



MEDICAL CANNABIS REGISTRY INFORMED CONSENT

Introduction

You are invited to participate in the *Registry for Santé Cannabis Patients Authorized Cannabinoid-based Products in Canada*, referred here as “the study.”

The study is being created by our team at Santé Cannabis, led by Dr. Michael Dworkind, Medical Director at Santé Cannabis and Associate Professor in the Family Medicine Department at McGill University, and is being funded by Santé Cannabis.

The purpose of this study is to learn more about patients for whom medical cannabis or cannabinoid treatments were prescribed in one of our clinics. To fulfill this purpose, Santé Cannabis will look at coded data collected during your treatment with medical cannabis. This will allow us to understand important questions such as whether medical cannabis is effective for certain symptoms and conditions, and what the common product information, dosing patterns, and side effects are.

Procedures

The clinical information from your medical record will be coded and stored in the study database. This means we will copy information from your medical record and remove all information that can identify you such as your name, address, date of birth, or Medicare number, and replace it with a code.

All information will be collected as part of your routine care. At each appointment – whether in person, by phone or by telemedicine – our staff will interview you to assess and collect data on your medical condition. You will also fill standardized questionnaires to assess targeted conditions. A questionnaire about your experience and associated effects with the medical cannabis products you are taking will also be completed after initial visit and during follow-up visits. This questionnaire asks about onset, duration and intensity of effect, taste, texture, and easiness of administration. Completing these questionnaires should take between 20 to 30 minutes. Information collected include demographics, symptoms (general and targeted questionnaires), medical history, assessment of symptoms, concomitant medications, cannabinoid-based treatment plan and status, any side effects, and information on ending your treatment.

Evaluation	Pre-initiation	Initial Visit	Scheduled Follow-up	Unscheduled Follow-up
Demographic Form	X	X		
Informed Consent	X	X		
General Questionnaire		X	X	X
Product effect questionnaire		X	X	X
Review of Medical History	X	X		
Assessment of Symptoms		X	X	X
Concomitant Medications	X	X	X	X
Treatment Plan and Status		X	X	X

Adverse Drug Reactions			X	X
Targeted Questionnaires		X	X	X
Termination Forms			X*	X*

* If termination visit.

Number of Participants and Study Duration

The study is expected to include 4000 participants who will be recruited over 5 years. Data from the study will be stored for seven (7) years after the study is complete.

Eligibility

To participate in the study, you must be 18 years old or older and be prescribed medical cannabis or cannabinoid-based medication at a Santé Cannabis clinic. You must consent to participate in the study and be capable of completing or answering questionnaires. Pregnant or breastfeeding individuals are not eligible to participate.

Risks and Benefits

Risks: The risks for participating in this study are low. The procedures proposed here are part of standard care for Santé Cannabis' patients. As with any database, there is a slight risk of information breach and the possibility of exposing your identity. To protect against this risk, we employ state-of-the-art safeguards, including training personnel, limiting access to data, file encryption and password protection.

Benefits: You may indirectly and directly benefit from participating in this study. By taking part, you will be indirectly contributing to advance the knowledge on medical use of cannabis for patients, doctors and researchers. This new knowledge may result in better medical practices that can be translated directly into better care for you.

Confidentiality

All data will be treated confidentially. To ensure confidentiality, medical records are striped of anything that may identify you and replaced by a code. Files are stored in a secure, proprietary server, protected by state-of-the-art firewall and encryption. Our personnel receive periodic training on privacy and are required to treat data confidentially. Data is shared only among authorized personnel in a "need to know" basis. Data will be reviewed by a team of researchers at Santé Cannabis. Insights from this study may be shared with partners, medical doctors, healthcare professionals, researchers, and other patients. The results from the study may be published in specialized journals, press releases, or presented in conferences and workshops. It will not be possible to identify you in any of the shared or published material. As required by the Research Ethics Board these data will be stored for seven (7) years after completion of the study. If other studies in the future require access to these data, prior authorization from the Research Ethics Board will be sought.

Costs and Compensation

Participation in the study will have no costs to you. You will not be compensated for taking part in the study.

Conflicts of Interest

Dr. Michael Dworkind is a co-founder and Medical Director of Santé Cannabis. To mitigate this potential conflict of interest, this information is disclosed to you and will be mentioned at each time results from this study are published in specialized journals, press releases, or presented in conferences and workshops.

Your Rights

Please take your time to read this form. You may ask any question, at any moment. A qualified person at Santé Cannabis will explain to you any concern you may have regarding this study.

- Your participation in the study is voluntary. Your refusal to participate will not affect the quality of care you will receive.
- If you accept to take part in the study but later change your mind, you can end your participation by contacting us via email, phone, or in person.
- The information collected in the study is strictly confidential and protected by the Act Respecting the Protection of Personal Information in the Private Sector.
- You have the right to access, rectify, or cancel access to your personal information at any time by contacting us via email, phone, or in person.
- A copy of this form will be provided to you.

Contact Information

For questions related to this research study contact Santé Cannabis at 1(844) 419-4131 or info@santecannabis.ca.

For questions concerning your rights as a research participant contact McGill University Institutional Review Board at 1(514) 398-8302 (Ms. Ilde Lepore).

Informed Consent

I have read the information provided in this consent form. I am aware of the risks and benefits of study participation. I am aware that I can withdraw from this study at any time. Any questions I had were answered. I consent to take part in this study. I do not give up any of my legal rights by signing this consent form.

Name

Name of person obtaining consent

Signature

Date
(MM-DD-YYYY)

Signature

Date
(MM-DD-YYYY)