Clinician Participant Information Sheet (PIS)

v1.1 [2nd April 2019]

Information for the Clinician

The broad aim of this research project is to use objective (measurable) test results to validate evidence and better inform mental health management.

In addition to standard **questionnaires** and **physical assessments**, these tests take the form of blood, urine and stool **laboratory tests** and hearing and vision **sensory processing tests** so that doctors can tell who has a risk of mental illness and who has resilience against it.

What's involved in taking part in this research?

General Information

In order to take part in this research, participants need to be at least 15 years of age. Patients who are between 15 and 18 years of age will require the consent of a parent or legal guardian to participate.

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.

The online research protocol in this study does not diagnose or treat a mental health condition, though already-diagnosed participants may consent to be contacted to enter a later treatment trial of adjunctive natural bio-chemical cofactor substances that will be tailored to their specific biochemical phenotype.

Specific Information

This research is beginning with a PILOT Study, during which your practice/clinic will be responsible for recruiting 4 participants and 4 age and sex-matched controls in a research design that has two arms:

1. A prospective 2 year follow up of 2 high risk of psychosis persons with 2 controls*.
2. A retrospective once-off assessment of already-diagnosed, relatively-stable persons with some residual symptoms. One with schizophrenia plus control X 1 and one with depression plus control* X 1.

*Selection of asymptomatic controls with no diabetes or mental health condition from your waiting list or other local venue. Matched to age and sex.

Eligibility

Your Eligibility Criteria

You need to:

- be a registered GP or mental health specialist or nurse with an **AHPRA number**.
- have read and agreed to **Terms and Conditions** for the online use of the web.
- have signed a **Clinician Consent Form** for participation.

Your recruited participants' Eligibility Criteria

- > 15 years of age
- read and agreed to the **Terms and Conditions** of the website use.
- met **eligibility and risk assessment** criteria in the preliminary paper-based questionnaire.
- signed a **Patient Consent Form** to participate.

You will advise patients of their eligibility. If they do not meet these criteria, you will address their health concerns as usual. If they are eligible to enter the PILOT research, they will be assigned an identity number that will enable them to contact you in completing the research.

Initial Procedure

You will conduct a **half-hour guided assessment**, during which you will:

- ask the participant demographic questions
- assess safety to proceed
- assess substance use
- undertake a short clinical examination that determines weight height, blood pressure, muscle strength and vision.
- undertake a screening symptom questionnaire
- briefly indicate functional capacity level
- carry out DSMV checklist symptom threshold checks
- give them a yellow-top pot to collect a later stool specimen at home and
- print out three laboratory request forms for them to take to their local SONIC laboratory.

The website has been designed so that the greater share of the assessment questionnaires should be answered by the participant, who can enter the website to answer a streamlined series of questions that take half an hour to complete. These can be completed in portions and results saved at any time either before, after or in between your assessments.

Participants will also be required to complete a half-hour series of **vision and hearing sensory tests** designed to test your brain's visual and auditory performance. These should be supervised in a quiet part of your practice with earbuds attached to a computer.

Follow-up Procedure

X 2 First arm, high risk participants, 18-35 years: If symptoms indicate risk of psychosis, the participant may need referral, however they and their X 2 controls, will need to continue to see you at 3 months and then six monthly intervals, for two years - until the meaning of the high risk symptoms becomes clear.

During this time, they will need follow up blood and urine tests at six monthly intervals.

Second Arm, already-diagnosed participants with schizophrenia X 1 and depression X 1. Follow-up is at your discretion, however the participant may indicate their willingness to take part in a later *treatment trial* of natural substances, which may follow on from this pilot and we will contact you if and when this becomes available.