**Guidance Notes**

**For Research Ethics Board Application to Access Existing Health Data**

The following Guidance Notes (GNs) are intended to ensure that applicants have the necessary information to be able to fill out the Application for Research Ethics Review correctly. The guidelines in this document comply with those of the Tri-Council Policy Statement (TCPS 2) on 'Ethical Conduct for Research Involving Humans' (2018) as well as Section 29 of the Saskatchewan Health Information Protection Act.

The purpose of a REB is to determine whether the research question or hypothesis is scientifically and therefore ethically valid; and, if so, whether the research is in compliance with the relevant ethical requirements for carrying out research involving human participants, which includes their personal information. In accordance with TCPS, the research project cannot begin until the REB issues its written approval of the research proposal. All investigators are responsible for understanding and adhering to the TCPS and other relevant guidelines. These Guidance Notes are not intended to be a substitute for this responsibility. Refer to the original documents for complete information.

These notes are offered as guidance to investigators. They are not intended to apply to every situation. The Board may, under certain circumstances, require different procedures than those described here. Similarly, investigators may request that a process other than that described here be followed for a particular project.

**Submitting Your Application**

All applications for ethical approval of research proposals (i.e., those requiring full board review and those qualifying for expedited review) are made by submitting **ONE electronic copy** of the completed application form and all attachments.  *Please submit signature pages either as scanned PDF pages of hand written signatures or a signature that has been created using digital signature technology. Typed text submitted in lieu of a signature will* ***not*** *be accepted.*

Applications must be type written. Hand written applications will be returned.

Theelectronic copy of your application and all related files can be sent to ResearchEthics.Regina@saskhealthauthority.ca.

All signatures requested must be obtained prior to submission to the Board. Applications with missing signatures will be returned to the investigator without review. Delegated Minimal Risk studies will be reviewed by the Research Ethics Specialists or Chair of the REB on a regular basis. Full Board Above Minimal Risk applications must be received at least fourteen working days prior to a scheduled meeting and will be reviewed at the following monthly meeting. The application is recorded and forwarded to the Chair of the Board. Following review by the Committee, the Chair will communicate the decision regarding suitability to the applicant in writing. For REB meeting dates and submission deadlines, see the website.

All personnel of studies involving contact with patients (e.g. consenting participants for prospective chart reviews, participant interviews, participant surveys, focus groups, etc.) must complete the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS) tutorial, available at <https://tcps2core.ca/welcome>, prior to submission to the Board.

**How to Use the Guidance Notes With The Application Form**

The GNs are numbered and correspond to the same numbered box in the Application Form. It is the responsibility of the investigator(s) to ensure that the information contained in each GN is applied in a manner appropriate to each individual project for both the Application Form and any accompanying documentation. The REB requires a complete response to each question in the Application Form.

|  |
| --- |
| PART 1: Identification\* |

**GUIDANCE NOTE 1.1:****PROJECT TITLE**

The title of the project should accurately reflect the nature of the project.

The title given in Box 1.1 of the Application Form and the title of the protocol submitted should be the same and correspond to the title of any consent form(s) also submitted. If applicable, include the protocol number in brackets at the end of the title.

**GUIDANCE NOTE 1.2: PRINCIPAL INVESTIGATOR**

The "principal investigator" is the individual who is ultimately responsible for the actions of those acting with delegated authority. He/she is the person responsible for the conduct of the project at a research institution or the responsible leader of the team.

The Principal Investigator for a project must notify the REB office in writing when this responsibility is going to be assumed by a different investigator. Principal Investigators must also ensure that a process is put into place to ensure the ongoing safety of research participants in the event that the Principal Investigator leaves or retires from their University or Saskatchewan Health Authority affiliated position and the project remains ongoing.

Unless noted otherwise in Section 1.5, the REB office will send all *Notices of Ethical Review, Acknowledgements*, and *Certificates of Approval* to the email address provided for the Principal Investigator.

Institutional email addresses are recommended to assure confidentiality of REB correspondence.

**GUIDANCE NOTE 1.3: AFFILIATION REQUIREMENTS**

The Principal Investigator bears the overall responsibility for the conduct of the project, including the activities of sub-investigators, who are assumed to be acting under the delegated authority of the Principal Investigator. All research being conducted by a University and/or Saskatchewan Health Authority affiliated investigator must receive REB approval.

A Principal Investigator (PI) either has a faculty appointment (Clinical Assistant Professor, Clinical Associate Professor, Clinical Professor, Professor, or SCA Investigator) or is deemed a PI by an affiliated institution or by a Dean.

