INFORMATION AND CONSENT FORM

Title of research project:	The Quebec Cannabis Registry: A Database on the Use of Dried Cannabis for Medical Purposes Established for Research Purposes
Principal Investigator and person responsible for the registry	Dr. Mark A. Ware, Department of Family Medicine and Anesthesia, McGill University Health Centre
Co-researchers:	▪ Yola Moride, Full Professor, Faculty of Pharmacy, Université de Montréal. ▪ William Barakett, Department of Family Medicine, McGill University. ▪ Antonio Vigano, Associate Professor, Department of Medicine and Oncology, McGill University. ▪ Andrée Néron, Pharmacist, CHUM [Centre hospitalier de l'Université de Montréal (Université de Montréal hospital centre)] - Notre-Dame. ▪ Pierre Beaulieu MD, Ph. D., Associate Professor, Department of Anesthesiology and Pharmacology, Faculty of Medicine, Université de Montréal and CHUM.
Collaborators:	▪ Yves Robert, Collège des médecins du Québec (Quebec doctors association) (CMQ). ▪ François Gobeil, Association d'anesthésiologistes du Québec (Quebec anesthesiologists association) (AAQ). ▪ Jacques Laliberté, Association québécoise de la douleur chronique (Quebec chronic pain association) (AQDC). ▪ Pierre Fréchette, Ministère de la Santé et Services sociaux du Québec (Quebec Ministry of Health and Social Services) (MSSS). ▪ Louis Godin, Fédération des médecins omnipraticiens du Québec (Quebec federation of general practitioners) (FMOQ). ▪ Yv Bonnier Viger, Fédération des médecins spécialistes du Québec (Quebec federation of medical specialists) (FMSQ). ▪ Marie-Josée Rivard, Société québécoise de la douleur chronique (Quebec chronic pain society) (SQD).
Organizations:	This research project is supported by the Canadian Consortium for the Investigation of Cannabinoids (CCIC)
Sponsors:	This research project is funded by financial contributions to the Canadian Consortium for the Investigation of Cannabinoids (CCIC) by Bedrocan Canada, Mettrum ,Tweed and the Collège des médecins du Québec (CMQ).

1. Preamble

We are inviting you to take part in a research project designed to create a database on the use of dried cannabis for medical purposes established for research purposes.

Before you agree to take part in this project and sign the information and consent form, please take the time to read, understand and carefully consider the following information.

This form may contain words that you do not understand. Please ask the designated researcher in charge of the project or a member of his research staff any questions you might have or explain any word or detail that is not clear.

2. Nature and objectives of the research project

The Marijuana for Medical Purposes Regulations, adopted by the federal government in June 2013, came into force in the Canadian provinces on April 1st 2014. These regulations stipulate that to acquire dried marijuana for medical purposes from an authorized commercial producer, it is mandatory that patients obtain a prescription from a physician.

However, at the present time in Canada, the use of dried cannabis for medical purposes is not recognized as a medical treatment, and Health Canada has not approved dried cannabis as a drug. This means that its therapeutic indications, efficacy and safety have not been defined.

Consequently, the Marijuana for Medical Purposes Regulations adopted by the federal government oblige the medical profession to prescribe this product outside the usual framework for prescription drugs and without the conclusive scientific data required to ensure good medical practices. Furthermore, according to articles 48 and 49 of Quebec's Code

of ethics of physicians, physicians are not required to prescribe dried cannabis, and since April 1st 2014, those who agree to prescribe it can only do so within a research framework.

Researchers in Quebec from the Canadian Consortium for the Investigation of Cannabinoids (CCIC) and other organizations have decided to develop a database on the use of dried cannabis for medical purposes, in order to allow the prescription of dried cannabis within a research framework and to constitute a significant resource that could possibly address a number of concerns regarding the safety and efficacy of dried cannabis for medical purposes.

The aim of this database is to gather together and preserve clinical data collected from Quebec users of dried cannabis for medical purposes. The research data could be made available to researchers from the province of Quebec and elsewhere and, in accordance with specific criteria, from other organizations seeking to undertake research projects aimed at developing new knowledge on the use of dried cannabis for medical purposes.

This database has the following objectives:

1. To establish an infrastructure for research aimed at producing new knowledge on the use of dried cannabis for medical purposes, and specifically pharmacovigilance studies of the product.
2. To carry out a scientific watch to identify new research questions emerging on the subject.
3. To foster collaboration among researchers in the province of Quebec, and possibly other Canadian provinces, the United States and elsewhere, who are conducting projects on the use of cannabinoids, specifically by enabling them to share research data.

To carry out this research project, we are planning to recruit 3,000 participants, both men and women, aged 18 years of age and older.

This research project will be carried out in in a number of Quebec medical clinics and health and social services system institutions. It will be under the responsibility of the designated researcher in charge of the project, Dr. Mark Ware.

