Health Research in Nunavut
Special Considerations for Remote Data Collection

This document was prepared by the Joint Health Research Review Committee of the Nunavut Research Institute (the Committee).[1] It provides guidance for researchers planning projects that require a license under Nunavut's Scientists Act (the Act) and involve collecting data from or about Nunavummiut using either of these methods.

- Medical Chart Review at Tertiary Care Centres
- Survey-based Research originating from outside of Nunavut

It is recognized that there are many other types of research that would fall under the NRI licensing process. The NRI website can be checked for further details.

Medical Chart Review at Tertiary Care Centres

A chart review is an evaluation or analysis of a patient's medical record as a method of answering a research question. As the information contained in medical records was originally collected for another purpose (e.g., clinical treatment), when used for research purposes, chart reviews are considered "secondary use of identifiable information for research purposes" (see Chapter 5 – Privacy and Confidentiality, D. Consent and Secondary Use of Information for Research Purposes, Tri-Council Policy Statement: Ethical Conduct for Research Involving Human, "TCPS2, 2018"). As with any health research, it is important that the research question must be relevant (i.e. to improve health care, to answer community questions, etc.) and that the need for a chart review methodology be well justified. The review of research involving chart reviews will consider the same factors addressed in all health research

[1] This document will be updated as needed. Each project must be responsive to the Committee, even if a requirement is not initially included in this document.

projects (i.e. community engagement, communication and knowledge transfer, feedback of results to the appropriate people/groups, etc.).

Significance. Nunavut relies on tertiary care centres in Ottawa, Winnipeg, Edmonton and Yellowknife to provide advanced and specialized care to patients from the territory. At times, medical specialists and researchers are interested in reviewing the charts of Nunavummiut attending these institutions to improve care or identify challenges specific to Nunavut's population. The ultimate goal of chart review based research should be to improve care and/or health outcomes for Nunavummiut.

Approach of the Review Committee. Tertiary care centres are an important part of Nunavut's health care system and many patients receive services outside of territory. As a result, the review committee evaluates requests to review medical charts held at Tertiary care centres with the similar process as applied to a researcher asking to review charts located physically in Nunavut. Any chart review that takes place in Nunavut must be discussed with the Government of Nunavut Department of Health.

Considerations

Research vs. quality assurance. The use of health information about Nunavut residents for research purposes always requires the review and approval of an Institutional Research Ethics Board (REB). However, the use of the health information for certain types of organizational program evaluation and quality assurance and improvement (QA/QI) studies may not require REB review. Researchers planning to use Nunavut residents' health information for program evaluation or QA/QI studies must obtain written confirmation from their home REB that the requirement for a full REB review has been waived.

A chart review is generally considered to be human participant research and therefore REB review and approval is required prior to commencing chart review activities from the home institution of the researcher. Depending on the custodian of the medical records you wish to access, additional administrative, operational or research agreements must be in place prior to accessing the data, in addition to seeking review from the Committee.

Waiver of Consent. It is a common misconception that consent is not required for research-related medical chart reviews. While in most cases this may be true, **any researcher who wishes to use Nunavut residents' medical records for research purposes must first request a waiver of consent from the NRI**. The researcher must provide a sufficient and detailed rationale for why it would not be reasonable, feasible or practical to obtain individual consent.

In all cases, the reasons for not obtaining consent must be addressed. Article 5.5A, TCPS2, states:

> *"Researchers who have not obtained consent from participants for secondary use of identifiable information shall only use such information for these purposes if:*
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> *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; and

f. the researchers have obtained any other necessary permission for secondary use of information for research purposes."

A waiver of consent will only be grated if the researcher can demonstrate that:

1) the research involves no more than minimal risk to the subjects, and
2) the waiver or alteration will not adversely affect the rights and welfare of the subjects, and
3) research could not practicably (feasibly) be carried out without the waiver or alteration, and
4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.
5) the research does not involve a therapeutic intervention, or other clinical or diagnostic interventions.

To obtain a waiver, the researcher must clearly demonstrate how their proposed research meets the above criteria, particularly point number three.

Researchers should consider the following when outlining their rationale to request a waiver:

- **Sample size.** Is the sample size too large to contact all individuals or is it small enough that contacting individuals is feasible?
- **The dates on the medical records.** Many individuals may be lost to follow up from older medical files whereas it may be possible to contact individuals who recently received medical care.
- **The impact of contact for consent.** Depending on the nature of the medical condition under study, will contact from the research team cause undue stress to the individual?
- **Impossible or impracticable.** TCPS2 specifically defines impracticable as referring to "undue hardship or onerousness that jeopardizes the conduct of the research; it does not mean mere inconvenience". Researchers must provide substantial evidence that obtaining consent would be unnecessarily intrusive (well beyond "slowing down the process")
- **Costs.** The researcher would need to provide evidence that obtaining consent would place undue cost and burden on the team and render the research unfeasible.

Where the above criteria cannot be sufficiently demonstrated, the Committee may determine that written informed consent is required. This is almost always the case in prospective chart reviews where an investigator intends to review the charts of patients within his/her practice. In this situation, the Committee will likely determine that the investigator should obtain written informed consent since there will be an opportunity for patients to be consented during a scheduled clinic visit (consent is feasible and practical).

