CPN | RDC

CHRONIC PAIN NETWORK | RÉSEAU DE DOULEUR CHRONIQUE

CAPDR RCDDA

CANADIAN ADULT PAIN DATA REGISTRY | REGISTRE CANADIEN DE DONNÉES SUR LA DOULEUR CHEZ LES ADULTES

Registry Management Policy

Chronic Pain Network
Canadian Adult Pain Data Registry

Version 2, January 31 2022

Table of Contents

1. Acronyms

Acronym	Complete name
CAPDR	Canadian Adult Pain Data Registry
CAPDR MC	Canadian Adult Pain Data Registry Management Committee
CR	Central REDCap
CITADEL	Centre d'intégration et d'analyse des données médicales
CNCP	Chronic non-cancer pain
CPN	Chronic Pain Network
CRCHUM	Centre de recherche du Centre Hospitalier de l'Université de Montréal
CRN	Clinical Research Network
DAA	Data Access Authorization
DAR	Data Access Request
DDF	Data Destruction Form
DM	Data manager
eICF	Electronic Informed Consent Form
LR	Local REDCap
LI	Local investigator
PSF	Patient Summary Form
PtID	Patient identification number
QCR	Quality of Care Report
RC	Registry Coordinator
REB	Research Ethics Board
RS	Registry staff
RWG	Registry Working Group
RWG ASc	Registry Working Group Adult Subcommittee

2. Introduction

The Registry Working Group Adult Subcommittee (RWG ASc) of the Chronic Pain Network has, as one of its mandates, created the Canadian Adult Pain Data Registry (CAPDR), a registry of clinical data collected from adults suffering from chronic pain (CP). Funding for the establishment and maintenance of the CAPDR is provided by the Chronic Pain Network (CPN) which is itself funded by the Canadian Institutes of Health Research's Strategy for Patient-Oriented Research Program. The latter received a five-year grant for $12.5 million from the Canadian Institutes of Health Research's Strategy for Patient-Oriented Research (SCA-145102), to which is matched another $12.5 million from various institutions and organisations. The grant began in January 2016 and will conclude in March 2022.

This document sets out the database management policy of the CAPDR.

3. General information

3.1. Overview of the CAPDR

The goals of the CAPDR are 1) to provide pain clinicians with a national standardized and harmonized tool to monitor health outcomes and quality of care of their patients; 2) to help clinicians and managers/decision makers to determine if organizational and clinical changes made to services and care offered to CP patients translate into benefits for patients and society; and 3) to create a stepping stone to conduct research on data contained in the Registry and to set up new research initiatives.

All the multidisciplinary pain treatment clinics which are part of the CPN's Clinical Research Network (CRN) (see Annex 1: List of participating sites) recruit adult patients into the CAPDR. Patients scheduled for a first visit at the pain clinic are enrolled into the CAPR if they are 1) aged ≥ 18 years, and 2) able to provide informed consent. No definite recruitment target has been established for the CAPDR. The CAPDR contains a database of personal information, a Patient Inscription Form, a Patient Questionnaire and a Patient Summary Form (PSF).

3.2. Definitions

Applicant: a researcher who has submitted a Data Access Request to the CAPDR Management Committee (CAPDR MC) in order to access CAPDR data.

Authorized Study: a research study approved following the review and approval of a Data Access Request.

Authorized User: an Applicant whose Data Access Request has been authorized.

CAPDR: a national registry collecting pain-related health and outcome data for clinical and research purposes.

Central REDCap (CR): CAPDR data collected and hosted on the REDCap platform at the Centre hospitalier de l'Université de Montréal (CHUM) for several CRN sites.

Database: CAPDR data to be used for research purposes. While the CAPDR will also contains clinical information, it will not be considered as being part of the Database for the sake of data access. Only data available for research purposes and recruitment statistics related to the research component are part of the Database and made available through a Data Access Authorization.

Data Access Authorization (DAA): a letter emitted by the CAPDR MC following the approval of a DAR. This document indicates the nature and duration for the use of data obtained from the Database.

Data Access Request (DAR): an application form detailing the research study. This form must be submitted to the CAPDR MC by the Applicant.

Data Destruction Form (DDF): a form detailing the procedure executed to finalize a participant's withdrawal.

Data Manager (DM): Team members of the *Centre d'intégration et d'analyse des données du CHUM (CITADEL)* who are in charge of overseeing the creation and management of the CAPDR database in REDCap.

Local REDCap (LR): CAPDR data collected and hosted on a REDCap platform a local REDCap server.

Local Investigator (LI): a pain clinician who oversees the management of CAPDR data collection at one of the participating CRN sites.

Patient Summary Form: an automated report generated in REDCap using Patient Questionnaire data. As part of usual follow-up, this form is provided to clinicians in order to monitor the clinical evolution of their patients using standardized outcomes.

Registry Staff (RS): research personnel in charge of coordinating CAPDR data collection at each participating CRN site.

