research records must be retained for not 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;

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.

## **Computer 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.

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## **McMaster Chart Review**

Students will be required to complete the McMaster Chart review tutorial and submit the certification number (or an e-copy of the certificate) to us if accessing patients' health records for research. This must be done before final approval can be given. The tutorial takes approximately 15 minutes to complete and can be found at: <https://ethics.mcmaster.ca/chart/>