For research being conducted within the Saskatchewan Health Authority (SHA), the Principal Investigator of the project must hold a staff appointment within a SHA affiliated institution. Projects being conducted by residents, students, or Out-of-Region investigators must appoint a local Principal Investigator who will be responsible for the conduct of the project at that institution for all Above minimal risk studies, but may be able to conduct research that is deemed minimal risk but will require that a CV and all other necessary certifications and training be submitted to the REB with their application.

**GUIDANCE NOTE 1.4:****PROJECT PERSONNEL**

All persons assuming a role within the project that are to be listed on the *Certificate of Approval* must be noted on the application. This includes, but is not limited to sub-investigators, residents, student investigators, and faculty advisors.

For each person noted in this section, the particular position/role they serve in the project should be identified. Typical positions may include statistician, research assistant, study/project coordinator, sub-investigator, transcriptionist, or student researcher.

All personnel who are associated with a research project involving access to health data are expected to have completed the McMaster Chart Review tutorial. Non-faculty personnel includes (but is not limited to) undergraduate and graduate students, medical residents, research assistants, research coordinators, etc. The REB requires that all Principal Investigators be familiar with the McMaster Privacy Tutorial and recommends that PIs also complete it.

The tutorial is free and can be completed in 15 minutes. The certificate of completion should be attached to this application. The McMaster Chart Review Tutorial can be found at the following address:

 <http://ethics.mcmaster.ca/chart/>

**GUIDANCE NOTE 1.5: PRIMARY CONTACT PERSON**

Include the name and contact information for anyone other than or in addition to, the Principal Investigator that should receive a copy of all REB-related correspondence.

**GUIDANCE NOTE 1.6:****INSTITUTIONS WHERE THE RESEARCH WILL BE CARRIED OUT**

Enter the names of locations/institutions where the research will be carried out under this Research Ethics Board approval. The project cannot begin until you receive approval from the institutions specified. It remains the PIs responsibility to obtain necessary research approvals from these institutions, for SHA Research Approval please go to (add link to OA page). Once an REB file number is received the Research Approval process can be initiated, for projects at SHA institutions it is prudent to inform departments that may be impacted by research while formulating an REB proposal to assure that departments can accommodate the research requests.

**GUIDANCE NOTE 1.7:****PROPOSED PROJECT PERIOD**

Enter the estimated start date and end date of this project. In order to extend the proposed end date of a project an amendment must be submitted to the REB. Also indicate if there are extenuating circumstances that the REB should be aware of that necessitate the delegated/expedited review of this project.

**GUIDANCE NOTE 1.8:****PROJECTS BEING SUBMITTED FOR REB APPROVAL AT OTHER INSTITUTIONS**

Indicate whether this project is under review OR has received approval from another REB in Saskatchewan and/or a REB outside of Saskatchewan. Projects that have received approval from another REB may be eligible to receive an expedited/delegated review.

For projects being conducted in multiple sites within Saskatchewan or that require REB approval from multiple institutions, the research ethics review process can occur simultaneously at all of these sites, provided the PI informs the REB at the time of submission.

**GUIDANCE NOTE 1.9:****SOURCE OF FUNDS**

Source of funds refers to the agency/sponsor of the proposed research that will be providing the funds needed to undertake the project.

Note that research receiving its funding from an industry sponsor (i.e. pharmaceutical/medical devices company or an agent thereof) is participant to the fee for ethical review. Please contact your Research Ethics Office for more information regarding the payment amount and submission requirements.

The ethics review fee is waived for the following projects:

1. Projects that have received a grant-in-aid (normally an investigator-initiated project with partial funding-e.g. supply of drugs or devices or a very limited amount of funding from an industry sponsor);
2. Projects that are funded by not-for-profit agencies;
3. Projects that receive internal grants from an affiliated institutions or are self-funded;
4. Projects funded by SHRF, CIHR, NSERC, CHSRF, and NIH (including NIH Institutes), and;
5. Projects without external funding.

**GUIDANCE NOTE1.10:****FUNDING STATUS**

Indicate whether or not the funds have been awarded yet. Investigators must send a letter to the REB office informing them of any changes or additions to the funding source(s).

