PARTICIPANT INFORMATION AND CONSENT FORM

Cannabinoid Medicine Observational Study (CMOS): Observation of cannabinoid prescribing and dosage patterns in Australian clinical practice

1. Introduction

You are invited to participate in the CMOS Study. This study involves collection of information about your medicinal cannabis treatment. This study seeks to collect information about your medicinal cannabis treatment from your treating doctor, but also from you. If you agree to participate in the CMOS study, you will be contacted by a member of the ACR research team and provided links to online questionnaires that will ask about your health status, any side effects and how much medication you are taking.

The study also involves collection of your personal information. We require your consent to collect personal information about you. Please read this consent form carefully and ask your doctor any questions you might have. When you are happy to give your consent, please sign the form where indicated below or provide your consent online using the REDCap link provided to you.

2. Applied Cannabis Research Privacy Policy

Applied Cannabis Research (ACR) collects information from you for the primary purposes of research and teaching aimed at improving the quality of health care provided in relation to medicinal cannabis.

We aim to collect and analyse your personal details and details of your medical treatment at _____ Clinic so that we may better understand the effectiveness of different medicinal cannabis preparations to treat disease.

All data we collect about you will be grouped and de-identified for reporting and analysis so that you will not be identified nor will you be able to be identified outside the study team. We will use the information you provide in the following ways:

- Grouped, de-identified data will be disclosed to other doctors in the practice for the purpose of patient care and teaching.
- Disclosure for research and quality assurance activities to improve community health care and practice management, all information in these instances is de-identified.
- Disclosure to determine pharmaceutical quality and prescribing patterns in relation to disease therapy.
- Conducting analysis specific to certain medicinal cannabis products or indications for the purposes of research and development

Research data will be collected using Research Electronic Data Capture (REDCap). Your data will be stored on a local cloud server (located in Sydney, Australia) hosted by Amazon Web Services. Data will be transmitted, stored, and analysed locally in Australia. Only investigators and ACR research staff with permitted access to REDCap will be able to see your patient-reported data.
Any export of your data for analysis purposes will be done in a way that removes any identifying information (i.e. Name, Date of Birth) so that your data will only be associated with a study ID number with nothing identifying attached. This ensures your data is kept private and confidential and removes the risk of your data being identified.

3. What data will we collect within the study and what is expected from me?

We will collect two types of data within this study.

1. <u>We will collect information about your medical treatment that is provided by your treating doctor.</u> This information is related to your treatment with medicinal cannabis and your medical history. It also includes information about any adverse events that you may report to your doctor during your medicinal cannabis treatment. Your doctor will provide this information to ACR in the form of online questionnaires; once at your enrolment into the study (where they will provide your diagnosis, details of other medications you take, your contact information as you have provided to them) and then every 3 months that you are still enrolled (specifically about any adverse events you have experienced whilst taking medicinal cannabis).

2. <u>We will collect information directly from you about your medicinal cannabis treatment.</u> As part of this research study, members of the ACR research team will contact you at regular intervals (see Table 1 below) to ask about your progress. You will be asked to complete online surveys. These will include questions about what dose you are taking, any side effects you may have experienced, how you are feeling and changes to other medications.

A member of the ACR research team will email you a link to an online survey to complete each month. They will also follow up with you by phone or email if you have any issues with completing these surveys or to remind you if you have not completed them. They will contact you (in one form or another, i.e. phone, SMS, email) a maximum of 3 times per month if required to provide reminders or assist you in completing the surveys.

If you have any concerns about your ability to complete these questionnaires please discuss this with your treating doctor. You are able to ask someone to assist you in completion of these questionnaires (i.e. a friend, family member or caregiver). Alternatively, you will be provided the option to complete these over the phone with a member of the ACR research team if you prefer and if this may help with any literacy concerns you may have.

Table 1: Study data collection schedule

CMOS Data collection/Month	**Baseline**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
Clinician Baseline Enrolment form and **informed consent (PICF)** completed	X												
Prescription of cannabinoid medicine[$] [$] Regularity of prescription and prescription length may vary by clinician	X												
Participant study progress questionnaire (includes PROMIS29, PGIC, MARS and PSQI/BPI/HADS plus AE/dosing) *Month 3 and 12 include TSQM	X	X		X*			X			X			X*
Participant dosing and safety questionnaire (includes PGIC, AE/dosing)			X		X	X		X	X		X	X	

There are two different surveys that you will be asked to complete:

- **<u>Study progress questionnaire</u>**

This survey will take 5-15 minutes to complete online. You will be asked to complete this survey every 3 months.

It asks you about any side effects of your treatment, what dose of medicinal cannabis you are taking, how adherent you are to your medication and some questions about your current health status using Patient-Reported Outcome Measures (PROMs). PROMs are used in clinical research to monitor a participant's response to treatment. We are using several validated PROMs within the progress survey to keep track of your treatment response. These include the PROMIS29 and the PGIC.

- **<u>Dosing and safety questionnaire</u>**

This survey will take 2-6 minutes to complete online. You will be asked to complete this on the alternating months when you do not complete the more comprehensive "Study Progress questionnaire".

It asks you about any side effects of your treatment, what dose of medicinal cannabis you are taking and changes to any other medications you may be taking (i.e. opioids, if applicable). This short survey will be asked of you monthly whenever you are not completing the complete study progress questionnaire.

