C-OPN: Data Sharing Policy

1. Purpose

The purpose of this policy is to outline how information collected under the umbrella of the Canadian Open Parkinson Network (C-OPN) is shared. Our overarching goal is to make data as accessible as possible for Parkinson's researchers while protecting the privacy of participants. This policy is guided by the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) and Good Clinical Practice (GCP).

2. Overview of C-OPN Information

C-OPN contains three different types of research infrastructures:

1) The National Patient Registry: contains nominal data including participant contact information, and health card number. This information is stored in a seperate University of Calgary REDCap. Information within this infrastructure will be referred to as the "**registry**" within this document. Local sites will manage their own registry data in accordance with their respective institution or applicable policies.
2) The De-Identified Database: contains de-identified participant information including demographic, clinical, epidemiological, imaging, and results to different assessments (example: Montreal Cognitive Assessment). This information is stored in the University of Calgary REDCapin a different project than the registry. . The project stores date of birth (DOB) data internally solely for de-identifying purposes, such as determining the duration of diagnosis or symptoms. Some sites collect only the year and month of birth or just the year, all referred to as DOB in this document. It's important to note that DOB is never shared externally, and only site coordinators have access to this information. Information within this infrastructure will be referred to as the "**database**" within this document.
3) The Biobank: contains de-identified biological materials collected by local sites, and housed and stored at the Clinical Biological Imaging and Genetic (C-BIG) Repository at the Montreal Neurological Institute. Information within this infrastructure will be referred to as the "**biobank**" within this document.

3. C-OPN Information Access

C-OPN supports and makes specific information available for the purpose of Parkinson's research. Data access procedures will depend on the type of material/data and will range from openly sharing data with the research community, requiring the researcher to register with C-OPN before accessing the data, to necessitating individual review of the projects by the C-OPN Review Committee.

Parkinson's researchers that may be given access to this information are classified in one of two categories:

1) **C-OPN Members**:

a. Regular member: Any academic clinician or researcher considered to be an independent principal investigator according to the tri-council norms. Additionally, clinicians who contribute to the participant registry by involving their patients.
b. Associate member: Any academic employee in the clinical or research domain (e.g. research assistant, research nurse, excluding principal investigators).
c. International member: Any academic clinician or researcher considered to be an independent principal investigator outside of Canada.
d. International associate member: Any academic clinician or researcher outside of Canada.

Note: Any trainee of regular members is also considered an associate member of C-OPN.

Membership is obtained by sending a request to the central C-OPN coordinator team who verifies the potential member's affiliation, and is then approved by the C-OPN Director or Co-Director. Membership can be obtained within two business days of request.

2) **Industry**: Entities conducting Parkinson's research outside of academia or clinic. Industry does not include insurance companies or any other organization that are not stakeholders in C-OPN's mission.

4. Overview of Different Data Access Levels

C-OPN data access are divided in three different tiers:

- **Open access:** Data with very low risk of re-identification and that do not present particular sensitivity that will be publicly available. See section 5 for more details.
- **Registered access:** Data with low risk of re-identification and that do not present particular sensitivity that will be made available through the C-OPN coordinator team. This type of access is only available to C-OPN members. See section 6 for more details.
- **Controlled access:** Data with a direct or higher risk of re-identification and/or particular sensitivity that will require approval through a formal review process by the C-OPN Review Committee. See section 7-10 for more details.

This three tier system is also explained in the table below:

Type of Data	C-OPN Members Access Process	Industry Access Process
Data with low risk of re-identification (e.g. raw data from de-identified questionnaires)	Registered Access	Controlled Access
Data with a direct or higher risk of re-identification and/or particular sensitivity (e.g. de-identified biological material)	Controlled Access	Controlled Access

5. Open Access Procedures for Data

Data with very low risk of re-identification and that do not present particular sensitivity ("**Open Access Data**"), such as metadata and aggregated patient cohorts, etc. will be made publicly available online. Examples of data shared accordingly include:

- # of participants enrolled in the C-OPN registry
- # of participants that have completed the REDCap questionnaire (at baseline and at 18 months follow-ups)
- # of participants that have donated blood
- List of questions included in questionnaires

These data will be completely anonymized, and the goal in sharing them is to promote network transparency.

6. Registered Access Procedures for Data

Data with low risk of re-identification and that do not present particular sensitivity such as aggregated clinical data, raw data from de-identified questionnaires or with phenotypic information about the participant, results from different assessments (e.g. Montreal Cognitive Assessment), or basic laboratory analysis, and images processed with the "de-identification" standard of the field, etc. hosted on the University of Calgary REDCap may be made accessible through a request process for C-OPN members ("**Registered Access Data**"). The C-OPN University of Calgary REDCap database only shares de-identified data in compliance with Alberta Health Services (AHS) Non-identifiying Health Information Policy (IPO-2013-0004).

C-OPN members can request access by completing a form on the C-OPN website. The form requires:

- Providing their name, institutional association, and email
- Affirming their C-OPN membership. Non-members will need to complete the membership process
- Providing a project title and brief description
- Selecting the type of request

Upon verification by the C-OPN coordinator team that they are C-OPN members, the researchers must agree and sign the C-OPN Data Use Agreement that minimally includes that:

- The researcher identifies themselves and their affiliation.
- The research project is in line with the C-OPN objectives.
- The project follows all applicable ethical norms and requirements in the C-OPN jurisdiction (e.g. research is overseen by a duly constituted REB).
- The researcher agrees to not attempt to re-identify participants, keep the data secure, not to re-distribute the data, acknowledge C-OPN in any publications or dissemination of results, etc.

