



**Participant Information Sheet – General (Extended)**

**Project Title:** International Cannabis for Endometriosis Survey

**Project Summary:**

Researchers from Western Sydney University and the University of New South Wales are interested in investigating how cannabis use affects your endometriosis symptoms. We want to know what varieties (i.e., strains) of cannabis you use, how you take them (e.g., smoked, vaped, eaten or by oil/tincture), the dose you use and cannabinoid levels/concentrations in the products chosen. We also want to know about your other prescribed and non-prescribed medication use, what side effects you may experience and gather evidence on the severity and scope of your endometriosis through two questionnaires.

Our research so far has found that people with endometriosis who live in Australia or New Zealand use cannabis, mostly from non-legal, non-prescribed or recreational sources, to help manage their endometriosis symptoms and reduce their endometriosis-related medication. We want to increase the information on cannabis use for endometriosis, so as to plan a clinical trial to investigate the safety, tolerability and effectiveness for cannabis for pain and associated symptoms of endometriosis. It is very important that we get input from people in the community who have endometriosis so we can be sure that we are designing an appropriate trial. This information will help us better understand the role that cannabis may play in the management of endometriosis symptoms.

The researchers involved with this project are Mr Justin Sinclair (PhD Candidate), Dr Mike Armour (Primary Supervisor), Prof Jerome Sarris, Adj Prof David Pate, all from the NICM Health Research Institute of Western Sydney University, Australia, and Professor Jason Abbott from the University of New South Wales, Australia.

This research project has been approved by the Western Sydney University Ethics Committee (H14115).

**How is the study being paid for?**

This research project has been funded by a Blackmores Institute Scholarship, forming part of Mr Sinclair's PhD degree program.

**What will I be asked to do?**

This survey is open to people worldwide who must fulfil the following:

- You must have been told by your medical doctor that you have endometriosis;
- You must be aged between 18-55; and

You must have used cannabis or cannabinoid-based products (e.g., cannabidiol (CBD) oil, cannabis oils, dried bud (flower) with known levels of THC and/or CBD, or non-legal cannabis), in the past 3 months specifically for the purpose of managing your endometriosis pain or related symptoms.

The survey will ask about your background (such as your age and in which country you live), how your endometriosis was diagnosed, what symptoms you have and how you manage these. Questions about cannabis usage will be based upon the variety (or strain) of cannabis or cannabis product that you have used, the way you use it (known as a dosage form - such as smoked, vaped or oral ingestion), the amount of dose you use and how you rate its effectiveness in managing your symptoms. Other information, such as any side effects that you have experienced, and if known from dispensary or label information, the concentration or levels of cannabinoids such as THC or CBD that was in your cannabis.

Lastly, you will be asked to complete two short questionnaires related to endometriosis (the Endometriosis Health Profile-30) and pelvic pain symptoms (the Pelvic Pain Impact Questionnaire) to allow the research team to compare the severity of endometriosis symptoms to other studies on endometriosis.

#### **How much of my time will I need to give?**

Participation in the study will involve completing an online survey that will take 15-30 minutes. You will be required to complete the survey in one sitting as we do not collect your IP or use cookies. This is to protect your privacy as you may be disclosing illegal activity if you are using cannabis when it is not legal in your area.

#### **What benefits will I, and/or the broader community, receive for participating?**

At this stage there may not be any direct benefits for participating in this survey. However, the information this survey provides will help inform a clinical trial design investigating the safety, tolerability and effectiveness of medicinal cannabis for endometriosis-related symptoms. This information may also be used to direct future research to help improve health outcomes for women with endometriosis.

#### **Will the study involve any risk or discomfort for me? If so, what will be done to rectify it?**

We do not foresee any risk to you from participating in this study, and your answers are completely anonymous. We do not use cookies or collect your IP address. We also do not collect any identifiable information from the demographic questionnaire, nor the quality of life survey, namely the Pelvic Pain Impact Questionnaire or the Endometriosis Health Profile-30. We also recognise that some people feel uncomfortable when talking about matters relating to endometriosis and pelvic pain. Depending on your

location, please contact your local support and advocacy group if you need support or more information (<https://endometriosis.org/support/world-endometriosis-organisations-weo/>)

### **How do you intend to publish or disseminate the results?**

It is intended that the collective results of this study will be published in journal articles, reports, and presented at conferences and other scientific meetings. Reports regarding safety and health effects, using a combination of the information we collect in the survey, may also be provided to specific groups/organisations to help facilitate safe practice. Only the members of the research team will be able to see the individual answers you provide and only in an anonymous manner. Please note that minimum retention period for data collection is five years post publication, but data may be kept for up to 15 years to allow other researchers access to this data.

### **Will the data and information that I have provided be disposed of?**

Please rest assured that only the researchers will have access to the raw data you provide. However, your data may be used in other related projects for an extended period of time, such as helping inform clinical trial design of potential trials on cannabis for endometriosis or pelvic pain.

### **Can I withdraw from the study?**

Participation is entirely voluntary and you are not obliged to be involved. If you do participate, you can stop filling in the survey at any time. Once you have submitted your answers, we cannot remove them as we have no way of identifying your answers due to the anonymous nature of the survey. Whatever your decision, it will not affect your medical treatment or your relationship to anyone involved in this study.

### **Can I tell other people about the study?**

Yes, we encourage you to tell other people about the study by providing them the Qualtrics link. If they would like more information, they can then contact Mr Sinclair to discuss their participation in the research project.

### **What if I require further information?**

Please contact Mr Justin Sinclair should you wish to discuss the research further before deciding whether or not to participate:

Mr Justin Sinclair, Chief Investigator, email [j.sinclair@westernsydney.edu.au](mailto:j.sinclair@westernsydney.edu.au)

**What if I have a complaint?**

If you have any complaints or reservations about the ethical conduct of this research, you may contact the Ethics Committee through Research Engagement, Development and Innovation (REDI) on Tel +61 2 4736 0229 or email [humanethics@westernsydney.edu.au](mailto:humanethics@westernsydney.edu.au).

Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

This study has been approved by the Western Sydney University Human Research Ethics Committee. The Approval number is H14115.