Lumir Mission Study (US)
SUBJECT INFORMATION AND INFORMED CONSENT FORM (USA)

Protocol Title: Lumir Mission Study: US
Protocol #: 2023-257
Sponsor: Cannim USA, LLC

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Key Information About this Research Study

The following is a concise and focused presentation of key information to assist you in understanding why you might or might not want to participate in this research.

You are being asked to be in a research study because you are using medical marijuana for a health complaint and/or to improve your wellbeing. Your participation is voluntary. The purpose of the study is to understand the characteristics of medical marijuana products which are more effective for a range of medical conditions as well as to understand if medical marijuana use is associated with improvements in symptoms over time in a range of medical conditions. You may participate in this survey-based study for as long as you want. The study is expected to run for four years, beginning in 2024. aa A minimum of one month's participation in the study would be appreciated. The main study procedures area survey which asks you to answer 9 questions about your health via an App on your phone, on a weekly basis, for as long as you choose to stay in the study. No physical risks to you are expected as part of this study. There is no direct benefit to you from taking part in this study. However, the study results may help people in the future. There may be other options for treatment of your condition, including creating a treatment plan with your doctor.

This overview does not include all the information you need to know before deciding whether or not to take part. Much additional detail is given in the full consent document, which can be found on the pages that follow. Be sure to review the rest of this consent form before deciding about participation.

INFORMED CONSENT FORM

This consent form explains the research study. Before you decide to be a part of this study, you need to know why the research is being done, what it will involve and the risks and benefits. Contact the study doctor and study staff to explain anything in this form or if you want more information. Please take time to read this form carefully. Feel free to discuss it with your relatives, friends and your primary care physician. If you agree to take part in this research study, you must sign this consent form.

Disclosure of financial interests
Cannim US LLC , the sponsor of this study, is providing funds for the conduct of this research study**.** Cannim US LLC has a medical marijuana clinic that provides telehealth services focused on medical marijuana.

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 medical marijuana through a range of research activities.

What's the Research Study About?
The purpose of this study is to evaluate which medical cannabis products are most effective in alleviating a range of medical conditions and associated common symptoms, and what characterizes them (i.e. what particular compounds such as terpenes or phytocannabinoids, components of the cannabis plant).

Number of subjects and length of study participation
About 1 million subjects are expected to participate in this study at three research sites in the United States, Australia and the UK, though other research sites may be included in the future. The study will begin in 2024.

There is no fixed time period for which you may participate in the study. At a minimum, it is expected that you participate for at least a month, however, you may participate in the study by logging your monthly data for as long as the study continues (up to four years).

What Am I Required to Do?
In the US you must have a medical marijuana card to access medical marijuana. It is advised that anyone taking medical marijuana seeks advice from a qualified healthcare practitioner (medical practitioner or where states allow it, a nurse practitioner). The Lumir Clinic in the US has doctors and nurses/nurse practitioners who are trained in medical marijuana and can help you find the right medical marijuana products. Please note, you must already be using medical marijuana marijuana for a health issue to participate in this study.

A key component of this study is finding out if medical marijuanamarijuana 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 Mission Journal 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 medical marijuana) and any secondary complaints.

<u>Weekly Survey</u>
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 more questions, one question about whether your use of pharmaceutical medications for your primary complaint has changed, and a question about whether you have experienced any side effects associated with medical marijuana use.

<u>Optional Daily Journal</u>
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.

<u>Sync Your Smart Watch</u>
You may also be able to synchronise your Smart Watch to the App and track your sleep and fitness.

How will the Information I Give Be Used?
Aside from your own use and reports within your personal Lumir Mission Journal App, all data collected is deidentified (your name removed) and added to the anonymous data from other study participants within the US as well as combined with data from other study sites (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 marijuana.

Are There Any Risks Involved in the Research?
There are no physical risks expected from participating in this study. There is the risk of loss of confidentiality of your medical and personal information collected for this study.

New Information
You will be notified in a timely way if important new findings become known that may affect your willingness to continue in the study.

Benefits
There is no expectation that you will benefit from your participation in this study. However, the information learned from this study may help other people in the future by improving the treatment of different medical conditions or symptoms.

Alternatives
Your alternative to being in this study is to not take part.

Costs of participation
There are no costs to participating in this study.