Upon completion of the Data Use Agreement by the researcher, the C-OPN coordinator team will furnish a securely password-protected, de-identified report extracted via REDCap. The de-identified report will be in compliance with the AHS Non-identifiying Health Information Policy (IPO-2013-0004). This report will be transmitted in encrypted form through Microsoft Outlook to the researcher's institutional email address, ensuring strict confidentiality and data security measures are upheld throughout the process.

Data with low risk of re-identification can be shared with industry but through a controlled access process described below. Industry requests are not eligible for registered access.

7. Controlled Access to Material/Data Requiring Formal C-OPN Review Committee Approval

Access to de-identified biological material and to the data that have not been formally identified by the C-OPN Review Committee as "Open Access" or "Registered Access" data is granted by the C-OPN Review Committee after formal review by at least 4 of its members ("**Controlled Access Material/Data**"). Data with a direct or higher risk of re-identification and/or particular sensitivity will always be considered controlled access data.

8. C-OPN Review Committee Controlled Access Application Process

Request of information can be done through the C-OPN website (https://copn-rpco.ca/research/), or by requesting access directly to the C-OPN central coordinator team or a site coordinator.

Once a request for information from C-OPN is received, a C-OPN Data Access Request Form must be completed filling out the following information:

- Name
- Institution or organization
- Affiliation
- Email/phone
- Attach ethics approval certificate for study/project
- Brief description of project (Purpose of the study, Hypothesis, Inclusions and exclusions (if applicable), What C-OPN data will be needed for the project)
- Informed consent form
- Signed data, or material use agreement

The C-OPN Data Access Request Form is a digital instrument hosted on REDCap. Requesters can access the form either by a generated link through REDCap or by requesting a PDF version via email, which they can then complete and submit. When the Request Form is completed, it is delegated to the C-OPN Review Committee for assessment.

9. C-OPN Review Committee Approval Process

Request for controlled C-OPN data access will be reviewed by the C-OPN Review Committee with the exception of the Quebec Parkinson Network that may approve requests for their respective site-specific acquired information (McGill, CHUM, CHUQ) through their review committee process.

Access proposals will be reviewed initially by at least one member of the C-OPN Review Committee to ensure the project meets the following minimum conditions:

- Projects must be approved by a duly constituted REB from the institution from which the project originates.
- Proposals will need to explicitly describe the project background, aims and objectives.

- Proposals will have to justify why C-OPN material/data is required, the nature of the analysis, a timeline for the use of the material/data, and a mechanism for reporting the results of the experiments and reporting that the material/data was used as proposed.
- Proposals will include provisions for acknowledging the contribution of C-OPN in any publications or dissemination of results.

Proposals lacking these details will be dismissed as incomplete. The request for data proposal will be sent to the C-OPN Review Committee via email by the National Coordinator. The C-OPN Review Committee will convene within a month of receiving a complete proposal. The group will evaluate the proposal based on scientific merits and justification for the material/data request. At least one representative per province will have to support the request to receive approval. If one of the members is involved in the proposal, they will recuse themselves from the discussion and will not be eligible to vote. The committee may also request clarifications or corrections from the authors of the proposal. Electronic approvals through e-mails will be accepted following review by members of the C-OPN Review Committee. If the C-OPN Review Committee unanimously approves the request, the proposal may be approved without convening a formal meeting. Where external expertise is required, C-OPN Review Committee may designate an expert to aid in the review of the complicated technical aspects (science/content review). The C-OPN Review Committee can choose whether to re-convene within six weeks to review these clarifications/changes or whether a single member can perform a delegated review. If the committee opts for the latter, a designated member will be selected during the meeting.

Review Committee approvals will be sent to the National Coordinator via email. The National Coordinator will log the given number associated with the request, the name of the requester, the name of the Review Committee member(s) that approved the request, and the date of approval within a document stored on a secure UCalgary server.

10. Sharing of Controlled Access Data Process

Once a request is approved by the Review Committee, the process of data sharing is managed by the National Coordinator or C-OPN central coordinator team. Any sharing of controlled access data with industry will require a legal agreement while sharing within research institutions may be exempt from this process (subject to specific institution policies).

If applicable, a de-identified report will be created using LORIS or REDCap, and will only contain the specific information requested for the REB approved project. The de-identified report will be in compliance with the AHS Non-identifiying Health Information Policy (IPO-2013-0004). Once finalized, the report will be reviewed by either the National Coordinator, C-OPN central coordinator team, or appropriate reviewers (for example Alberta Health Services) to ensure the report is in compliance with the Data Sharing Policy. Once reviewed, the report will be transmitted in encrypted form through Microsoft Outlook to the researcher's institutional email address, ensuring strict confidentiality and data security measures are upheld throughout the process. The report will be in a password protected file, and the password will be sent in a separate email. Reports will only be sent to University issued email addresses, or professional email addresses with a secure research environment. In the event that destruction of data is necessary, the National Coordinator will follow-up with the requester to delete the electronic file containing data and ask for proof of this deletion.

Researchers will be strongly encouraged (but not always required) to submit back analyzed data that used C-OPN data or materials. Examples include but are not limited to, DNA sequencing, quantification of protein expression, RNA-expression, mRNA expression, and processed images.

11. Information Sharing Cost

All industry requests approved by the C-OPN Review Committee may be subject to a cost decided via a legal agreement. Member's requests will be free of charge but may operate on a cost-recovery basis if additional resources are needed for the request (example: coordinator time to help with recruitment).