We will also be asking about your treatment satisfaction with regards to medicinal cannabis at two time points during the study, 3 and 12 months after starting medicinal cannabis treatment. This will be asked in the form of the Treatment Satisfaction Questionnaire for Medication (TSQM).

Additionally, if you are accessing medicinal cannabis treatment to manage certain conditions there may be an additional questionnaire that you are asked to complete every 3 months alongside the "Study progress questionnaire". This depends on your underlying medical condition and symptoms.

If you are accessing medicinal cannabis for treatment of a **sleep disorder or sleep problems** you will be asked to complete the Pittsburgh Sleep Quality Index (PSQI) at the same time as you complete the study progress questionnaire. The PSQI is used routinely in clinical research to evaluate changes to a participants sleep, including as a result of treatment. This survey takes 5-10 min to complete.

If you are accessing medicinal cannabis for treatment of a **pain condition** you will be asked to complete the Brief Pain Inventory (BPI) at the same time as you complete the study progress questionnaire. The BPI short form is used to assess severity of pain and its impact on functioning and is widely used in clinical and research settings to monitor changes. This survey takes 5 min to complete.

If you are accessing medicinal cannabis for treatment of **anxiety or depression** you will be asked to complete the Hospital Anxiety and Depression Scale (HADS) at the same time you complete the study progress questionnaire. The HADS is a brief measure used to identify and quantify depression and anxiety symptoms. This survey takes 2-5 min to complete.

Participants with poor literacy may require additional time to complete these questionnaires, although we have tried to account for this in the time ranges provided above. Participants that may require assistance do have the option of asking someone to assist them with survey completion and there is the option to have this person enter their details in the survey.

As part of this research project a member of the ACR research team may call you to follow up about survey completion or to assist you in completing the survey over the phone if you prefer or do not have access to the internet. An ACR researcher may contact you by phone or email to remind you to complete your questionnaires if they are not completed.

All study data collected about you during this study will be stored in REDCap, (Research Electronic Data Capture system), which is a web-based secure database software used for clinical and translational research data collection. The specific data collected for this study will be stored on a local (Sydney, Australia) cloud server with appropriate security measures in place to protect your data. The REDCap system is used in many clinical trials and allows for secure, restricted access to only relevant study investigators. It also meets all relevant compliance requirements for clinical trial data collection.

4. What if I do not want to be in the study or wish to withdraw from the study?

There is no requirement for you to participate in the CMOS study in order to receive medicinal cannabis treatment from your doctor, and there is no penalty for not participating. The study is

optional. The goal of this study is to collect much needed research data that can be used to evaluate medicinal cannabis in a real-world setting. It is your choice to participate in this research effort.

You may withdraw your participation from the study at any time. There is no penalty for doing so. There is the possibility that some medicinal cannabis products available within the study may be subsidised in price for study participants. If this is the case, then withdrawal from the study could financially disadvantage you should you be prescribed one of these subsidised products.

You should know that the information collected about you prior to your withdrawal will be used in the study analyses. This is because we will be conducting regular analysis and reports that are fed back to participating doctors. Therefore, we will not be able to retrospectively remove your data from these reports. Any reporting of your data from the study will not allow for you to be identified in any way.

5. How is the study funded and who is conducting the study?

Applied Cannabis Research is funding this study with support from industry, which includes Australian licensed medicinal cannabis producers and suppliers that have an interest in research.

The study is conducted by Applied Cannabis Research, which is a contract research organisation that specialises in studies of medicinal cannabis products. We work with industry and also clinical collaborators from universities and hospitals. Dr John Barlow is the principal investigator of this study. This study also requires the participation of your treating doctor, who has agreed to take part in the study.

If you have any questions about the study you may discuss these with your treating doctor, or you may contact the Study lead, Dr Melissa Benson at (02) 8294 6406, or email the study team at cmos@appliedcannabisresearch.com.au.

6. Declaration

By signing below, I give permission for ACR to be given access to information concerning my relevant medical history and details of medicinal cannabis that I have been prescribed for the sole purpose of study monitoring, compliance or study conduct. ACR is at liberty to discuss this information with my relevant healthcare professional/s to clarify and confirm study eligibility, progress and enrolment status.

I understand that such information will remain confidential.

By signing below (Section 7 or 8), I hereby confirm that:

- I am 18 years of age or older.
- I have read and understood all information contained in this consent form.
- I have had sufficient opportunity to raise any questions I have concerning the study.
- I have had sufficient opportunity to discuss my participation with family, friends or another doctor.

- I am providing consent for any information relating to my medical condition and the medicinal cannabis prescribed to me to be discussed by ACR in relation to study analysis and publications only, and in a format in which I am not able to be identified.

7. Participant Signature

Participant Name: _____

Participant Signature: _____ Date (dd/mm/yyyy): _____

8. Participant Signature - Substitute Decision Maker

In the instance that you are not able physically to provide a signature, then a substitute Decision Maker (DM) can be used. If you have signed the above declaration, then you can ignore this section. The signature of a DM below indicates that the participant has agreed to the above declaration.

DM Name: _____ DM Relation: _____

DM Signature: _____ Date (dd/mm/yyyy): _____

Source of decision-making authority (tick one):

- ❑ Participants own consent
- ❑ Tribunal-appointed guardian
- ❑ Attorney/s for health matters under Enduring Power of Attorney or Advice Health Directive
- ❑ Statutory Health Attorney
- ❑ If none of the above, the Adult Guardian has provided consent