**GUIDANCE NOTE1.11:****NAME OF SPONSOR**

“Sponsor” refers to an individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial. For unfunded/investigator-initiated projects, the sponsor could be the principal/qualified investigator. The sponsor is usually responsible for applying for regulatory approval with the Health Protection and Food Branch of Health Canada.

|  |
| --- |
| PART 2: BRIEF OVERVIEW OF THE RESEARCH PROJECT\*  |

**Guidance Note 2: SUMMARY OF RESEARCH PROPOSAL**

Provide a short summary of the research project written in lay language and suitable for the non-scientific REB members. Do not exceed one page.

**Guidance Note 2.1: RESEARCH QUESTION/HYPOTHESIS**

Specify the precise research questions being evaluated in the project. It is the main reason that the project is being conducted (e.g. to determine efficacy, equivalence, safety, dosage levels, effectiveness).

**Guidance Note 2.2: RESEARCH DESIGN/METHODS**

This should include a description of the sample, sample size, sampling method, and justification for the sample size.

**Guidance Note 2.3: POTENTIAL SIGNIFICANCE/JUSTIFICATION**

Explain what is unique about the project in order to support the ethical tenet that the proposed research has value. In particular this section should explain what new research questions can be answered.

|  |
| --- |
| \*PART 3: DATA ACCESS  |

**GUIDANCE NOTE 3.1: DATA SOURCES REQUIRED:**

Please be sure to check all applicable data sources and please note that ehealth data may require a data sharing agreement with the Ministry of Health. The eHealth viewer cannot be used for research purposes. Please note that SCA has a separate process for data access and that information can be found here: <http://www.saskcancer.ca/research-article/data-access-requests>. SCM access will require a research specific account and this should be requested through the SHA Research Approval Process. Clinical SCM accounts should not be used for research data collection. If private office data is being used please specify in the “other” section what data sources will be used (EMR, Accuro etc.)

**GUIDANCE NOTE 3.2: TYPE OF DATA SOURCE:**

Please specify whether data is in hard copy charts or is from an electronic data source such as SCM or an EMR.

**GUIDANCE NOTE 3.3: NUMBER OF RECORDS/CASES/CHARTS REQUIRED:**

Please note that there may be associated fees for accessing SHA health data form Health Information Services. The fee per chart is $7.10 for on-site charts and $17.70 for charts requiring retrieval from off-site long-term storage. If no external funding is available to cover this fee, a strict limit of 200 charts per study will be imposed.

**GUIDANCE NOTE 3.4: INCLUSION CRITERIA:**

The data to be collected off of the charts/records need to be clearly outlined. Provide all inclusion criteria as described in the protocol. If you require only aggregated data (i.e., you do not need to collect and use personal health information from individual medical charts/health records) indicate your search criteria such as: ICD codes, diagnosis, procedure, time period, etc.

**GUIDANCE NOTE 3.2: WAIVER OF CONSENT**

*HIPA* states: Regarding the Use and Disclosure of Personal Health Information for research where it is not reasonably practicable for the consent of the subject individual to be obtained, a trustee or designated archive may use or disclose personal health information for research purposes if:

(a) the research purposes cannot reasonably be accomplished using de-identified personal health information or other information; (the research data will be de-identified by staff who would normally have access to this information)

(b) reasonable steps are taken to protect the privacy of the subject individual by removing all personal health information that is not required for the purposes of the research; (only the information specific to the research is being collected)

(c) in the opinion of the research ethics committee, the potential benefits of the research project clearly outweigh the potential risk to the privacy of the subject individual; and

(d) all of the requirements set out in clauses (a) to (c) are met.

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 the REB that each of the following from TCPS 2, 2018 Article 5.5A are addressed:

1. identifiable information is essential to the research;
2. the use of identifiable information without the participants’ consent is unlikely to adversely affect the welfare of individuals to whom the information relates;
3. the researchers will take appropriate measures to protect the privacy of individuals and to safeguard the identifiable information;
4. the researchers will comply with any known preferences previously expressed by individuals about any use of their information;
5. it is impossible or impracticable to seek consent from individuals to whom the information relates; and
6. the researchers have obtained any other necessary permission for secondary use of information for research purposes.