4. Governing body and management

4.1. RWG Adult Subcommittee

The CAPDR was established through a consultation process led by the RWG ASc, which included the following members:

- Manon Choinière, Designated chair, Centre de recherche du Centre Hospitalier de l'Université de Montréal (CRCHUM);
- Richard Hovey, Patient representative co-chair, McGill University;
- Sarah Ahmed, Member, McGill University;
- Nicolas Beaudet, Member, Université de Sherbrooke;
- Kimberly Begley, Ex-officio member, McMaster University;
- Norman Buckley, Ex-officio member, McMaster University;
- Ian Gilron, Member, Queens University;
- James Khan, Member, University of Toronto;
- Irina Kudrina, Member, McGill University;
- Brenda Lau, Member, University of British Columbia;
- Curtis May, Patient representative member, University of British Columbia;
- Dwight Moulin, Member, University of Western Ontario;
- Richard Nahas, Member, University of Ottawa;
- Dave Walton, Member, University of Western Ontario;
- Mark Ware, Member, McGill University;
- Owen Williamson, Member, Monash University;
- Ramesh Zacharias, Member, University of Western Ontario.

4.2. CAPDR Management Committee

The role of the Canadian Adult Pain Data Registry Management Committee (CAPDR MC) is to ensure that scientific, ethical, administrative and financial requirements are met when establishing and managing the CAPDR. The CAPDR MC ensures that the Database is developed in compliance with the regulations of the granting agency, and that the required ethical authorizations are obtained and respected. The CAPDR MC also evaluates all research projects that request an access to the Database. Composition of the CAPDR MC is as follow:

- Manon Choinière, Designated chair, CRCHUM;
- Richard Hovey, Patient representative co-chair, McGill University;
- Ian Gilron, member, Queen's University
- Norman Buckley, Ex-officio member, McMaster University.

4.3. Ethics approval

Since the CAPDR MC designated chair is based at the Research Center of the CHUM, the Research Ethics Board (REB) of the CHUM is in charge of overseeing ethics approbations, renewals and amendments of the CAPDR. However, based on the nature of the submissions, other REBs might be involved.

5. Consent of participants

As part of their follow up at the pain clinic, patients should complete the Patient Questionnaire (PQ) prior to their appointment. Patients who do not complete the PQ will not have their medical follow up impacted. **Completing the PQ is part of their routine clinical care and does not require prior consent**. However, allowing use of CAPDR data for research requires prior consent. This consent must be informed and freely given.

5.1. Patient consent: use of data for research

Patients are contacted prior to their appointment at the pain clinic and are informed they should fill out the Patient Questionnaire, as this information will be needed by the clinical team. After completing their questionnaire, patients access the electronic informed consent form (eICF) where they will be asked:

- if they allow their data to be used for research;
- if they agree to have their CAPDR data merged to their medical record data;
- If they consent to have their CAPDR data merged to their provincial administrative health data; and
- If they agree to be contacted for future research projects.

The consent form will be unique to each participating site and will have been approved by each site's REB. The eICF clearly indicates that all data collected are stored in the CAPDR for 25 years following the creation of the Registry (March 2021).

In order to ensure the proper use of this latitude offered to investigators by participants, all research that uses Database data requires the prior authorization of at least the CHUM REB (see section *9.4. Transfer of data for research studies*)

5.2. Obtaining additional data for clinical purposes

Since the data collected as part of the CAPDR is a minimal set of pain-related outcomes, some pain clinics may wish to collect additional information on their patients. They will be allowed to do so, and will have to collaborate with the DM in order to set up additional questionnaires. Expenses related to the design, programming and implementation of new local questionnaires will be covered by the site having made the request.

5.3. Obtaining additional data for research

Local investigators (LI), clinicians, and researchers may require supplementary data or biological material for a new project that would use Database data. This may allow them to conduct certain research projects that could not otherwise have taken place or to carry out studies that are more thorough. In order to collect additional data or biological material for research purposes, additional patient consent is required and only patients who consented to be contacted for future research projects will be approached.

5.4. Recontact of patients

Patients who have consented to be contacted for future research studies and who meet the inclusion criteria of a given new study will be contacted by the RS, either by phone or by email, to discuss their potential participation to the new study. The list of eligible patients to be approached, identified with

their PtIDs, will be based on the eligibility criteria provided by the Principal Applicant of the study and will be prepared by the RC. CAPDR patients will not be in contact with the research team of a new study until the study has been fully approved and they have agreed to participate in the new study.

5.5. Withdrawal of participation

Each participant is allowed the opportunity to withdraw his/her participation at any time for one or all of the additional components. A participant may do so by asking, verbally or in writing, to withdraw completely (data destruction) or partially (not to be contacted again for other research but allowing the use of the data already in the Database). Participants do not have to provide a reason for their decision and will be informed that this decision will not impact their care.

Withdrawal will apply only to the consent to use data for research purposes, to allow the combination of CAPDR data to medical record data, to allow the combination of CAPDR data to data from provincial administrative health databases or to be contacted for future research studies. Data collected for routine clinical care will not be affected by the participant's withdrawal.

Extracted data relevant to a publication will not be destroyed at the participant's request if it has been analyzed and used for a scientific publication, in order to maintain the scientific integrity of the publication.

6. Hosting and management of the CAPDR

REDCap is used as the data collection platform for the CAPDR. Two hosting options are available for the REDCap data collection platform of the CAPDR: the Central REDCap (CR) and the Local REDCap (LR). The CR will offer a centralized REDCap platform hosted at the CHUM, while the LR will involve installing and hosting the REDCap project template and add-ons created for the CAPDR on a local REDCap server.