3. How the research project will be conducted

3.1 Condition for prescribing dried cannabis for medical purposes

At the present time, dried cannabis for medical purposes is not a treatment recognized by Health Canada. Consequently, in Quebec, prescribing dried cannabis for medical purposes is conditional on participating in a research project on dried cannabis for medical purposes.

3.2 Duration and number of visits

Your participation in the research project will last four years, and will involve 10 visits. During the first two years, you will have a visit every three months. For the remaining two years, you will have a visit once a year.

3.3 Nature of your participation

Your participation in this database consists in allowing your physician-collaborator in this research project, who will be prescribing dried cannabis for medical purposes to you, to communicate to the research team sociodemographic information such as your age, sex and occupational status, clinical data concerning you, and the effects that dried cannabis could have on your health condition.

This information will be collected on each of your medical visits: the visit to establish the reasons for first prescribing the product, then the follow-up visits, at least every three months for two years and once a year for the remaining two years, for a total duration of four years.

Your information and data will be transmitted to the research team by your physician-collaborator as quickly as possible after each of your visits.

3.4 Long-term longitudinal component

This research project could also include a long-term longitudinal component. Depending on funding sources and government priorities, the longitudinal component could be carried out for a number of years, under the same terms and conditions.

Were this to be the case, do you agree to participate in the long-term longitudinal component? ☐ **Yes** ☐ **No**

3.5 Participation in later studies

Do you agree to have your physician-collaborator contact you again to give you the opportunity to take part in other research projects related to this study? When you receive such a call, you will of course be free to agree or refuse to take part in the proposed research projects.

☐ Yes ☐ No

3.6 Ownership of the data

You will remain owner of your data at all times. Your data will not be sold under any circumstances. Your data will only be used for the purposes of research.

The designated researcher in charge of the research project will act as trustee for the data that will be collected in the database. In accordance with the management framework of the database on the Use of Dried Cannabis for Medical Purposes Established for Research Purposes, the Principal Investigator and person in charge for the registry will be responsible for the preservation, custody and security of the data collected. He will also be responsible for the distribution of data to researchers who wish to carry out research projects to develop new knowledge concerning the use of dried cannabis for medical purposes.

4. Benefits associated with the research project

It is possible that you will derive a personal benefit from taking part in this research project, but we cannot guarantee this. The results obtained, however, will contribute to the advancement of scientific knowledge in this field of research.

5. Disadvantages associated with the research project

The only disadvantages associated with your participation in this project are the time you will have to spend on visits, and the travel involved.

6. Voluntary participation and possibility of withdrawal

Your participation in this research project is voluntary. You are therefore free to refuse to participate in it. You can also withdraw from this project at any time, without having to give reasons for doing so, by advising your physician-collaborator of your decision. Your physician-collaborator will transmit this information to the designated researcher in charge of the project.

Your decision to not participate in this research project or to withdraw from it will not have any impact on the quality of care and services to which you are entitled or on your relationship with the designated researcher in charge of the project, the co-researchers, your physician-collaborator and the others involved in the project. However, if you withdraw or have withdrawn from the project, you will not have access to dried marijuana for medical purposes unless you take part in another research project.

The designated researcher in charge of this project, the central research ethics committee of the Minister of Health and Social Services, the Canadian Consortium for the Investigation of Cannabinoids (CCIC), the College ds médecins du Québec (CMQ) and the sponsors may terminate your participation, without your consent, if new discoveries or information indicate that your participation in the project is no longer in your best interests, if you do not follow the instructions of the research project, of if there are administrative reasons for abandoning the project.

If you withdraw or have withdrawn from the project, the information already obtained in connection with this project will be preserved and used for as long as it is useful for the advancement of scientific knowledge. When the information is no longer of use, it will be destroyed. Nonetheless, you may request that your research data not be used by speaking to your physician-collaborator. Your physician-collaborator will see to it that your request is transmitted to the designated researcher in charge of the project. In that case, the information concerning you will be preserved for as long as necessary to comply with regulatory requirements, but will not be used for any new research project.

Any new knowledge acquired while the project is taking place that might affect your decision to continue to take part in it will be communicated to you promptly, both verbally and in writing, by your physician-collaborator.

7. Collection, preservation, access to the database, and confidentiality

During your participation in this research project designed to create a database on the use of dried cannabis for medical purposes established for research purposes, the designated researcher in charge of the project, your physician-collaborator and members of their research staff will collect information on you. Only information required to meet the scientific objectives of this project will be collected.

This will include information on your past and present health condition and lifestyle, the answers to the questionnaires, and the effects that dried cannabis might have on your health condition. Other information, such as your sex and month and year of birth, will also be collected.

All the information collected as research data will be securely preserved in the database on the Use of Dried Cannabis for Medical Purposes Established for Research Purposes housed in the Research Institute of the McGill University Health Centre, in accordance with the management framework of the database on the Use of Dried Cannabis for Medical Purposes Established for Research Purposes.

Your research data will remain confidential within the limits provided by law. In order to safeguard your identity and the confidentiality of the information, you will only be identified by a code number. The key for the code linking your name to all your data will be kept by your physician-collaborator.

