

Patient Combined Consent Form

1. Patient Details

First Name: _____ **Surname:** _____
Address: _____ **Suburb:** _____ **Postcode:** _____
D.O.B ___/___/____ (DD/MM/YYYY)
Gender: Male Female Other (Please Specify) _____

Medicare Number: ____/____/____ **IRN (# Next to Name):** _
Medicare Expiry Date: __/____

Are you of Aboriginal or Torres Strait Islander origin? Yes No

Employment Status:

Full-Time Employment Part-Time Employment Self-Employed
 Unemployed Retired Full-Time Student
 Part-Time Student Other (Please Specify) _____

Are you an Australian Veteran? Yes No

Entitlement: Gold White Orange **Card Number:** _____ **Expiry:** __/____

Is English your native language?: Yes No

If no, will you require the use of a certified translator for you consultations?: Yes No N/A

Have you ever been advised or told by a doctor or medical professional not to take cannabis or medicinal cannabis? Yes No

Do you currently experience, or have a history of, any of the following potential contraindications for THC (please note CBD may still be suitable)?

A history of, or currently active psychosis <input type="checkbox"/>	A history of, or currently active Bipolar disorder <input type="checkbox"/>	An active mood disorder or severe anxiety disorder <input type="checkbox"/>
Severe and unstable cardio-pulmonary disease <input type="checkbox"/>	Women who are pregnant, planning to become pregnant or breastfeeding <input type="checkbox"/>	A current or past history of drug dependence or substance abuse <input type="checkbox"/>

2. Emergency Contact

First Name: _____ **Surname:** _____
Address: _____ **Suburb:** _____ **Postcode:** _____
Relationship: _____ **Contact No.** _____

3. Purpose of this Document

This patient consent form has been created to ensure any potential patients are aware of currently available relevant information pertaining to medicinal cannabis, as prescribed by Cannabis Access Clinics.

For a potential patient to give informed consent they must be aware of the following;

- The majority of medicinal cannabis products are currently unregistered in Australia.
- The quality, safety and efficacy has not been fully assessed by the Therapeutic Goods Administration (TGA).
- The possible benefits of treatment and any risks/side effects.
- The possibility of unknown risks and side effects.
- Alternative treatments that may be available which are currently registered with TGA.
- The implications of taking medicinal cannabis and the effects this may have on operating heavy machinery and driving.

Please read this consent form carefully. If you have any questions then please don't hesitate to raise them with Cannabis Access Clinics. The taking of medicinal cannabis is voluntary. Your decision on whether to take medicinal cannabis will not affect any future care you may receive. Before making this decision you may wish to discuss with a relative, friend or local doctor.

If you decide you do wish to proceed with an initial consultation with a Cannabis Access Clinics doctor then you will be asked to sign this consent form.

4. About Cannabis Access Clinics

Cannabis Access Clinics focuses on helping patients with chronic conditions who may benefit from medicinal cannabis. We have a network of General Practitioners (GPs) and specialists around Australia who diagnose and prescribe according to Australian TGA and State regulations.

Cannabis Access Clinics is an independent clinic and does not have any exclusivity or preferential deals with a specific supplier or sponsor of medicinal cannabis. Our GPs and specialists are free to prescribe medications of their own choosing, without influence.

5. Timeline

While Cannabis Access Clinics strives to process applications as quickly as possible, medicinal cannabis is a relatively new therapy and it can take several weeks from submission of a Special Access Scheme B (SAS B) pathway until a decision is made regarding an application by the Therapeutic Goods Administration (TGA) and the relevant state authorities.

6. Are Medicinal Cannabis Products 'Approved' For Use in Australia?

When an individual refers to an 'approved' medicine they are generally referring to whether or not a medicine is registered on the Australia Register of Therapeutic Goods (ARTG). All medicines which are to be lawfully supplied in Australia must be registered on the ARTG unless they have special exemption. The majority of medicinal cannabis products are not registered on the ARTG and must be accessed via special access schemes such as Special Access Scheme B (SAS B).

At present only one medicinal cannabis product is currently registered with the TGA. This product is Nabiximols which is also known under the trade name of Sativex. Nabiximols is currently recommended by the TGA for use in the treatment of muscle spasticity associated with Multiple Sclerosis (MS) only. There is limited available evidence for the efficacy of Nabiximols in treating other conditions.

Medicinal cannabis products which are not currently registered on the ARTG have still been reviewed by the Australian Therapeutic Goods Administration (TGA) to ensure it meets the required quality standards. It is to be noted that TGA has not fully assessed the products safety, quality and efficacy.