6.1. Central REDCap at the CHUM

CR management is under the responsibility of the *Centre d'intégration et d'analyse des données médicales (CITADEL)* at the *Centre hospitalier de l'Université de Montréal* (CHUM), Quebec, Canada.

CITADEL's REDCap platform is hosted on secure servers of the CHUM. The CITADEL team oversees the respect of strict measures to ensure the security of their installations and confidentiality of the data stored on the servers.

6.2. Security of the Central REDCap

Several measures are implemented in order to ensure the security of the CR.

- User accounts are valid for a period of 1 year, after which they are automatically deactivated.
- Accounts can be closed before expiration upon request, with certification of complete destruction of data.
- Infrastructures are constantly being monitored for intrusions and abnormal use.
- Suspected misuse causes account deactivation.
- Connections are made to front-end servers, via ssh encrypted connections. Compute servers and storage are not visible from the outside.
- The facilities are located in rooms reserved for high performance computing and physical access to facilities is restricted to authorized personnel.

- User connection to the website is protected using SSL security protocol, which creates a secure channel between the browser and the REDCap web server.
- Each server is protected by a firewall or an access control list, based on the level of exposure.
- Data are stored on shared infrastructure where the user is responsible for securing data (read and write rights, encryption). Tools include Linux access controls and access control list, available on the filesystem.
- Externally exposed data is encrypted during transfer.
- Each server saves user data and main system components in an encrypted file on a daily basis. Saved files will be stored on a secure and separate infrastructure. This will allow data restoration in case of a major incident. After a reasonable time, saved files will be destroyed.
- Users who have not been active for 5 minutes are automatically logged out.

To ensure that users only access data and information that they are allowed to within the application, each site has its own project and user privileges are employed within REDCap. Each user has his/her own account, with his/her unique username and password. New users are created by the DM and user privileges are assigned by the RC. Thus, each site is able to access the data for their site, but will not obtain access to data from other sites. Moreover, the RC will be blocked from seeing the Patient Inscription Form, as it contains the patient's email address.

REDCap has a built-in audit trail that automatically logs all users' activities and all pages viewed by every user, including contextual information (e.g. the project or record being accessed). The built-in audit trail allows administrators to be able to determine all the activity and all the data viewed or modified by any given user.

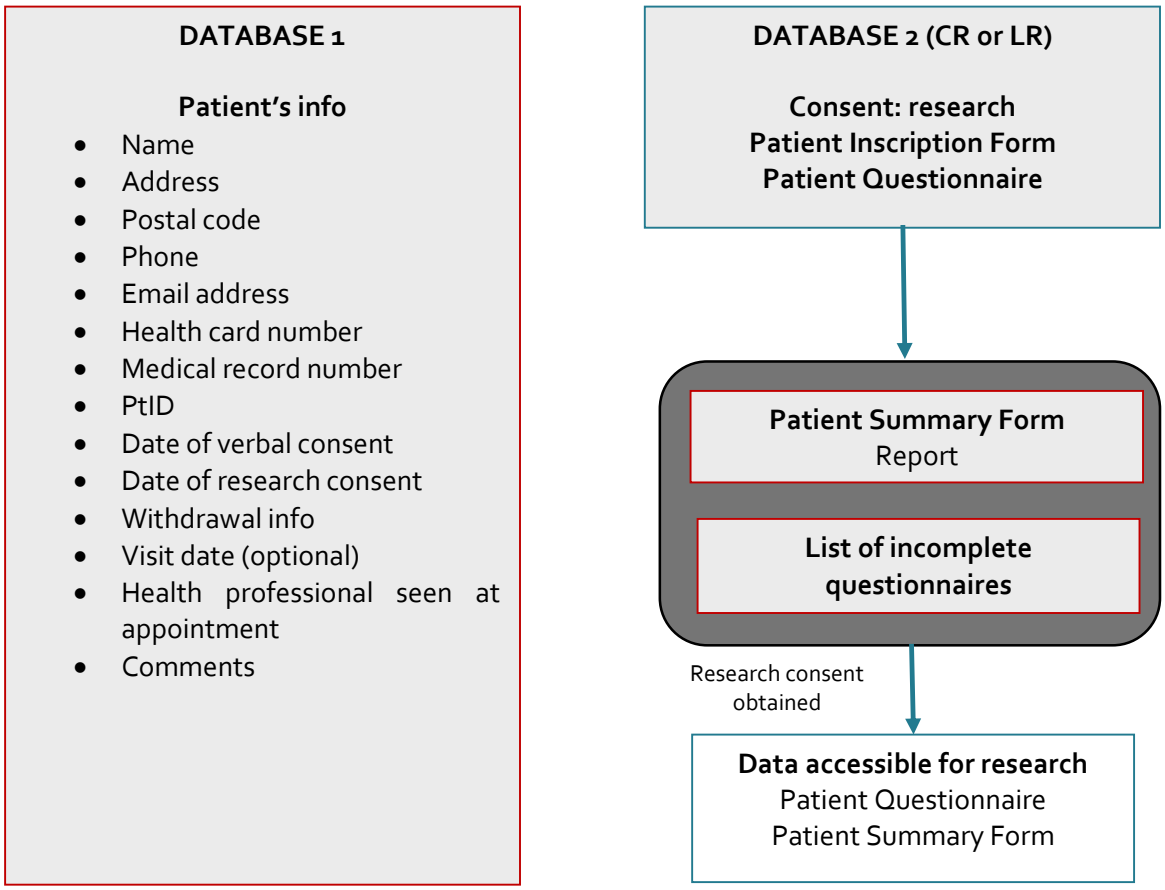
No data is ever transmitted at any time for research without prior authorisation from the CAPDR MC and signature of a Data Transfer Agreement. Data files transferred to Authorized Users will be encrypted.