A **Retrospective Chart Review** evaluates patient data that already exists in the subject's medical record at the time the project is submitted for initial REB review. The patient data does not result from the research activity.

A **Prospective Chart Review** evaluates patient data that does not yet exist in the subject's medical record at the time the project is submitted for initial REB review.

Survey-based research originating from outside Nunavut

An online survey is the systematic collection of data over the internet. One of the most widely utilized survey methods, an online survey is the systematic gathering of data from the target audience characterized by the invitation of the respondents and the completion of the questionnaire over the World Wide Web. The Internet has been used by many researchers to conduct studies all over the world. It is viewed as more expeditious than pen-and-pencil surveys or in-person interviews.

Telephone surveys and interviews involve the collection of information from Nunavut residents over the telephone for research purposes. Telephone surveys and interviews remain an important research tool in Nunavut where many households do not have the means (computers, bandwidth) to participate in online surveys.

Significance. Nunavut's Scientists Act explicitly applies to research "in or based upon" Nunavut. As such, research activities conducted with or about Nunavut residents remotely (where the researcher collecting data is physically outside of Nunavut) still require licensing under the Act. Furthermore, due to restrictions on travel to Nunavut as a result of COVID-19, an increasing number of researchers are using online and telephone survey methods for data collection instead of travelling to Nunavut. This creates the potential for unethical research practices where sensitive and confidential information and data about Nunavummiut are gathered by researchers without properly securing informed consent and/or without ensuring adequate protections of private personal information.

Approach of the Review Committee. Projects that use remote methods to collect data from Nunavummiut are subject to Nunavut's Scientists Act. As such, the Committee reviews these projects with the same criteria and rigor as survey-based research that is conducted physically in person in Nunavut.

Considerations

Information and Protection of Privacy. Researchers planning to use online and phone survey companies should acquaint themselves with the relevant laws governing the collection of personal information and the protection of privacy. For all data collection, including in-person, virtual or phone methods, researchers must ensure adequate privacy for survey respondents (i.e. especially for surveys addressing sensitive subject matter) and minimize disruption (e.g., make calls at reasonable times of day).

Collection of Personal Information. Researchers who are not collecting any personal information in a survey may use whatever online survey tool they prefer as long as the survey is completely anonymous.

For example, the online survey tool should have the capability to switch off the IP tracking feature (online survey tools collect IP information from users as a matter of course).

Consent. In all applicable instances, the consent information must clearly indicate the location of the survey company's server and include a description of any associated limits to confidentiality. Researchers must also have processes for securing informed consent of survey respondents. See the following for an example.

Translation and Interpretation. Inuktitut and Inuinnaqtun translation and interpretation must be available for all in-person, phone, and virtual communications (e.g., Zoom and other online video platforms). This requirement applies to all other considerations listed here, along with all research products/tools (e.g., questionnaires, posters).

Reporting and Results Communication. As part of the knowledge transfer/mobilization and communications strategy, each research project should have a clear plan to share any results, reports, manuscripts, etc. with the Committee before any results regarding Nunavummiut are published (particularly regarding medical records research). Researchers must also have a plan to return results to respondents, subject to the Committee's approval.

Example: Participant Consent for Online Surveys

- If the study is limited to an online survey, a preamble or cover letter may be used instead of a full signed consent form, provided that it includes the information needed by the participant to make an informed decision about participating in the survey study.
- If you are using a cover letter instead of a full consent form, ensure to include the following or similar wording in the letter:

  "By completing the questionnaire, you are consenting to participate in this research."
- For most basic survey studies, the cover letter needs to include:
  - the study title,
  - contact information of the PI,
  - a short description of the study,
  - risks and benefits,
  - limits to confidentiality,
  - details of compensation/remuneration if applicable (honoraria, etc.)
  - a statement that participation is optional, and
  - the phone number to call for questions or withdrawal.
- Where possible, the cover letter should also include a letterhead.

Note: If you are unable to include any of these elements in the cover letter because of the study design, ensure that this is clearly described and justified in your application, e.g. in box 6.6.

Other Topics

Research Ethics and Expectations in Nunavut

The Joint Health Research Review Committee of the Nunavut Research Institute emphasizes the importance of working respectfully and ethically with Nunavummiut. Health research conducted in Nunavut and remotely with Nunavummiut must comply fully with Chapter 9 of the TCPS 2 (2018), "Research Involving the First Nations, Inuit and Métis Peoples of Canada," [2]. All researchers who plan to conduct health research in Nunavut are encouraged to carefully review this chapter and to complete the online tutorial TCPS 2: CORE (Course on Research Ethics), available at http://tcps2core.ca/welcome

All researchers who plan work in Nunavut must also review the Nunavut Research Institute's Research Licensing Guidelines, available at:
https://www.nri.nu.ca/sites/default/files/public/nri_research_licence_application_guidelines.pdf

[2] TCPS 2 (2018) - Chapter 9: Research Involving the First Nations, Inuit and Métis Peoples of Canada: https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter9-chapitre9.html