

## **LUMIR MISSION STUDY AUSTRALIA**

### **PARTICIPANT INFORMATION FORM**

#### **Help Us Understand What Works Best for You: Be Part of Our Research**

The Lumir Mission aims to help over 1 million patients worldwide. The Lumir Mission aims to contribute to the scientific evidence base of medicinal cannabis through a range of research activities.

#### **What's the Research Study About?**

There are hundreds of cultivated varieties of cannabis, and thousands of cannabis products on the market. Not only does cannabis contain the major phytocannabinoids, tetrahydrocannabinol (THC) and cannabidiol (CBD), but it also contains minor phytocannabinoids and terpenes (essential oil-like substances) which also have therapeutic effects. Different cannabis flowers therefore have different amounts of these components- a different 'phytochemical profile'. The same can be said of individual medicinal cannabis products. Relatively little is known about which characteristics of MC products are most effective in alleviating a range of medical conditions and associated common symptoms. This study aims to collect data from tens of thousands of medicinal cannabis users, in Australia, the US and the UK to help answer this question.

This study is being conducted in Australia, the US and the UK. This Participant Information form is relevant to the Australian study only.

#### **Who Can Participate in the Study?**

It is strongly advised that anyone taking medicinal cannabis is under the care of and/or receives advice about medicinal cannabis from a qualified healthcare practitioner trained in medicinal cannabis.

#### **Inclusion Criteria:**

- The study is open to anyone 18 years and over who is using medicinal cannabis for a health complaint. In Australia, medicinal cannabis (all types of products) is available by prescription only.

#### **Exclusion Criteria:**

- Individuals who are not under the care of a medical practitioner (or a nurse practitioner in states of Australia that allow nurse practitioners to prescribe medicinal cannabis).

#### **What Am I Required to Do?**

In Australia you need to have medicinal cannabis prescribed by a medical practitioner (in some states, nurse practitioners may also prescribe medicinal cannabis). Natura Clinic in Australia have doctors and nurse practitioners who are trained in medicinal cannabis and can help you find the right medicinal cannabis products.

A key component of this study is finding out if medicinal cannabis helps your primary condition as well as if it impacts on pain, sleep, anxiety, mood, general functioning and energy level. We also want to know if you experience any side effects, positive or negative, and if your use of pharmaceuticals for your main condition changes over time.

To participate in the study, you need to download the Lumir App to your phone. You will need to read and agree to the terms of participation in the study. Then you need to fill in some demographic details about yourself including age, gender, level of education, regular treatments and so on. You are required to nominate a primary complaint (for which you are using medicinal cannabis) and any secondary complaints.

### Weekly Survey

You then complete the baseline survey which asks you to rate the severity of your primary complaint and some associated common symptoms (mood, anxiety, pain, energy level, general functioning, quality of sleep) on a sliding scale from 0 to 10. There are also two questions about any side effects experienced and whether your use of pharmaceutical medications has changed over the past week (these are not relevant if you are filling out the baseline survey just prior to beginning your first medicinal cannabis prescription).

This survey is sent to you again on a weekly basis.

### Optional Daily Journal

There is also a daily dosing journal in the App. You can rate the severity your primary and secondary complaints before and after a dosing session and track your progress over time.

### Sync Your Smart Watch

You may also be able to synchronise your Smart Watch to the App and track your sleep and fitness.

## **What Do I Gain from Participating?**

By participating in the study, you may gain a sense of enhanced awareness of your personal wellbeing. Continuous tracking of your health can help inform you and you can also share the information with your healthcare provider. You will also be contributing to the knowledge base around medicinal cannabis which may help a larger community of people in the future.

In addition, as a thank you for participating:

- In Australia and the UK, for each 4 weeks of active participation you will receive access to a wellness activity or service provided by a partner organisation.