6.3. Local REDCap

When institutional policies of a CRN site do not allow clinical data to be hosted on an external server, a copy of the CAPDR REDCap project and its add-ons can be transferred and installed on a local server. Management and security of the REDCap platform will be insured by the local REDCap team and details on a per-site basis are annexed to the protocol (Annex 7 in protocol).

Data to be used for research purposes will be transferred to the RC on a scheduled basis and will be merged to data collected via the CR where consent to use the data for research was obtained. Security of exported data is detailed under *6.6 Storage of exported data*.

6.4. Structure of the CAPDR



In order to limit access to identifying information but still allow the production of reports for clinical purposes, two separate databases have been created to host CAPDR data. **Database 1** includes administrative information only, which is stored locally at each pain clinic and is accessible only by the LI and local RS. **Database 2** refers to data collected using the CR or LR platforms. This includes the e-consent for research (identified with a PtID), the Patient Inscription Form, the Patient Questionnaire and the Patient Summary Form. The only identifying information that may be entered in Database 2 is the participant's email address, as it has to be entered in REDCap in order to send automated invitations to complete the PQ. For the CR, Database 2 is accessible by the LI, the RS, the DM, the CAPDR MC and the RC; however, the Patient Inscription form, which contains the email address, is only accessible by the LI, local RS and the DM.

Database 2 contains Patient Questionnaire data from both patients who have agreed and patients who have refused to share their data for research. Exportations of data for research purposes are programmed to ensure that only data obtained from patients who have consented to research is exported and available for research projects. Data extractions are carried out by:

- Central REDCap: RC, under the supervision of the CAPDR MC

- Local REDCap: RS or LI.

6.5. Conservation of data

Database 1 will be stored as an excel file on the network of each site for a duration of 25 years after the creation of the Registry (March 2021). Database 2 data will be hosted on the secured servers of the CHUM for information collected using the CR, with each site only having access to their data. Database 2 information collected using the LR will be hosted on a local secured server of the local institution.

6.6. Storage of exported data

Data exported from Database 2 for **clinical purposes** (PSF, data files requested by clinicians from participating CRN clinics, etc.) is considered as clinical data following its exportation from REDCap. Site-specific storage procedures for extracted data is documented in the CAPDR Manual of procedures and follow local conservation guidelines.

Data exported for **research purposes** is saved on the CHUM "I" drive, with its access restricted to Prof. Manon Choinière and the RC only. This drive is automatically backed up by on a regular basis by the CHUM IT department. Additionally, a copy of the extracted data files will be kept on an external hard drive, stored in a locked filing cabinet in-Prof. Choinière's office. Detailed guidelines on the storage of data extractions are documented in the CAPDR management procedures.

6.7. Transfer of data for research

Research data from the LR will be transferred on a scheduled basis by the LI to the RC, and details will be included in a site-specific Data Transfer Agreement.

6.8. Use of CAPDR data for quality reports

In order to fulfill its role as a tool to improve the quality of care of CP patients, the de-identified CAPDR data will be used to generate a Quality of Care Report (QCR) every 6 months. Data from the Patient Questionnaire will be analyzed with descriptive statistics to document the following parameters at each pain clinic: age, sex, gender, pain intensity on average and at its worst, pain interference, physical functioning, psychological distress (global, anxiety, depression). For data from the CR, the datafile used for this analysis will temporarily be stored on the CHUM "I" drive. Once the QCR has been generated, it will be sent the LI along with the datafile. Following the reception of the documents by the LI, the RC will delete the datafile and report from the 'I' Drive. For data hosted on LR, the RC will provide a SPSS syntax to the LI so the report can be generated locally.

6.9. Data access

Access to the CAPDR is limited to people whose functions are related to its operation and maintenance and who require this access. External collaborators who have obtained all the necessary authorizations to access data for research will be provided with a datafile containing the selected data and/or scores. Exportation of data for research purposes will be carried out by the RC under the supervision of the CAPDR MC.

7. Protection of confidentiality

The CAPDR holds some information of a personal and/or identifying nature (name, address, age, sex, gender, health card number, etc.) This information deals with the participants' privacy, thus its confidentiality must be protected.

The best way to ensure confidentiality is not to store information that may link to identity. However, this is impossible given the principles and objectives of the CAPDR. In fact, it is necessary to retain some links to identity in order to:

- Allow clinicians to identify participants following the reception of a Patient Summary Form;

- Allow participants to exercise their right to withdraw from the research component;
- Obtain consent for future research studies.

