Patient Survey: Therapeutic Use of Cannabis for Inflammatory Bowel Disease

PARTICIPANT INFORMATION STATEMENT

What is this study about?

You are invited to take part in a research study exploring the perspectives on and experiences with the use cannabis for medical reasons in people with inflammatory bowel disease (IBD) in Australia.

You have been invited to take part in this study as you have indicated that you have a diagnosis of IBD. This Participant Information Statement tells you about the study. Knowing what is involved will help you decide if you want to take part. Please read this information carefully and ask questions about anything that you don’t understand or want to know more about.

Participation in this research 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

You will be able to print this Participant Information Statement to keep, if you choose.

Who is running the study?

This study is being conducted by a team of researchers at the Brain and Mind Centre, the University of Sydney, and affiliate specialist clinicians, which includes the following researchers:

- Professor Iain McGregor (Professor of Psychopharmacology)
- Associate Professor Susan Connor (Gastroenterologist & Hepatologist, Head of IBD service at Liverpool Hospital)
- Dr Crispin Corte (Gastroenterologist, Clinical lead of IBD at Royal Prince Alfred Hospital)
- Associate Professor Jonathon Arnold (Associate Professor of Pharmacology)
- Dr Melissa Benson (Clinical Research Fellow, School of Psychology)
- Anastasia Suraev (Research Officer, School of Psychology)
- Sarah Abelev (Research Assistant, School of Psychology)
- Lucy Gold (Masters Student, School of Medical Sciences)

This study is funded by the Lambert Initiative for Cannabinoid Therapeutics, University of Sydney.

What will the study involve for me?

This study is a survey of people with IBD to explore their attitudes towards and/or experiences with using cannabis products as a way to manage their gastrointestinal symptoms.
If you consent to participate in this study, you will be asked to complete an online survey about your IBD symptoms and your perspectives on medical cannabis. The survey covers a range of topics, including:

- your IBD diagnosis and associated symptoms
- your satisfaction with current drug treatment in managing your symptoms
- your perspectives on medical cannabis use in Australia
- your history of cannabis use (for medical reasons), and, if using:
  - how you obtain and use your cannabis products
  - how the cannabis products affect symptoms relating to your IBD
  - your opinion of cannabis’ efficacy and any positive or negative aspects to your use of cannabis
- how you believe medical cannabis should be available in Australia.

4. **How much of my time will the study take?**

The survey will take approximately 20 minutes to complete.

5. **Who can take part in the study?**

Any Australian resident aged 18 years or over with a diagnosis of IBD.

6. **Do I have to be in the study? Can I withdraw from the study once I've started?**

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 the University of Sydney.

If you decide to take part in the study and then change your mind during the survey, you are free to withdraw at any time. You can do this by simply stopping answering survey questions and exiting the browser window.

Submitting your completed questionnaire is an indication of your consent to participate in the study. As the study is completely anonymous and confidential, we have no way of identifying responses, and it will not be possible to remove or withdraw data after a person has submitted the completed survey.

7. **Are there any risks or costs associated with being in the study?**

Aside from giving up your time, we do not expect that there will be any risks or costs as a result of taking part in this study.

However, if any of the questions cause you unease or make you feel uncomfortable, you are encouraged to either discontinue participation in the experiment or skip the particular question/s you do not like. Please do not hesitate to contact the research team (contact details at end) if you have any concerns or distress from questions in the survey.

8. **Are there any benefits associated with being in the study?**

We cannot guarantee that you will receive any direct benefits from being in the study.
The information collected in this study may serve to provide a basis for future research into the benefits of medicinal cannabis that may eventually contribute to changes in its regulatory status. However, we cannot and do not guarantee or promise that any such thing will occur.

9. What will happen to information about me that is collected during the study?

By providing your consent, you are agreeing to us collecting personal information about you for the purposes of this research study, although we ask no identifying details (e.g. we do not ask for your name, address or birthdate).

As part of the study, you will complete a survey which will be hosted by the website, REDCap, a securely encrypted website which makes no claim of ownership of the data you provide. No identifying information will be directly linked to any data you provide (your data is entirely anonymous). Data will be stored on a secure password-protected server and will be kept strictly confidential. Only researchers involved in this study will have access to the data collected.

Your data will be stored for 5 years following the completion of this study, in following with standard ethical requirements for studies of this nature. After this time, all data provided in the survey responses will be permanently and securely deleted and disposed of.

Study findings may be published, but you will not be individually identifiable in these publications.

Your information will only be used for the purposes outlined in this Participant Information Statement.

10. Can I tell other people about the study?

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

11. What if I would like further information about the study?

When you have read this information, Dr Melissa Benson will be available to discuss it with you further and answer any questions or concerns you may have. If you would like to know more at any stage during the study, please feel free to contact:

Dr Melissa Benson on melissa.benson@sydney.edu.au or telephone +61 2 9114 4027

12. Will I be told the results of the study?

A summary of the study findings will be posted on University Sydney website (Lambert Initiative).

As the study is anonymous and confidential, we have no way of sending information to you directly.

13. What should I do if I am interested in participating in future clinical trials of medical cannabis for the treatment of IBD?

If you are interested in taking part in future clinical trials of medical cannabis for IBD, you can click the link at the end of the survey which will take you to a separate website. Here, you will be asked to provide consent for a researcher to contact you in the future about a potential clinical trial using the contact details that you provide.
Your personal contact details will in no way be linked to the main survey (entirely separate website) so it would be impossible to link your personal information to your survey data.

14. 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 the HREC of the University of Sydney (2018/989). 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 outlined below. Please quote the study title and protocol number.

The Manager, Ethics Administration, University of Sydney:

- Telephone: +61 2 8627 8176
- Email: ro.humanethics@sydney.edu.au
- Fax: +61 2 8627 8177 (Facsimile)

Please print and keep a copy of this information sheet.