**Please note that a to f must be individually addressed in section 3.5 of this application for a consideration of waiver of consent.**

**GUIDANCE NOTE 3.6: CONFIDENTIALITY OF PARTICIPANTS**

As with all research and other activities, assuring patient privacy and confidentiality is of utmost importance. Privacy risks arise at all stages of the research life cycle, including initial collection of information, use and analysis to address research questions, dissemination of findings, storage and retention of information, and disposal of records or devices on which information is stored. As a result, it is the responsibility of the principal investigators and associated research personnel to maintain patient confidentiality of all information to which they are privy in the context of their research activities. Specifically, this requires that participants not be identified in any way in all research reports and/or documents generated through the research activity (e.g., no names, initials, or unique identifiers). In addition, it is the responsibility of all investigators and research personnel to be familiar with the Freedom of Information and Protection of Privacy Act (FOIPPA) and other relevant legislation and requirements concerning confidentiality.

When it is not possible to anonymize research related records (i.e. anonymity is defined as the removal of all personal identifiers from a participant's records), the use of a unique project code or scrambled initials is considered acceptable by the REB.

The REB expects that research-related documents (except the master list) do not include information that would allow the participant to be identified.

Information is considered de-identified if the following conditions are met:

* The unique project code is not derived from or related to the information about the individual;
* The unique project code could not be translated to identify the individual; and,
* The investigator or their institution could not use OR disclose the unique project code for other purposes OR disclose the mechanism for re identification.

It is not necessary to use a personal identifier (for example, birthdate) as a secondary identifier in order to confirm the identity of the participants. This can be accomplished by using any two unique identifiers.

The data to be collected off of the charts/records need to be clearly outlined and framed within the context of a Data Collection Tool. To ensure that the data is anonymous, a Master List should be developed for use during data collection and then appropriately destroyed when data collection has been completed.

**Data Collection Tool**

The Data Collection Tool should contain no names or other personal identifiers. The Data Collection Tool needs to be attached to determine whether or not HIPA Legislation is being adhered to.

**The Master List**

Documents or databases, which correlate participant names with project code numbers, must be kept on the locked premises of the Principal Investigator or in an appropriately secured electronic or hard copy form. They should be stored separately from any of the other data. The Master List is to be appropriately destroyed when the data collection for the project has been completed. The REB recommends master lists have as few identifiers as possible to assure participant privacy (e.g. only MRN or HSN and no other identifiers such as name or date of birth). If other identifiers are required for data linkage this should be specified and a rationale needs to be provided in this section.

**Disclosure of Information**

Include information on what measures are taken to prevent unauthorized access to the research data.

Include information on the provisions in place to protect the anonymity of data when it is transferred to other project institutions outside of the local institution (e.g. countries outside of Canada, institutions in other parts of Canada).

|  |
| --- |
| PART 4: DATA SECURITY AND STORAGE |

**GUIDANCE NOTE 4.1: PROJECT PERSONNEL WITH ACCESS TO PERSONAL HEALTH INFORMATION**

**Personal information** is defined in the TCPS 2, 2018, Chapter 5A as being “*information that may reasonably be expected to identify an individual, alone or in combination with other available information*”. Such information may include name, addresss, age, birthdate, ethnicity, social insurance number, educational background, employment history, life experience, religion, or social status.

**Personal health information** is considered to be any information about an individual’s physical or mental health gathered in the course of providing a health service. It includes personal health information on computers, in paper files, on microfilm, on x-ray film, and anywhere the personal health information is stored by a data trustee. Examples of personal health information include health background, health care provider’s name, MRN, HSN, medical history, lab test results and X-rays, doctor/nurse notes, or medical diagnosis.

Sources of personal health information may include a medical record held by a physician, a patient record held by a hospital, registration information held by the Department of Health to register individuals for insured services, information about lab tests being performed for an individual, or records of prescriptions filled by a pharmacist.

Please specify a) who will have access to identifiable health data; b) who will be responsible for data abstraction and c) who will retain any list that links a de-identified data set with a personal identifier such as MRN or HSN.

**GUIDANCE NOTE 4.2: DATA RETENTION AND STORAGE**

Research records must be recorded or preserved in accordance with the highest standard of scientific and academic practice and procedures. Research records are those documents and other records and materials recorded by or for an investigator that are necessary to document, reconstruct, evaluate, and validate research results and the events and processes leading to the acquisition of those results. Research records may be in many forms including but not limited to laboratory notebooks, survey documents, questionnaires, interview notes, transcripts, machine-generated data or performance outputs, recruitment materials, consent forms, correspondence, other documents, computer files, audio or video recordings, photographs including negatives, slides, x-ray films, samples of compounds, organisms (including cell lines, microorganisms, viruses, plants, animals) and components of organisms.