The contact information of participants (last name, first name, address, etc.) is stored as part of Database 1. In each study site, the LI is responsible, on the behalf of the CAPDR MC, for the conservation of this information, and the list that links each PtID with a participant's identity. Information that allows participants to be directly identified is stored separately from Patient Questionnaire data, which is stored as part of Database 2.

It is the obligation of each LI to ensure the conservation of consent forms and the contact information of participants for 25 years following the creation of the registry (registry creation: March 2021). Each LI must advise the CAPDR MC if he/she can no longer fulfill his/her obligation. The CAPDR MC will oversee the transfer of this information, after having obtained the approval of the local REB.

Individuals providing data will under no circumstances be identifiable in communications, publications or presentations related to the CAPDR.

7.1. Identifying information in data extractions

Participant's health card number is stored and is visible as part of Database 1. Local RS, LI and clinicians are able to extract them or to see them on the Patient Summary Form, as it is used for clinical purposes. All data found in Database 2 is identified using the PtID only; however, in the event that selected information from the Database must be linked to other datasets using the health card number, and that all ethical/administrative approvals have been obtained, information from Database 1 could be exported and be used temporarily to match Database 2 information to other data sets.

7.2. Use of data for research

Following the approbation of their research project (see section *9. Research studies*), investigators may use Database data for research. A Data Transfer Agreement will be concluded with each Authorized User accessing data for research purposes. This agreement will include a clause stating that a limited number of people can access the data, and the complete list of authorized people will have to be provided to the RC. Use of Database data cannot be for any other purpose than the one approved by the CAPDR MC as part of the DAA. In addition, Authorized Users will have to provide their procedure on storage and destruction of data and results, which will be annexed to the Data Transfer Agreement.

8. Data ownership, stewardship and custodianship

LI will have access to and will own the data generated at their study site as part of the CAPDR. However, by participating in the study, they agree that the CAPDR MC becomes the owner of the data provided by patients who have consented to research. LI can use their site's data obtained from the CAPDR for research purposes, as long as its use does not compete with current research projects underway based on Database data.

Data stewardship of the CAPDR is under the responsibility of the CAPDR MC. The data custodianship will be ensured by CITADEL.

9. Destruction of data

CAPDR data used for clinical purposes cannot be destroyed upon patient request, as it was collected as part of routine clinical care and it is considered part of the medical record.

Participant data extracted from Database 2 is destroyed if a participant withdraws his/her consent to the research component and requests the destruction of data he/she provided. The CAPDR MC, in collaboration with the RC and the DM, will be responsible for carrying out this destruction in a safe

manner. For each withdrawal, a Data Destruction Form (DDF) (see annex 3) will be completed and will be transmitted to the CRN RS for safekeeping.

10. Data Access Requests and Types of Research study

The structure of the CAPDR allows research studies to be implemented, as long as specific criteria are met. There are 3 different types of studies that can be implemented using the CAPDR:

1. Research studies using Database data;
2. Research studies using Database data, in combination with other variables or biological specimens;
3. Research studies aiming to recruit CAPDR participants for new research studies.

10.1. Access to data: studies

Data is made available to CPN members and external collaborators in various disciplines who wish to develop scientific knowledge in the field of CP. The Database is made available to Canadian investigators and investigators from abroad who are conducting research and who are linked with public or private organizations. Use of the Database is subject to conditions that, on one hand, make it possible to respect the consent provided by participants and, on the other hand, allow this information to be used as efficiently as possible. The attribution process of data is described under Figure 1. Each study must first undergo a scientific and feasibility evaluation by the CAPDR MC. Should the CAPDR MC lack the expertise to evaluate a proposed project, an additional opinion on the project will be obtained from an external expert. A data access fee may be charged.

10.2. Application to access data

Applicants who wish to access the Database must submit the following documents:

- Completed Data Access Request form
- Study protocol
- Study budget
- Proof of funding (if applicable)
- CV of the Principal Applicant

In their application, Applicants must indicate the objectives of the research project, scientific bases, methods, funding, expected benefits, foreseeable risks, measures aimed at protecting confidentiality, duration, investigators involved in the project including their affiliation, and type of data needed.

Following the evaluation of the project, the CAPDR MC makes a well-founded decision in writing. Applicants authorized to access Database data will receive a Data Access Authorisation letter. The CAPDR MC may impose conditions on its decision. It will also consider requests from Applicants who are applying for funding and are requesting a letter of support from the CAPDR MC.

Access to Database data will be granted for a finite period of time. Renewal of Database data access approval will be required to extend use of data after that period.

10.3. General evaluation criteria of requests

Any application to use the Database must meet the following criteria:

- The project is aimed at developing knowledge about CNCP;
- The project must be feasible and scientifically valid;

- The investigator will provide sufficient funding in the event additional data/specimen collection is required on site;
- The investigator and the investigator's team, if applicable, have the required knowledge, qualifications and resources to conduct the project;
- The planned use of the data is in accordance with the consent provided by participants;
- The project provides measures to adequately protect the data;
- The project is acceptable in terms of research ethics;
- The project will obtain approval from the CHUM REB, the REB of the establishment with which the investigator is affiliated (local ethics approval) and any other required ethics approval, based on the specific nature of the project.

