University of Manitoba | Faculty of Health Sciences
College of Medicine
Department of Family Medicine

Collection of Primary Care Data by the Manitoba Primary Care Research Network (MaPCReN) as part of the Canadian Primary Care Sentinel Surveillance Network (CPCSSN)

RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

Title of Study: Collection of Primary Care Data by the Manitoba Primary Care Research Network (MaPCReN) as part of the Canadian Primary Care Sentinel Surveillance Network (CPCSSN)

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National CPCSSN Director: Dr. Richard Birtwhistle
Centre for Studies in Primary Care
Department of Family Medicine
Queen's University

You are being asked to participate in a research study. Please take your time to review this consent form and discuss any questions you may have with the study staff. You may take your time to make your decision about participating in this study and you may discuss it with your colleagues before you make your decision.

Background and Purpose

The aim of the Canadian Primary Care Sentinel Surveillance Network (CPCSSN) is to collect valid and reliable data from electronic medical records about diseases in primary care, such as hypertension, chronic obstructive pulmonary disease, diabetes mellitus, depression, osteoarthritis, Alzheimer's disease, epilepsy, and Parkinson's disease. The goal of this project is to develop a researchable database comprised of de-identified information about patients from primary care providers' practices. The data obtained will allow better estimation of the prevalence of chronic illness and diseases, predisposing risk factors, impact on health and quality of life, and management at the primary care level.

This agreement applies for the duration of the project, which began in 2008 and will be ongoing with yearly renewals with the ethics board.

What Your Participation Involves

Your participation will involve completing a questionnaire and allowing the CPCSSN Regional Data manager to access the electronic medical records (EMR) of your patients.

1. Health Professional Questionnaire:

   We are collecting information about participating health professionals and their practice types and patterns. This information will be used as the basis for comparisons of the characteristics of all participating practitioners.

   All participating physicians and allied health professionals will be asked to complete a questionnaire, which will include items such as gender, hours spent in patient care, certification, and year of graduation from professional school, as well as aspects of the health care team. This questionnaire will take approximately 15 minute to complete.

Please note: A unique identification number will be assigned to the information received from each health professional's completed interview and questionnaire. No health professional's names will be included in the database.

2. Collecting Electronic Medical Record Data

   A CPCSSN Research Agreement will be completed and signed by the person at your medical practice responsible for the security and integrity of your patient's health information. By signing, this data custodian agrees to grant access to this information stored in the Electronic Medical Record system at your practice.

   Patients in each practice will be informed of the study through brochures and posters in the waiting areas and examining rooms at your practice. These posters and brochures will inform your patients that providers in your practice are taking part in the CPCSSN Study and that they may choose not to participate. These will also inform patients that they may contact the local CPCSSN project leaders for further information about the project if they wish to do so. The CPCSSN Regional Research Assistant will be responsible for providing your practice with the posters and brochures but it will be the responsibility of a designated person at your practice to post/place them in locations within your practice.

   Should any patients choose to opt-out of this study, a Patient Opt-Out Form is available on request from the CPCSSN Regional Research Assistant.

Information Extraction

Information from the practice Electronic Medical Record System will be gathered in the following manner:

At each participating medical practice

- The Electronic Medical Record System at the practice will be accessed by the local CPCSSN Data Manager via an encrypted Virtual Private Network (VPN) connection. This will occur quarterly and will be done during non-practice hours so as not to interfere with the functioning of the medical practice;
- Practice-level patient medical data will be extracted from the system into standard text-based "flat files". Copies of these extracted files will be maintained on the practice server. The information extracted will not include patient names, addresses, telephone numbers, family contact information, or any other information which might identify the patient. Copies of the extracted files will be stored in a compressed, password-protected format;
- The created files will be securely transmitted to the Network's Regional Server, which is located at the Centre for Advanced Computing at Queen's University. This facility is physically secure and access to the servers is both firewall and password protected. Queen's University performs regular security audits to ensure its operations are in keeping with industry standards;
- As required, a secondary extraction of patient personal identifiers will occur to permit the creation of a key file to facilitate the linkage of previously extracted primary care data with other administrative healthcare data. The creation of the key file will occur at Manitoba Health. This information will be kept separate from the primary EMR data extract, and will be destroyed on successful creation of the key file.