## **How will the Information I Give Be Used?**

Aside from your own use and reports within your personal Lumir Mission App, all data collected is deidentified (your name removed) and added to the anonymous data from other study participants within each country as well as combined (US, UK, Australia). This deidentified global data set will then be analysed to inform future research directions in pursuit of furthering the understanding of applications of medical cannabis.

## **Are There Any Risks Involved in the Research?**

There are no additional risks of participating in this research study above those risks that are associated with the use of medicinal cannabis that have been or will be discussed with your nurse practitioner or doctor. Known side effects of medicinal cannabis, both CBD and THC, include fatigue, sedation, vertigo, nausea, vomiting, fever, decreased or increased appetite, dry mouth and diarrhoea. THC and products containing high amounts of THC have also been associated with convulsions, feeling high, feeling dissatisfied, depression, confusion, hallucinations, paranoid delusions, psychosis, and cognitive distortion (having thoughts that are not true) (for more information please see: <https://www.tga.gov.au/publication/guidance-use->

[medicinal-cannabis-australia-patient-information](#)). Note that participants should not drive or operate heavy machinery if consuming THC-containing medicines.

**Note:** You remain under the care of your medical practitioner or where relevant a nurse/nurse practitioner in relation to your medicinal cannabis. This study simply measures and tracks a range of patient outcomes in a formal sense. If you decide to not continue under the care of a medical practitioner (or nurse/nurse practitioner where relevant) in relation to medicinal cannabis use, you may not remain in the study and should remove yourself from the study.

### **Withdrawing from the Study**

Your participation in this study is voluntary. You may withdraw from the study at any time by deleting the App from your phone. You do not need to notify anyone specifically. Withdrawing from the study will in no way impact on your medical care with your medical doctor or nurse practitioner.

### **Privacy and Confidentiality**

At all times your data will be managed with the strictest adherence to the data legislation relevant in your region. This includes (but is not limited to); HIPAA compliance (USA), UK GDPR compliance (UK) and The Privacy Act 1988 and Australian Privacy Principles (Australia). All data collected for statistical analysis will be de-identified (this means your name is removed) and aggregated (combined with the data of other participants). Your participation in this study therefore remains confidential.

### **Who is Conducting the Study?**

This study is sponsored by Cannim Group Pty Ltd, a medicinal cannabis company based in Australia, with business interests in the US, UK, Canada, Jamaica and Germany.

The following people are involved in the study:

- **Chief Investigator Australia:** Professor Kylie O'Brien PhD (Chief Scientific Officer, Cannim Group Pty Ltd and Adjunct Professor Torrens University and Adjunct Fellow NICM Health Research Institute, Western Sydney University); Email: [kylie.obrien@cannim.com](mailto:kylie.obrien@cannim.com)
- **Associate Investigator:** Dr Adam Abodeely MD (Medical Director, Cannim USA LLC; email: [adam.abodeely@cannim.com](mailto:adam.abodeely@cannim.com))
- **Associate Investigator:** Dr Anup Mathew (MD, MA, MSc, BSc (Hons), FRCPsych, FHEA, DCP, MDCH, DCBH, PGCDM, PGCCCE, MAcadMEd) (Medical Director Cannim UK, consultant psychiatrist); Email: [avmathew@doctors.org.uk](mailto:avmathew@doctors.org.uk)

### **Who Do I Contact for Any Questions in Relation to the Study?**

Contact the Chief Investigator: Professor Kylie O'Brien PhD (Chief Scientific Officer, Cannim Group); email: [kylie.obrien@cannim.com](mailto:kylie.obrien@cannim.com)

### **Ethics Approval**

The conduct of this research project in Australia has been approved by the National Institute of Integrative Medicine (NIIM) human research ethics committee (HREC) (see [www.niim.com.au](http://www.niim.com.au)). If you have any queries or complaints about the way you have been treated or your rights as a participant, you may contact the NIIM HREC at: [hrec@niim.com.au](mailto:hrec@niim.com.au).