10.4. Transfer of data for research studies

The CHUM REB must approve new research projects before data can be transferred for research purposes. Should the project require contacting participants in order to obtain an additional consent (e.g. additional collection of data and/or samples), REB approval is obtained from all sites where participants are contacted, from the CHUM REB and from the investigator's institution.

10.5. Progress and results of research studies

Authorized users who have been granted access and obtained CAPDR data for research purposes will have to send to the CAPDR MC an annual progression summary for the duration of their study (annex 4), and a final report (annex 5). The latter will summarize research findings, resulting benefits to the public, and a list of publications generated using CAPDR data. In addition, Applicants will be asked if they have any suggestions or comments regarding data access procedures.

10.6. Return of research results

No return of results or research findings are expected when CAPDR data is used for research purposes. Exceptionally, a clause to this effect may be integrated to the Data Transfer Agreement if an Authorized User and the CAPDR MC have agreed to it.

11. Publication of results

Publications and presentations about findings from research projects that used CAPDR data must respect certain rules. They must respect the *Tri-Agency Framework: Responsible Conduct of Research* (2016) and *Tri-Agency Open Access Policy on Publications (2015)* of the CIHR, the Natural Sciences and Engineering Research Council of Canada (NSERC) and the Social Sciences and Humanities Research Council of Canada (SSHRC). Authorized Users must agree beforehand to respect the requirements described below.

At a minimum, publications of results based on CAPDR data must respect the following terms:

- "Including as authors, with their consent, all those and only those who have made a substantial contribution to, and who accept responsibility for, the contents of the publication or document. The substantial contribution may be conceptual or material."
- "Acknowledging appropriately all those and only those who have contributed to research, including funders and sponsors."

The order of authors will, as much as possible, be agreed upon by team members in advance and in the conception phase of each publication.

11.1. Authorship

RWG ASc members, CAPDR MC members, and LI will be listed by name if their contribution to a given article or abstract justifies it. In addition, external collaborators may be included as listed authors if their contribution justifies it. When the number of authors is limited, investigators may be listed collectively as '*CAPDR Team'*.

11.2. Acknowledgements

For all publications that used data from the Database, contribution of the CAPDR, the CPN and its sponsors must be acknowledged as follow:

> *"(Part of the) Data used for this research was provided by the Canadian Adult Pain Data Registry of the Chronic Pain Network, which is(was) funded by the Canadian Institutes of Health Research as part of its Strategy for Patient-Oriented Research."*

12. Intellectual property

The CAPDR is not for profit. Should any inventions, discoveries, new uses, processes, or compounds (the "Invention(s)") arise directly out of a study which used data from the CAPDR, they shall be owned by the inventing party in accordance with the institutional policies of the inventing Party.

13. Revision history

Revision History			
Version	**Date**	**Modified by**	**Summary of changes**
1	2020-12-07	AJM	First version
1.1	2021-01-21	AJM	Correction of pagination Clarification of annex 1 by adding MUHC
1.2	2021-02-23	AJM	Clarification storage duration: 25 years starting March 2021
2	2022-01-31	AJM	Name changed to 'Canadian Adult Pain Data Registry (CAPDR)' Exception to mantatory completion of PQ as part of routine care Distinction between local/central REDCap hosting Data transfer for locally hosted data Generation of QCR for locally-hosted data Annual/end of study report for projects using CAPDR data for research Updated name of clinics in Annex 1 Update of Figure 1

Annex 1: List of participating sites

Site	Location	Institution	Investigators
01-AEPMU	Montreal	Alan Edwards Pain Management Unit (McGill University Health Centre)	Site Investigator (SI): Marc-Olivier Martel Clinician : Yoram Shir
02-CHUM	Montreal	Clinique anti-douleur du Centre hospitalier de l'Université de Montréal	SI: Gabrielle Pagé Clinician : Aline Boulanger
03-KGH	Kingston	Kingston Health Sciences Centre - Hotel Dieu Hospital Site (KHSC-HDH) – Chronic Pain Clinic (Queen's University)	SI: Scott Duggan
04-HHS	Hamilton	Michael G. DeGroote Pain Clinic (McMaster University)	SI : Ramesh Zacharias
05-DAL	Halifax	Pain Clinic of the Queen Elizabeth II Health Sciences Centre (Dalhousie University)	SI : Mary Lynch
06-CHUQ	Quebec	Centre de traitement de la douleur du Centre hospitalier de l'Université Laval	SI : Anne-Marie Pinard
07-UBC	Vancouver	Pain Management Clinic - Fraser Health Authority (University of British Columbia)	SI : Aaron MacInnes
08-OHRI	Ottawa	Ottawa Hospital Pain Clinic (University of Ottawa)	SI : Patricia Poulin
09-UofA	Edmonton	University of Alberta - Multidisciplinary Pain Clinic	SI : Saifee Rashiq
10-MSH	Toronto	Mount Sinai Hospital - Wasser Pain Clinic (University of Toronto)	SI : Keith Jarvi
11-UofM	Winnipeg	Health Sciences Centre - Pain Management Centre (University of Manitoba)	SI : Renee El Gabalawy
12-CHUS	Sherbrooke	Clinique universitaire de réadaptation de l'Estrie, (Université de Sherbrooke)	SI : Yannick Tousignant-Laflamme