7. Risk Factors & Side Effects

As with any medication, medicinal cannabis products can have side effects. I understand that there may be risks associated with the use of medicinal cannabis treatment and I am aware that:

1. I may experience side effects including, but not limited to, fatigue and sedation, vertigo, nausea and vomiting, fever, increased/decreased appetite, dry mouth, diarrhea, convulsions, a feeling of euphoria (intense happiness) or depression, confusion, hallucinations or paranoid delusions and psychosis or cognitive distortions (having untrue thoughts).
2. There is very limited evidence available about how medicinal cannabis reacts with other medications.
3. There may be adverse effects of long term use and that those effects remain unclear. I am aware that the adverse effects reported in long term recreational users, include the development of dependence.
4. Patients using any medicinal cannabis products should seek their doctor's advice before driving or operate machinery due to the risk of experiencing drowsiness. While drowsiness is not a known side of CBD alone, it may occur if CBD interacts with other medications. Some medicinal cannabis products may also include THC, in which case there is a strict ban on drive and operative machinery. Measurable concentrations of THC can be detected in urine for many days after the last dose. It may take up to five days for 80 to 90 percent of the dose to be excreted. Drug-driving is a criminal offence.
5. Please note elderly patients may be more prone to develop some Central Nervous System (CNS) adverse reactions with use of some products, so care should be taken in terms of personal safety.

6. In the event a patient does experience an unintended side effect then this should be reported as soon as is reasonably possible to Cannabis Access Clinics using the contact details at the bottom of this document.

8. Possession & Transport

It is an offence under the Drugs Misuse Act to administer and possess an illegally produced cannabis-based product, which has not been approved for use.

Before transporting medicinal cannabis across state or international borders, patients should enquire with the relevant authorities regarding the legality of this.

9. Contraindications for THC based products

A contraindication is any condition, factor or reason which may result in a medication being withheld due to the potential harm it may cause to a patient. Medicinal cannabis may not be suitable for people with;

1. A history of, or currently active psychosis
2. A history of, or currently active Bipolar disorder
3. An active mood disorder or severe anxiety disorder
4. Severe and unstable cardio-pulmonary disease
5. Women who are pregnant, planning to become pregnant or breastfeeding
6. A current or past history of drug dependence or substance abuse

The decision of whether to make an application for medicinal cannabis is decided on a patient by patient basis. The presence of risk factors such as severe disease or mental health issues may increase the likelihood that an application is not made. These risk factors will be discussed with a Cannabis Access Clinics doctor and do not apply to all product options.

10. Monitoring

Once a patient has been started on their medicinal cannabis prescription, regular monitoring by a CA Clinics doctor is required. The frequency of these monitoring sessions is at the discretion of the prescribing doctor and may vary from patient to patient depending on clinical requirements. During the first 3 months of your medicinal cannabis trial, you will partake in a minimum of 3 monitoring sessions.

In the instance of a severe reaction or side effect to medicinal cannabis, patients should seek immediate medical care at their nearest medical centre. Should patients experience any side effects (positive or negative) then these should be reported to Cannabis Access Clinics.

11. Privacy Policy

We require your consent to collect personal information about you. Please read this consent form carefully and sign where indicated below.

Cannabis Access Clinics collects information from you for the primary purpose of providing quality health care.

We require you to provide us with your personal details and a full medical history so that we may properly assess, diagnose, treat and be proactive in your healthcare needs. This means we will use the information you provide us in the following ways:

1. Administrative purposes in running our medical practice.
2. Billing purposes including compliance with Medicare
3. Disclosure to others involved in your healthcare including treating doctors and specialists outside this medical practice.
4. Disclosure to other doctors in the practice, locums etc. attached to the practice for the purpose of patient care and teaching.
5. Disclosure for research and quality assurance activities to improve individual and community health care and practice management, all information in these instances is un-identified.
6. We require your consent to collect personal information about you

12. PRODUCT CONSENT

My doctor has proposed using a cannabis-based product to help improve my health profile. I understand:

1. that this product is not registered for use in Australia and that the quality, safety and efficacy of the product (s) is not fully known
2. that the treatment is not guaranteed to work, as the scientific evidence of its effectiveness is limited
3. that I will be starting it as a trial, which we will stop or vary if there is not a significant benefit
4. that it may have some side effects, which my doctor and I have discussed, including include fatigue and sedation, vertigo, nausea and vomiting, fever, decreased or increased appetite, dry mouth, and diarrhoea.
5. using cannabis-based products in combination with alcohol is not recommended
6. that it may or may not lead to a reduction in some of my other medications
7. that the Therapeutic Goods Administration be notified of reasons for discontinuation should this occur
8. that patients should not drive or operate machinery while being treated with medicinal cannabis. **Drug-driving is a criminal offence, and patients should discuss the implications for safe and legal driving with their doctor. In addition measurable concentrations of THC (tetrahydrocannabinol – the main psychoactive substance in cannabis) can be detected in urine many days after the last dose. It may take up to five days for 80 to 90 percent of the dose to be excreted. In some states patients can lawfully drive whilst taking cannabidiol-only medicines, as long as they are not impaired. Please check the state specific legislation for information on safe and legal driving.**
9. that my Cannabis Access Clinics doctor is required to monitor my progress at least 3 times in the first three months from my initial prescription, then ongoing thereafter. The purpose of this is to monitoring is both the positive and negative effects of the medicinal cannabis, ensure patient safety and confirm efficacy.
10. that I need to advise my Cannabis Access Clinics of any future healthcare providers and that I should also make them aware that I am taking medicinal cannabis.