**Applications require a statement outlining the procedures investigators will use to securely store research records including the length of time the research records will be stored, the location of storage, the identity of the person responsible for storage of research records, and the procedures that will ensure secure storage and final disposition of research records.**

**Storage Requirements**

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.). Documents or files that link de-identified data to their primary source must be stored separately from the project data.

**Retention Requirements**

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;
* Five (5) years from the date of publication of a report of the project research; or,
* Five (5) years from the date a degree related to a particular research project is awarded to a student,

whichever occurs last.

All information collected in a clinical trial must be stored in accordance with C.05.012, which includes the requirement for the sponsor to store records for 25 years.

Research records must be retained for longer periods:

* If required to protect intellectual property rights;
* If such research records are participant to specific federal or provincial regulations[[1]](#footnote-1) requiring longer retention periods;
* If required by the terms of a research sponsorship agreement; or,
* If any allegations regarding the conduct of the research arise, such as allegations of academic misconduct or conflict of interest.

Research records may be retained for longer periods if retention is required for the continuity of scientific research or if the research records are potentially useful for future research by the PI or other investigators.[[2]](#footnote-2)

The Tri-Councils place the following responsibilities on grant holders:

* The Social Sciences and Humanities Research Council (SSHRC) Policy on Data Sharing states that all research data collected with the use of SSHRC funds must be preserved and made available for use by others within a reasonable period of time[[3]](#footnote-3).
* Canadian Institutes of Health Research (CIHR) grantees must deposit bioinformatics, atomic and molecular coordinate data into the appropriate public database immediately upon publication of research results[[4]](#footnote-4).
* CIHR grantees must retain original data sets arising from CIHR-funded research for a minimum of five years after the end of the grant. This applies to all data, whether published or not[[5]](#footnote-5).
* Collections of animal, culture, plant or geological specimens, or archaeological artifacts (“collections”) collected by a grantee with Tri-Council grant funds are the property of the University5.

Regulated databanks may also have specific requirements for record retention, which should be adhered to for projects using data from these sources.

**Destruction of Records**

Destruction of research records must be carried out so that personal information cannot practicably be read or reconstructed.  In some cases it may be advisable to document the manner and time of destruction.

Destruction of project records should be treated as confidential waste and disposed of in that manner. The exact length of time the records will be stored (e.g., 5 years, 25 years) must be disclosed and adhered to.

Paper documents containing personal information should be burned, pulverized or shredded into very small shreds. Erasing electronic files from a computer will not remove the information in that file from the computer. Applications are available that provide for secure erasure and will remove the records. When a computer is decommissioned, the disks must be erased using a secure disk erasure application or physically destroyed.

**Leaving the Institution**

When an investigator leaves the institution, she or he may take a copy of the research records related to her or his research. If a PI leaves the institution or a project is to be moved to another institution, the institution must be notified of the location of the original research records. In some instances (e.g., where institution intellectual property or other interests are involved), such transfer may not be permitted, and any such agreement may require diligent retention by the recipient and continued access by the institution. The obligations of investigators set out in these procedures continue to apply if an individual takes copies of research material to his/her new institution.

According to TCPS 2, 2018 Chapter 5A, “*Security refers to measures used to protect information. It includes physical, administrative and technical safeguards. An individual or organization fulfills its confidentiality duties, in part, by adopting and enforcing appropriate security measures. Physical safeguards include the use of locked filing cabinets, and the location of computers containing research data away from public areas. Administrative safeguards include the development and enforcement of organizational rules about who has access to personal information about participants. Technical safeguards include use of computer passwords, firewalls, anti-virus software, encryption and other measures that protect data from unauthorized access, loss or modification*.”

The PI is responsible for the collection, maintenance, privacy, and secure retention of research records in accord with these procedures and applicable privacy legislation. The PI should also ensure that all personnel involved with the research understand and adhere to established practices that are consistent with these procedures.

According to TCPS Article 5.3, *“Investigators shall provide details to the REB regarding their proposed measures for safeguarding information, for the full life cycle of information: its collection, use, dissemination, retention and/or disposal... Measures for safeguarding information apply both to original documents and copies of information. Factors relevant to the REB’s assessment of the adequacy of the investigators’ proposed measures for safeguarding information include:*

1. *The type of information to be collected;*
2. *The purpose for which the information will be used, and the purpose of any secondary use of identifiable information;*
3. *Limits on the use, disclosure and retention of the information;*
4. *Risks to participants should the security of the data be breached, including risks of re-identification of individuals;*
5. *Appropriate security safeguards for the full life cycle of information;*
6. *Any recording of observations (e.g., photographs, videos, sound recordings) in the research that may allow identification of particular participants;*
7. *Any anticipated uses of personal information from the research; and*
8. *Any anticipated linkage of data gathered in the research with other data about participants, whether those data are contained in public or personal records*.”