Annex 2- CAPDR Data Access Request Form

INSTRUCTIONS

Complete this form in order to complete your application to access CAPDR data. Please annex the following documents to this form:

- Completed Data Access Request form
- Study protocol
- Study budget
- Proof of funding (if applicable)
- Institutional ethics approval for the study (if available)
- CV of the principal applicant

All documents must be submitted by email to the registry coordinator, Mrs. Audrée Janelle-Montcalm, at audree.janelle-montcalm.chum@ssss.gouv.qc.ca. Documents will be reviewed by the CAPDR Management Committee (CAPDR MC). The registry coordinator will notify the principal applicant by email of the decision of the CAPDR MC. Please contact the registry coordinator if you have any questions.

Note that, once the study has been approved, research ethics approval for the study by the Ethics Committee of the Centre hospitalier de l'Université de Montréal and an executed agreement are required before the principal applicant is granted access to CAPDR data.

CONTACT INFORMATION OF PRINCIPAL APPLICANT

1. Last name, first name _____
2. Institution _____
3. Address _____
4. City _____ 5. Province/ State _____
6. Country _____ 7. Postal code _____
8. Phone number _____
9. Email address _____

Annex 2- CAPDR Data Access Request Form

INFORMATION ON RESEARCH STUDY

10. Title: Click or tap here to enter text.

11. Documents annexed to Data Access Request :

☐ Study protocol ☐ Study budget ☐ Proof of funding (if applicable) ☐ CV of the principal applicant

☐ REB approval (if available) ☐ Peer-review scientific evaluation

12. Start date *(yyyy/mm/dd)*: Click or tap to enter a date.

13. End date *(yyyy/mm/dd)*: Click or tap to enter a date.

14. Funding of study (check all that apply):

☐ No funding ☐ Provincial granting agency ☐ Federal granting agency ☐ Foundation/ patient association

15. Short summary of study (max 250 words):

Click or tap here to enter text.

16. Nature of research study (check all that apply):

☐ Use of CAPR data only ► *Go to question 18*

☐ Use of CAPR data and collection of additional data/ specimens from CRN sites ► *Complete question 17*

☐ Merge CAPR data with another dataset► *Complete question 17*

☐ Use CAPR data to recruit participants in a study ► *Complete question 18*

17. Please list additional outcomes you wish to measure or specimens you wish to collect.

Click or tap here to enter text.

18. Was an external scientific review of the protocol completed?

☐ Yes, as part of a peer-review grant ► *Please annex a copy of the reviewers' feedback to this application.*

☐ Yes, by a peer-review committee ► *Please annex a copy of the reviewers' feedback to this application.*

☐ No

19. Has this project received research ethics approval?

☐ No ☐ Yes ► *Please annex a copy of the REB approval to this application.*

20. Are there research-related risks to this study?

☐ No ► *Go to question 20* ☐ Yes ► *Complete question 20.1*

20.1. Please list all potential risks related to the study.

Click or tap here to enter text.

21. What are the expected benefits to patients participating in this study?

Click or tap here to enter text.

22. Have patients been involved in the design and implementation of the study?

☐ No ☐ Yes

DATA REQUESTED

23. Please select the timepoints for which you wish to obtain data.

☐ Initial

☐ 3 months

☐ 6 months

☐ 9 months

24. Please list which data you wish to access.

	Number of items	Initial questionnaire	Follow-up questionnaires
Study site	1	☐	☐
Language	1	☐	☐
Date of completion	1	☐	☐
Pain location (all pain)	1	☐	☐

Annex 2- CAPDR Data Access Request Form

	Number of items	Initial questionnaire	Follow-up questionnaires
Pain location (worst)	1	☐	☐
Pain location (pain prompting consultation)	1	☐	
Circumstances of pain onset	4	☐	
Pain duration in years	1	☐	☐
Pain frequency (intermittent vs continuous)	1	☐	☐
DN4 self-administered neuropathic component items	7	☐	☐
DN4 self-administered neuropathic component score	1	☐	☐
Presence of pain (past 7 days, Y/N)	1	☐	☐
Worst pain intensity (past 7 days)	1	☐	☐
Average pain intensity (past 7 days)	1	☐	☐
BPI pain interference items (past 7 days)	7	☐	☐
BPI pain interference score (past 7 days)	1	☐	☐
SF12v2 physical functioning items	2	☐	☐
SF-12v2 physical functioning score	1	☐	☐
PHQ-4 anxiety items	2	☐	☐
PHQ-4 anxiety score	1	☐	☐
PHQ-4 depression items	2	☐	☐
PHQ-4 depression scores	1	☐	☐
PHQ-4- psychological distress score	1	☐	☐
Age	1	☐	☐
Biological sex at birth	1	☐	
Preferred gender pronoun	1	☐	
Employment status	1	☐	☐

Annex 2- CAPDR Data Access Request Form

	Number of items	Initial questionnaire	Follow-up questionnaires
Service in the Canadian Armed Forces (CAF)	1	☐	
Currently active in the CAF	1	☐	☐
Year of release from the CAF	1	☐	☐
Pain related to work in the CAF	1	☐	

