

# PARTICIPANT INFORMATION STATEMENT



## QUality-of-life, Evaluation STUDY



CHIEF INVESTIGATOR: **A/Prof Richard Norman**

PROJECT MANAGER: **Dr Karl Gruber**

PROJECT TITLE: **The Global QUEST Initiative**

## 1) What is this study about?

Chronic disease, defined as a long lasting condition with persistent effects, is a widespread health issue globally. The social and economic consequences of chronic disease can impact on peoples' quality of life.

This study will examine the type and cost of health services used by people with chronic disease using medicinal cannabis, and collect patient-reported information about their quality of life.

You are invited to participate in this study because you are being prescribed medical cannabis. This Participant Information Statement tells you about the research study to help you decide if you want to take part. Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about.

## 2) Who can take part in the study?

### You **CAN** take part in the study if:

- you are an adult (aged  $\geq 18$  years)
- you are able to read and understand English
- you are able to provide informed consent
- you have a life-expectancy of more than 3 months
- you have been identified as eligible to receive medicinal cannabis by a TGA approved Authorised Prescriber, or doctor using the Special Access Scheme (SAS-B) (or equivalent in other countries and jurisdictions) and your prescribing doctor has TGA approval to prescribe Little Green Pharma products.
- you have:
  - **not** received any prescribed medicinal cannabis therapy in the previous 4 weeks
  - or**
  - you have only started prescribed Little Green Pharma medicinal cannabis **within the previous 2 days** (and not received any prescribed medicinal cannabis therapy in the previous 4 weeks)

### You **CANNOT** take part in the study if you:

- are unconscious, confused or have difficulty with attention, memory, or problem solving
- are pregnant or breastfeeding
- are unable to speak, read and/or write in English
- are denied access to medicinal cannabis under the relevant Special Access Scheme in your country
- are unable to provide informed consent
- are currently receiving prescribed medicinal cannabis treatment for more than 2 days
- have received prescription medicinal cannabis within the last 4 weeks (excluding previous 2 days)

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## 3) What will the study involve for me?

Your doctor will identify if the study is suitable for you and ask if you would like an invitation by email to participate. If so, they will enter some basic information about you into the study register. This includes your age, sex, health condition, and which medicinal cannabis product you are receiving. We will not collect key personal data such as your name, physical address, or birth date.

You will be sent a link via email to join the study. When you open the link you will be asked if you consent to taking part.

**Participation in this study is voluntary:** by giving your consent to take part in this study you are telling us that you:

- Understand what you have read.
- Agree to take part in the research study as outlined below.
- Agree to the use of your personal information as described.

If you decide you do not want to take part, select 'opt-out' and your email address will be removed from the study. If you do not open the link, two reminders will be sent to you, after which you will be automatically 'opted-out' and your email address will be removed from the study.

If you do wish to take part in the study, select 'yes'. After selecting 'yes' you can proceed to the first questionnaire. You will then receive emails to complete follow-up questionnaires when they are due.

The online questionnaire pack starts with some general information about you. For example, this information includes your living arrangements, whether you are employed, and what other medications you may be taking. This information is for research purposes only and will not be shared with your doctor.

You will then be asked about your quality of life and symptoms. Completing questionnaires involves choosing an answer to a set of questions on your own, in English without help or suggestions from others. An example of a question that you might be asked is:

**During the past week:**

(select the number response that best applies to you)

Not at all

A little

Quite a bit

Very much

**Have you had trouble sleeping?**

Your completed questionnaire will be used only by researchers involved in the project and will be stored securely on the Curtin University (Perth) servers.

We will also ask you to sign a consent form to allow us to request release of information about your use of the Medicare and Pharmaceutical Benefits Schemes (MBS and PBS). This will enable the study team to examine and compare the health service costs of people using medicinal cannabis.

## 4) How much of my time will the study take?

Questionnaires will take approximately 20-25 minutes to complete. You will be asked to complete questionnaires at these times:

- When you join the study
- 2 weeks and one month after starting medicinal cannabis therapy
- Three-monthly for the rest of the first year
- Six-monthly until the end of the study (2026)

## 5) Can I withdraw from the study once I've started?

If you decide to take part in the study and then change your mind later, you can withdraw at any time by contacting the doctor who prescribed medicinal cannabis.

Your responses to the questionnaires can be removed from the study before the data has been analysed. After analysis your response cannot be removed and will be included in the study.

Being in this study is completely voluntary and you do not have to take part. Your decision whether to participate will not affect your current or future relationship with the researchers or anyone else at Curtin University, and it will not affect your current or future treatment at the clinic you are having treatment or relationships with your doctor or treating team.

If you withdraw from the study, you may no longer receive the study participant discount on the cost of your medicinal cannabis prescription.

## 6) Are there any risks or costs associated with being in the study?

Aside from giving up your time, we do not expect there will be any risks or costs associated with taking part in this study. However, reflecting on your health when completing the questionnaires may cause emotional distress for some people. You may contact the researchers who will ask if you would like to withdraw from the study, and will suggest contacting your doctor or a helpline service where appropriate, such as Lifeline (13 11 14) or Beyond Blue (1300 22 4636) which provide immediate advice and support 24/7.

## 7) Are there any benefits associated with being in the study?

Little Green Pharma have agreed to standardise the cost of their products across Australia so that all patients taking part in this study will be charged the same rate. The cost of medicinal cannabis products for participants will be \$110 per unit of flower, \$105 per cartridge or from \$125 per unit of oil (excluding the high CBD medication which is from \$175 to \$195 depending on the amount of active ingredient). This pricing includes home delivery. Medication on average can last between four to six weeks (depending on the amount you have been prescribed), with an average annual cost of approximately \$1500. If you withdraw from the study, you may not receive your medicinal cannabis at the subsidised cost.

## 8) What will happen to information about me that is collected during the study?

By providing your consent, you agree to us collecting personal information about you for the purposes of this study. Personal and health information may include your age, health conditions, and the treatments that you have received. Your information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise.

Any information obtained for the purpose of this study that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law. Study findings may be published, but no individual participant will be identified in these publications. We will inform you of the project findings when results are published.

All study information will be collected using a secure web application (REDCap - Research Electronic Data Capture). All study data will be stored on a secure, password-protected server at Curtin University. Data will be archived and finally destroyed according to the archiving rules of the University and Health Department Guidelines.

We intend to give the information from this project to other researchers so that they can use it in their projects. Before we do so, we will take out all the identifying information so that the people we give it to won't know whose information it is. They won't know that you participated in the project and they won't be able to link you to any of the information you provided.

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## 9) Can I tell other people about the study?

Yes, you are welcome to tell other people about the study.

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## 10) What if I would like further information about the study?

If you would like more information about the study, please contact [info@thequestinitiative.com.au](mailto:info@thequestinitiative.com.au) or phone 1300 664 369.

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## 11) Who is funding the study?

Little Green Pharma is supplying medicinal cannabis at a standardised cost for study participants and has contracted the Centre of Clinical Research and Education at Curtin University to conduct the study.

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## 12) What if I have a complaint or any concerns about the study?

Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by Curtin University HRE2022-0085. As part of this process, we have agreed to carry out the study according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect people who agree to take part in research studies.

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the university using the details below. Please quote the study title and protocol number.

Should you wish to discuss the study with someone not directly involved, in particular, any matters concerning the conduct of the study or your rights as a participant, or if you wish to make a confidential complaint, you may contact the Ethics Officer on (08) 9266 9223 or the Manager, Research Integrity on (08) 9266 7093 or email [hrec@curtin.edu.au](mailto:hrec@curtin.edu.au).