Research data sent over the Internet may require encryption or use of special denominalization software to prevent risks to data security, such as interception by unauthorized individuals. In general, identifiable data that is kept on a computer and connected to the Internet should be encrypted.

**GUIDANCE NOTE 4.3: DATA LINKAGE**

According to TCPS 2, 2018 Article 5.7, *“Investigators who propose to engage in data linkage shall obtain REB approval prior to carrying out the data linkage, unless the research relies exclusively on publicly available information... The application for approval shall describe the data that will be linked and the likelihood that identifiable information will be created through the data linkage. Where data linkage involves or is likely to produce identifiable information, investigators shall satisfy the REB that:*

1. *The data linkage is essential to the research; and*
2. *Appropriate security measures will be implemented to safeguard information*.”

Only a restricted number of individuals should perform the function of merging databases, and investigators should use enhanced security measures to store the merged file. Where investigators seek access to datasets held by another organization, it may be preferable for the data holder to carry out data linkage and remove identifiers beforehand. Legislation and organizational policies may regulate data linkage in specific circumstances. Data holders, such as statistics agencies, may also have policies on data linkage.

**GUIDANCE NOTE 4.4: DATA LEAVING THE INSTITUTION**

Please note that if data is leaving the institution a data sharing agreement (DTA) may be necessary, please contact SHA Research Contracts to see if a DTA will be needed at:

ResearchContractsRegina@saskhealthauthority.ca.

Please specify where it will be stored at that site the data is being sent, who will then be the custodian (i.e. the person responsible for the data storage and integrity), who will have access to it, and security measures in place to ensure data confidentiality.

**GUIDANCE NOTE 4.5: METHOD OF DATA LEAVING THE INSTITUTION**

Please specify which method of data transfer will be used to send data and please note the REB does not endorse sending data via email as this would not be considered a secure method of data transfer.

**GUIDANCE NOTE 4.6: POTENTIAL PRIVACY RISKS AND SAFEGUARDS/SOLUTIONS TO MITIGATE RISKS**

Please check all applicable boxes.

|  |
| --- |
| PART 5: DECLARATION BY PRINCIPAL INVESTIGATOR\* |

**GUIDANCE NOTE 5: DECLARATION BY PRINCIPAL INVESTIGATOR**

Applications will not be accepted without the original signature of the Principal Investigator, Student Investigator (if applicable) and the Department Head.

|  |
| --- |
| PART 6: ATTACHMENTS |

**GUIDANCE NOTE 6: ATTACHMENTS CHECKLIST**

Please assure that all appropriate documents are sent with the application. For Retrospective and Prospective Chart Reviews that are requesting a waiver of consent we require:

* the application with signatures;
* a data collection tool;
* a master list if one will be generated;
* McMaster Chart Audit tutorial certificates for all study team members accessing Personal Health Information (PHI).

For prospective studies involving participant consent we require:

* the application with signatures;
* a data collection tool; a master list if one will be generated;
* McMaster Chart Audit tutorial certificates for all study team members accessing Personal Health Information (PHI);
* TCPS 2 tutorial certification for all study team members that will have interaction with participants;
* a consent form template.

Please note depending on the study design there may be other documentation required (i.e. consent logs, telephone consent scripts, transcript release forms etc.).

1. For example: Canada’s Food and Drug Regulations require certain clinical trial records to be stored for twenty-five (25) years and research conducted in provincial hospitals may be subject to The Hospital Standards Regulations, 1980 (Saskatchewan). [↑](#footnote-ref-1)
2. Future use of research records may be subject to the provisions of applicable privacy legislation and/or the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS) https://ethics.gc.ca/eng/policy-politique\_tcps2-eptc2\_2018.html [↑](#footnote-ref-2)
3. http://www.sshrc.ca/site/apply-demande/policies-politiques/edata-donnees\_electroniques-eng.aspx [↑](#footnote-ref-3)
4. http://www.cihr-irsc.gc.ca/e/34846.html#8 [↑](#footnote-ref-4)
5. http://www.nserc-crsng.gc.ca/Professors-Professeurs/FinancialAdminGuide-GuideAdminFinancier/Responsibilities-Responsabilites\_eng.asp [↑](#footnote-ref-5)