At Queen's University Centre For Studies in Primary Care

- The transmitted files will be processed on the regional server as part of an individual sentinel site database. Processing will include:
    - Secondary processing checks to ensure that only data for participating CPCSSN patients has been extracted. Any information inadvertently gathered will be removed from further processing;
    - The anonymization of all extracted patient information via the assignment of a unique CPCSSN Identification Number.
    - The removal of any secondary patient information, which might allow for the identification of a patient such as attached provider notes and/or comments.
- Once data is loaded into the sentinel database, the files containing the raw patient medical data will be securely deleted.
- Individual sentinel site databases will undergo further processing including the identification of the medical conditions being studied, and the standardization of formats and coded values.
- Individual sentinel site databases will then be merged into one network-level database, which will undergo a final set of de-identification algorithms before the network database is transferred to CPCSSN's Central Data Repository for inclusion in the national database.

At the CPCSSN Central Repository (Queen's University)

- A data analyst at Queen's University will analyze the de-identified data which has been combined from all participating sentinel sites for applicable research questions.
- **A copy of data for patients identified as having diabetes will contribute to the formation of a National Diabetes Repository for the prevention of the complications of diabetes for Canadians. This will be a subset of data for diabetes, and will be held in a virtual research environment hosted at the secure CPCSSN data centre at Queen's University**.

Please Note: No data that can identify patients or care providers will be part of the local or national CPCSSN databases.

Privacy and Confidentiality

Any reports generated will be of groups of people only. No information will be released in which it is possible to identify you, your patients, or other members of the health care team directly or indirectly.

Voluntary Participation

Physicians, nurse practitioners, and patients may refuse to participate. No health data relating to patients who decline to participate will be included in the CPCSSN database.

Participation in this project may be terminated by either party at any time. Taking part in this study is voluntary. If you do give your consent, you may refuse to answer any questions, as well as to withdraw from participation at any time. The CPCSSN regional network has the right to terminate this agreement should circumstances arise that require it. If new information becomes available that might affect your willingness to participate in the study, you will be informed as soon as possible.

Restrictions on Use and Disclosure of Health Information

1. CPCSSN agrees to only use the health information for purposes identified.
2. CPCSSN agrees to disclose information only to individuals with a need to know who are working on CPCSSN sanctioned projects.
3. CPCSSN agrees to ensure that all individuals on the project team that have access to the health information comply with all applicable legislation and health regulations governing the use of personal health information as well as with any conditions imposed by the Custodian.

Publication of Results

CPCSSN agrees that no identifying information or information that could be manipulated to identify an individual will be published.

Requirements to Safeguard Data

1. CPCSSN agrees to adequately safeguard the confidentiality and security of the health information obtained from the Data Custodian. CPCSSN also agrees to safeguard the privacy of the individuals who are the subjects of that information by ensuring that these individuals cannot be identified, directly or indirectly.
2. CPCSSN agrees to report to the Data Custodian any breaches of confidentiality and/or security respecting the information and to take steps to both remedy the breach and prevent similar occurrences in the future.

Risks and Benefits

There are no known risks to you in participating in this study. The benefit is that this study will show that useful information on chronic diseases can be obtained from EMRs of primary care providers and this information may be used by family physicians and nurse practitioners to monitor and improve their practice and to contribute to national health policy development.

Questions:

If you have questions about this study, you may contact the CPCSSN Regional Network Director: Dr. Alexander Singer at (204) 237-2885 or asinger@sbgh.mb.ca or the CPCSSN National Director: Dr Birtwhistle at (613) 533-6000, ext. 73934 or richard.birtshistle@dfm.queensu.ca

If you have questions about your rights as a research participant you may contact The University of Manitoba Bannatyne Campus Research Ethics Board Office at (204) 789-3389.

Statement of Consent

1. I have read this consent form and have had the opportunity to discuss this research study with the Regional Network Director and/or his study staff.

2. Any questions I have had have been answered and the risks and benefits have been explained to me.

3. I believe that I have not been unduly influenced by any study team member to participate in the research study and understand that my participation in this study is voluntary and that I may choose to withdraw at any time.

4. I understand that information regarding my personal identity and that of my patients will be kept confidential, but that confidentiality is not guaranteed.

5. I authorize the inspection of any of my records that relate to this study by The University of Manitoba Research Ethics Board, for quality assurance purposes.

By signing this consent form, I have not waived any of the legal rights that I have as a participant in a research study.

Participant Name: _____ **Date:** _____
(please print) **(day/month/year)**

Participant Signature: _____