

Patient Participant Information Sheet (PIS)

v1.2 [14th October 2019]

Thank you for considering taking part in this medical research.

What's involved?

You will need to be linked up with your local doctor to take part in this research. We need people of all ages over 15 years, with normal mental health and also people with mental health conditions in this study. If you are 15-18 years of age you can take part but will need the consent of a parent or legal guardian.

As a result of entering your data on the website, you will be taking part in an ethically accredited mental health research PILOT that is being conducted in collaboration with doctors and mental health specialists across Australia. This research does not diagnose or treat a mental health condition, so please join in the research if you are well, already have a diagnosis and are stable or have some symptoms. On the other hand, do not delay seeking medical advice if you are very unwell.

The aim of this research is to validate evidence that has already been discovered in a limited sector of the Australian population. This evidence has identified markers in blood and urine, that can assist doctors to know for certain who has a mental health condition and who does not. Obviously, these results have great potential to assist everyone. So, we are now asking helpful people across Australia to participate in this research in order to prove that these markers (called "biomarkers") hold true to their performance across the wider, Australian population.

At this stage, this research does not diagnose or treat a mental health condition, however if you would like to participate in a future treatment trial, please notify this intention to your doctor and record this during your registration on the website.

Whatever your age or state of mental health, you will need to answer a brief set of questions for us to find out whether your entering this study is in your best interests or whether you meet study criteria. You will be advised about this by your GP. If you do not meet these criteria, your GP will address your health concerns and care for you as usual.

If you wish to participate in this research, you will need to:

1. Read the **Terms and Conditions** of research participation and agree to these.
2. Be assigned an **identity number** that will enable you to be recognised by your GP and will also accompany any information you give us, so that you cannot be personally identified. This identity number and your password must be kept safe and secure and can be used to make contact with your doctor or nurse to assist you in completing the research.
3. Sign the provided **Patient Consent Form** to give your consent to participate. As part of this consent, you will also be giving consent for your local GP or nurse or a health professional at the GP's practice to contact you or assist you in this study, as you require it.

Initial Procedure

Your doctor will run through a short, half-hour **guided online assessment**, during which he/she will:

- ask you a few more questions about your lifestyle and thoughts.
- undertake a short clinical examination that determines your weight height, blood pressure, muscle strength and vision.
- give you some pots to collect a urine specimen and stool specimen at home.
These will need to be collected by you on the day before you attend your local laboratory for a blood sample (your doctor will give you a laboratory request form for these tests and instructions about how to do this).

You will be required to log in to the website and answer a series of questions that are streamlined and take about half an hour to complete. You can do these in portions if you like and save results in between. Some of the questions will ask you to tell us about your personality and you can request a personality profile at the end of the assessment.

You will also be required to complete a half-hour series of online vision and hearing sensory tests designed to test your brain's visual and auditory performance.

Additional Requirements

Attending the laboratory for tests

You should plan to:

- collect your stool sample the day before your blood sample is due
- collect a urine sample after fasting overnight on the morning your blood sample is due.

It will be necessary for you to label your specimen pots accurately and put kitchen foil around the outside of the urine pot. (You will be given written instructions about this by your doctor).

At the laboratory you will hand in your urine and stool samples and the laboratory technician will collect a blood sample from you (taken by venepuncture in the usual way) that should cause only cause minimal discomfort.

You may also be required to provide a saliva sample.

Follow-up with your GP

If you already have a mental health diagnosis, you need to continue to see your regular caring health professional for continuing care, but you will not require further assessment as part of this research.

If your symptoms indicate that you don't have a mental disorder, but may be at risk of one, you will need to continue to see your doctor or a specialist regularly for anything up to two years, until you are well, or the meaning of your symptoms becomes clear and a diagnosis is reached.

If you wish, you can sign to take part in a later treatment trial research project to determine if probiotics or natural substances will or will not assist your condition. We will contact you when this research becomes available.