25. Do you wish to access data for the whole cohort or for selected cases?

☐ Whole cohort ► *End of form* ☐ Selected cases ► *Continue to question 25.1.*

25.1. Please list all selection criteria applying to your research study.

Annex 3- CAPDR Data Destruction Form

DATA DESTRUCTION FORM

Once a patient has signified his/her intention to withdraw from the study, the following procedure must be applied.

a) The CRN coordinator will contact the Registry Coordinator by email to clarify the terms of withdrawal.

b) After having received withdrawal details from the Registry Coordinator, the CRN coordinator will complete the data destruction form.

c) Should the participant have requested a complete withdrawal, the CRN coordinator will send the partially completed Data Destruction Form to the Registry coordinator.

d) The Registry Coordinator will contact all parties involved in the destruction of the former participant's data and will request that they destroy said data and fill out the Data Destruction Form as a confirmation of data destruction. Once signed, the Data Destruction Form will be sent back to the Registry Coordinator.

e) Once all signatures have been obtained, the Registry Coordinator will send the final Data Destruction Form back to the CRN coordinator.

f) *The final signed version of this Data Destruction Form must be stored at the former participant's CRN site.*

1. Participant unique identification number:	
2. Date of withdrawal (*yyyy/mm/dd*):	

3. How did the participant manifest his/her wish to withdraw?

☐ In person ☐ Email ☐ Letter ☐ Phone ☐ Lost to follow up

4. Type of participation withdrawal *(check all that apply)* :

☐ Partial withdrawal- research

☐ Complete withdrawal- research

5. Type of data to be destroyed:

☐ None ☐ REDCap data ☐ Data extractions- CRCHUM ☐ Data extractions- Authorized user ☐ Data extractions- CRN site

Annex 3- CAPDR Data Destruction Form

CONFIRMATION OF WITHDRAWAL

I attest that I have documented the withdrawal of this participant in the local contact information log. This participant wil l not have to complete the CAPDR Patient questionnaire from this point on, and will not be approached for future research studies.

Signature of CRN coordinator:	
Date (yyyy/mm/dd):	

CONFIRMATION OF DESTRUCTION

** Complete the table below only for complete withdrawal from the study.*

Last name, Name	Position	Type of data destroyed	Date of destruction	Initials

Annex 4- Annual progress report for projects using CAPDR data

INSTRUCTIONS

As you have been given access to CAPDR data for research purposes, you must fill out this progress report yearly while your project is ongoing. Please annex the following documents to this form, if applicable:

- Copy of the most recent REB approval/renewal for this project
- Study protocol (if amended in past year)
- List of publications and presentations generated using CAPDR research data.

All documents must be submitted by email to the registry coordinator, Mrs. Audrée Janelle-Montcalm, at audree.janelle-montcalm.chum@ssss.gouv.qc.ca. Documents will be reviewed by the CAPDR Management Committee (CAPDR MC). Please contact the registry coordinator if you have any questions, or if you wish to make any suggestions regarding the data access.

CONTACT INFORMATION OF PRINCIPAL APPLICANT

Last name, first name _____

Institution _____

Address _____

City _____ Province/ State _____

Country _____ Postal code _____

Phone number _____

Email address _____

Annex 4- Annual progress report for projects using CAPDR data

PROGRESS OF RESEARCH STUDY

Title: _____

Start date *(yyyy/mm/dd)*:

Expected end date (yyyy/mm/dd):

Short summary of study progression:

Has this project received research ethics approval/renewal?

☐ No ☐ Yes ► *Please annex a copy of the most recent REB approval/renewal form and a copy of the protocol, if amended.*

Did any serious adverse events (SAEs) happen over the past year as part of your study?

☐ No ☐ Not applicable

☐ Yes ►Please list all SAEs that were recorded over the past year.

Annex 5- Final report for projects using CAPDR data

INSTRUCTIONS

As you have been given access to CAPDR data for research purposes, you must fill out this final report following the end of your study. Please annex the following documents to this form, if applicable:

- Copy of the REB study closure letter
- Study protocol (if amended in past year)
- List of publications and presentations generated using CAPDR research data.

All documents must be submitted by email to the registry coordinator, Mrs. Audrée Janelle-Montcalm, at audree.janelle-montcalm.chum@ssss.gouv.qc.ca. Documents will be reviewed by the CAPDR Management Committee (CAPDR MC). Please contact the registry coordinator if you have any questions.

CONTACT INFORMATION OF PRINCIPAL APPLICANT

Last name, first name _____

Institution _____

Address _____

City _____ Province/ State _____

Country _____ Postal code _____

Phone number _____

Email address _____

Annex 5- Final report for projects using CAPDR data

STUDY CLOSURE REPORT

Title: _____

End date (yyyy/mm/dd):

Short summary of research findings:

What are the resulting benefits of your research to the public?

Annex 5- Final report for projects using CAPDR data

CAPDR DATA ACCESS PROCEDURE

Do you have any suggestions or comments regarding the CAPDR data access procedure?

Figure 1: Authorisation process to access CAPDR data