The database on the Use of Dried Cannabis for Medical Purposes Established for Research Purposes will provide researchers with an infrastructure for carrying out research projects designed to develop new knowledge on the use of dried cannabis for medical purposes and to:

1. Establish an infrastructure for research aimed at producing new knowledge on the use of dried cannabis for medical purposes, and specifically pharmacovigilance studies of the product.
2. Carry out a scientific watch to identify new research questions emerging on the subject.
3. Foster collaboration among researchers in the province of Quebec, and possibly other Canadian provinces, the United States and elsewhere, who are conducting projects on the use of cannabinoids, specifically by enabling them to share research data.

All projects will be evaluated and approved by the central research ethics committee of the Minister of Health and Social Services before being carried out,. The central research ethics committee of the Minister of Health and Social Services will also monitor the projects.

The research data entered into the database on the Use of Dried Cannabis for Medical Purposes Established for Research Purposes will be shared with different researchers. This transfer of information implies that your research data may be transmitted to countries other than Canada. However, the designated researcher in charge of this research project will abide by the confidentiality rules in force in Quebec and the rest of Canada, and will do so in all countries.

Your research data will be preserved for as long as they are useful for the advancement of scientific knowledge. When they are no longer of use, your research data will be destroyed. Nonetheless, please note that at any time you can request that your research data not be used by speaking to your physician-collaborator. Your physician-collaborator will transmit this information to the designated researcher in charge of the project. In this case, the information already obtained in connection with this project will be preserved for as long as necessary to comply with regulatory requirements, but no new project will be carried out using your research data.

For the purposes of monitoring and control, the database on the Use of Dried Cannabis for Medical Purposes Established for Research Purposes may be consulted by a person mandated by the central research ethics committee of the Minister of Health and Social Services, or by a person mandated by authorized government agencies. All of these individuals and organizations observe a confidentiality policy.

You have the right to verify the information collected concerning you and to have it corrected if necessary, and you have this right for as long as your physician-collaborator and the designated researcher in charge of this research project hold this information.

8. Marketing possibility

The research results arising from your participation could lead to the creation of commercial products. However, you will not be able to derive any financial benefit from this.

9. Funding the research project

The designated researcher in charge of this research project has received funding from the Canadian Consortium for the Investigation of Cannabinoids (CCIC) to complete this research project.

10. Compensation

You will not receive any financial compensation for your participation in this project.

11. Indemnification in case of harm, and rights of the participant in the research

By agreeing to participate in this research project, you are not waiving any of your rights or discharging the designated researcher in charge of this research project, the co-researchers, the Canadian Consortium for the Investigation of Cannabinoids (CCIC), the Collège des médecins du Québec (CMQ) or the sponsors of their civil and professional liability.

12. Identification of resource persons

If you have questions about the research project or a problem that you believe is associated with your participation in the research project, you can contact the designated researcher in charge of this project, Dr. Mark A. Ware, or the clinical coordinator of the project at (514) 934-1934, extension 42784, or your physician-collaborator.

If you have a complaint, you can contact the Collège des médecins du Québec at (514) 933-4441.

13. Monitoring the ethical aspects of the research project

The central research ethics committee of the Minister of Health and Social Services has approved this research project and is monitoring it. The committee will also approve in advance any revision or amendment made to the research protocol or to the information and consent form. For any information, you can contact Ms. Johane de Champlain, vice-chair, at (514) 873-2114.

CONSENT

Title of research project: The Quebec Cannabis Register: A Database on the Use of Dried Cannabis for Medical Purposes Established for Research Purposes.

1. Participant's consent

I have read the information and consent form. I acknowledge that the project has been explained to me, that my questions have been answered, and that I have been given the time I wanted to make a decision. Having thought about the matter, I consent to participate in this research project on the conditions set forth therein.

Participant's signature Date

2. Signature of the person who obtained the consent, if different from the physician-collaborator.

I have explained to the participant the terms of this information and consent form, and have answered the questions that the participant put to me.

Signature of the person obtaining the consent Date

3. Signature and undertaking of the physician-collaborator.

I certify that the terms of this information and consent form have been explained to the participant, that any questions the participant had in this regard have been answered, and that it has been clearly indicated to the participant that the participant remains free to terminate their participation without prejudice.

As physician-collaborator, I undertake to abide by what has been agreed to in the information and consent form, and to deliver a signed and dated copy of the form to the participant.

Signature of the physician-collaborator. Date

4. Signature and undertaking of the designated researcher in charge of this research project

I certify that the terms of this information and consent form have been explained to the participant, that any questions the participant had in this regard have been answered, and that it has been clearly indicated to the participant that the participant remains free to terminate their participation without prejudice.

I undertake, as designated researcher in charge of this project, and together with the research team, to abide by what has been agreed to in the information and consent form.

9 June 2015

Signature of the Principal Investigator and person responsible for the registry Date