Reimbursement
For each 4 weeks of active participation you will receive a discount coupon (10-15% discount) for use in the Lumir Clinic online store which will be sent to you via the Lumir Mission Journal App. Other incentives also include access to a wellness activity or service provided by a partner organisation. The Lumir Clinic online store can be found at: www.lumirclinic.com/shop/.

Compensation for injury
Because this study involves only the sharing of medical information and requires no specific procedures, tests, or treatments, no research-related injuries are expected. No financial compensation will be offered by the sponsor or Lumir Clinic US or the Biomedical Research Alliance of New York.

Note: You should remain under the care of your medical practitioner or where relevant a nurse/nurse practitioner in relation to your medical marijuana. 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 medical marijuana 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

To the extent allowed by law, every effort will be made to keep your personal information confidential. However, information from this study will be submitted to the study sponsor and to the U.S. Food and Drug Administration (FDA). It may be submitted to governmental agencies in other countries where the study product may be considered for approval. Medical records, which identify you and the consent form signed by you, will be looked at by the sponsor or the sponsor's representatives and may be looked at by the FDA and other regulatory agencies, the Institutional Review Board, and the Biomedical Research Alliance of New York. While these parties are aware of the need to keep your information confidential, total confidentiality cannot be guaranteed. The results of this research project may be presented at meetings or in publications; however, you will not be identified in these presentations and/ or publications.

If you take part in this study, you will be assigned a unique subject code to help protect your privacy. Your study records and data will be labeled with this code that does not directly identify you. The study site staff securely stores the linking code between your name and study information.

AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor (Principal Investigator) must get your authorization (permission) to use or give out any health information that might identify you. If you choose to be in this study, the study doctor (study Principal Investigator) will get personal information about you. This may include information that might identify you. The study doctor may also get information about your health, including:

- Past and present medical records, including records about any consultations at Lumir Clinic US
- Research records
- Records about phone calls made as part of this research
- Billing records if associated with any service provided by Lumir Clinic US

Information about your health may be used and given to others by the study doctor (study Principal Investigator) and staff. They might see the research information during and after the study. Your information may be given to the sponsor of this research. "Sponsor" includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor. Information about you and your health which might identify you may be given to:

- The U.S. Food and Drug Administration
- Department of Health and Human Services agencies
- Governmental agencies in other countries
- Biomedical Research Alliance of New York (BRANY)
- The Institutional Review Board
- Accrediting agencies
- Data safety monitoring boards
- Health insurers and payers

Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the U.S. federal privacy laws. However, these groups are committed to keeping your personal health information confidential. If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others without your permission.

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how

the study is done, and they will be reviewing your information for this purpose. The information may be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the sponsor can receive marketing approval for new products resulting from this research. The information may also be used to meet the reporting requirements of governmental agencies.

This authorization does not have an expiration date. If you do not withdraw this authorization in writing, it will remain in effect indefinitely.

By indicating consent to participate in this study via the study App (Lumir Mission Journal App) by clicking the response that you agree to participate , you are giving permission to use and give out the health information listed above for the purposes described above. You do not have to sign this consent form. If you choose not to give consent to participate in the study via the study App, you will not be able to be in this research study. Your decision not to consent to agree to participate in this study will not have any effect on your medical care and you will not lose any benefits or legal rights to which you are entitled. You have the right to review and copy your health information which is contained within the study App (Lumir Mission Journal App).

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor (Principal Investigator) at the address on the front of this informed consent form. If you withdraw your permission, you will not be able to continue being in this study, but you will not have any penalty or loss of access to treatment or other benefits to which you are entitled. When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Who is Conducting the Study?
This study is sponsored by Cannim Group Pty Ltd, a medical marijuana company based in Australia, with business interests in the US, UK, Canada, Jamaica and Germany.

The following people are involved in the study:

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

Contacts for questions, complaints, concerns
If you have any questions or requests for information relating to this research study or your participation in it, or if you want to voice a complaint or concern about this research, or if you have a study related injury, you may contact Adam Abodeely, MD, FACS, FASCRS at 518-354-1978.

If you seek emergency care or hospitalization, tell the treating health care providers that you are in

this research study.

If you have any questions about your rights as a research subject or complaints regarding this research study, or you are unable to reach the research staff, you may contact a person independent of the research team at the Biomedical Research Alliance of New York Institutional Review Board at 516-318-6877. Questions, concerns or complaints about research can also be registered with the Biomedical Research Alliance of New York Institutional Review Board at www.branyirb.com/concerns-about-research. The IRB is a committee that reviews research studies to help protect the rights and welfare of study subjects.