13. Declaration

By signing below (Section 14 or 15) I give permission for the Cannabis Access Clinics to freely discuss and request information concerning my medical history with my relevant healthcare professionals, hospitals or laboratories and other regulatory federal and state authorities for the purposes of Special Access Scheme and Department of health approvals. I understand that such information will remain confidential.

By signing below (Section 14 or 15) I hereby confirm that I have;

- Read & understood all information contained in this consent form.
- Had sufficient opportunity to raise and questions I have relating to medicinal cannabis.
- Freely agreed to use medicinal cannabis as an unapproved/unregistered product and am aware of the risks this may involve
- Understood that I am free to stop taking medicinal cannabis at any time.
- Provided consent for any information pertaining to my medical condition and personal information to be requested and freely discussed by Cannabis Access Clinic with relevant health care professionals.
- Understood that there is no guarantee as to the efficacy of medicinal cannabis, as the scientific evidence of its effectiveness is limited.
- Understood that patients should not drive or operate machinery while being treated with medicinal cannabis, unless legal to do so.
- Understood to take the treatment strictly as recommended and only alter the dose in discussion with my doctor
- Understood to report any beneficial effects and any side-effects at the scheduled follow-up visits the doctor has made for me
- Understood to be honest with the doctor about my full medical and psychiatric history, as well as any history of recreational drug use
- Understood never to share the product with another person
- Understood not to drive or operate machinery while being treated with medicinal cannabis, unless legal to do so under state legislation (It is illegal in all states to drive under the influence of THC).
- Understood (if female) to inform my doctor if I become or are thinking about becoming pregnant or breastfeeding.
- Understood to report any side effects that I may experience to Cannabis Access Clinics as soon as is reasonably possible, using the contact details at the bottom of this document.

14. Patient Signature - please initial all pages.

Patient Name: _____

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

Certified Witness _____ Certified Witness _____
Name: _____ Profession: _____

Certified Witness _____ Date (dd/mm/yyyy): _____
Signature: _____

In Australia, the following people are authorised to certify signatures:

- **Health professions:** Chiropractor, Dentist, Medical practitioner, Nurse, Optometrist, Pharmacist, Physiotherapist, Psychologist¹
- **Legal professions:** Legal practitioner, Patent attorney, Trade marks attorney
- **Court positions:** Bailiff, Justice of the Peace, Judge, Magistrate, Registrar, or Deputy Registrar, Clerk, Master of a court, CEO of a Commonwealth court
- Commissioner for Affidavits, or Commissioner for Declarations (dependent on jurisdictions)
- **Government representatives** (elected): Federal, State or Territory or Local
- **Public servants:** Federal, State or Territory or Local – employed for five years or more.
- Permanent employees of the **Australian Health Practitioner Regulation Agency**
- Bank officer, building society officer, credit union officer, finance company officer – employed for five years or more
- Veterinary surgeon
- Accountant (member of ICA, ASA, IPA or CPA, ATMA, NTAA)
- Minister of religion, or marriage celebrant
- Member of:
 - Chartered Secretaries Australia
 - Engineers Australia, other than at the grade of student
 - Australian Defence Force (an officer; or a non-commissioned officer with 5+ years of continuous service; a warrant officer)
 - Australasian Institute of Mining and Metallurgy
- Notary public
- Holder of a statutory office not specified in another item in this Part
- Police officer
- Sheriff or Sheriff's officer
- Teacher (full-time) at a school or tertiary education institution

Outside Australia, the following people are authorised to certify documents:

- Justice of the Peace
- Notary public
- Australian Consular Officer or Australian Diplomatic Officer (within the meaning of the Consular Fees Act 1955)

- Employee of the Commonwealth or the Australian Trade Commission who works outside Australia.

15. Patient Signature - Substitute Decision Maker

In this instance that your are not able to physically 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 patient has agreed to the above declaration.

DM Name: _____ DM Relation: _____

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

Source of decision making authority (tick one):

- Patients 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

Certified Witness _____ Certified Witness _____
Name: Profession:

Certified Witness _____ Date (dd/mm/yyyy): _____
Signature:

16. Current Specialists

Please list all current medical and specialists practitioners that you are under the care of in the space below. If additional space is required then please complete on a blank sheet and attached to this form.

Practitioner Name: _____

Speciality: _____

Provider Number: _____

Practice Address: _____

Phone: _____ Fax: _____

Approx. Date of Last Consultation: _____

Practitioner Name: _____

Speciality: _____

Provider Number: _____

Practice Address: _____

Phone: _____ Fax: _____

Approx. Date of Last Consultation: _____

Practitioner Name: _____

Speciality: _____

Provider Number: _____

Practice Address: _____

Phone: _____ Fax: _____

Approx. Date of Last Consultation: _____

16. Return Details

Please email completed document to info@caclinics.com.au or fax to +61 294 75 51 58.