The Body and Mood Study: Biomarkers in Depression Pilot Study

INFORMATION SHEET

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Introduction

You are invited to take part in a research study investigating biomarkers in depression. This project will look at whether certain measures of body function can be used in the diagnosis and assessment of major depressive disorder (MDD)

This Participant Information Sheet and Consent Form tells you about the research project. It explains what the study involves. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

The decision to take part is entirely yours and completely voluntary and will have no effect on your current or future health care. You may withdraw at anytime for any reason and this will have no effect on your health care.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read;
- Consent to take part in the research project;
- Consent to have the tests that are described;
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep

Why is this research being conducted?

This research is a pilot study. While it has its own specific aims, the information gained will be used to apply to fund a much larger study. The overall aim of the larger study is to determine whether certain measures of body function (such as heart rate, blood pressure, markers measured in the blood or proteins made by active genes) could be used in the diagnosis and assessment of major depressive disorder (MDD). The pilot study and the large study will aim to establish a model of how the body works differently physiologically in

people with and without depression. This knowledge may be able to help in the diagnosis of depression and in monitoring existing depression treatments, or even point the way towards new treatments.

The aims of the Body and Mood Pilot Study are as follows:

1. To clarify relationships between individual measures of body function and mood.

2. To validate the use of a specific type of genetic research (gene expression markers) as more effective ways to analyse measures of body function, which are usually measured by levels in a blood sample. Gene expression analysis is possibly a cheaper and potentially more powerful technology.

3. To confirm whether new computer analysis methods (network analysis and deep learning) can be used in a relatively small sample of data to provide new patterns of how measures of body function and depressed mood are related.

The basis by which participants will be selected or screened

The pilot study will recruit young people between the ages of 18 and 25 who have no long-standing medical conditions. The pilot study will recruit people who have no mental illness, or those who suffer from depression (major depressive disorder).

The following people are not eligible to participate in the pilot study:

- People under the age of 18 or over the age of 25
- People who do not have the capacity to provide consent for the study for any reason
- People with chronic medical illnesses like diabetes
- Pregnant women
- People with intellectual impairment or who have suffered a brain injury
- People who are dependent on any substance such as alcohol
- People with longstanding mental illnesses such as bipolar disorder or schizophrenia are not eligible to participate in the study
- People under the Mental Health Act 2000 are not eligible to participate in the study
- **People who are already taking antidepressant medication are not able to participate on the study**

Who is conducting the research?

The Gold Coast Hospital and Health Service has partnered with Griffith University, the University of Queensland and Bond University to progress this research project. Dr Chris Stapelberg is the lead for the research collaboration:

Dr Chris Stapelberg
Gold Coast University Hospital
Parklands Drive, Qld 4215
Email chris.stapelberg@health.qld.gov.au
Contact by telephone can be made via the Lakeside Rooms on (07) 55 620 466

What you will be asked to do.

Your participation will involve the following activities:

- Undergoing a formal psychiatric evaluation. The psychiatric evaluation consists of a series of questions about your current mental health, your past mental health, your current lifestyle and social circumstances, your medical history and your family history (questions about mental and physical illnesses in your blood relatives).
- Undergoing a medical examination, including the following measurements: blood pressure, weight, height, waist and hip circumference.
- You will be asked to undergo a 24 hour Holter monitor assessment, which is explained below.
- All of the above will be performed on day one and will take approximately 75 minutes.

- You will be asked to return the Holter monitor on day two after 24 hours of recording
- A blood sample will be collected on day two, combined with the return of the Holter monitor. The collection of a blood sample is described below.
- Return of the Holter monitor and the blood test will take about 10 minutes.

A diagram of how a participant would proceed through the pilot study is shown below:

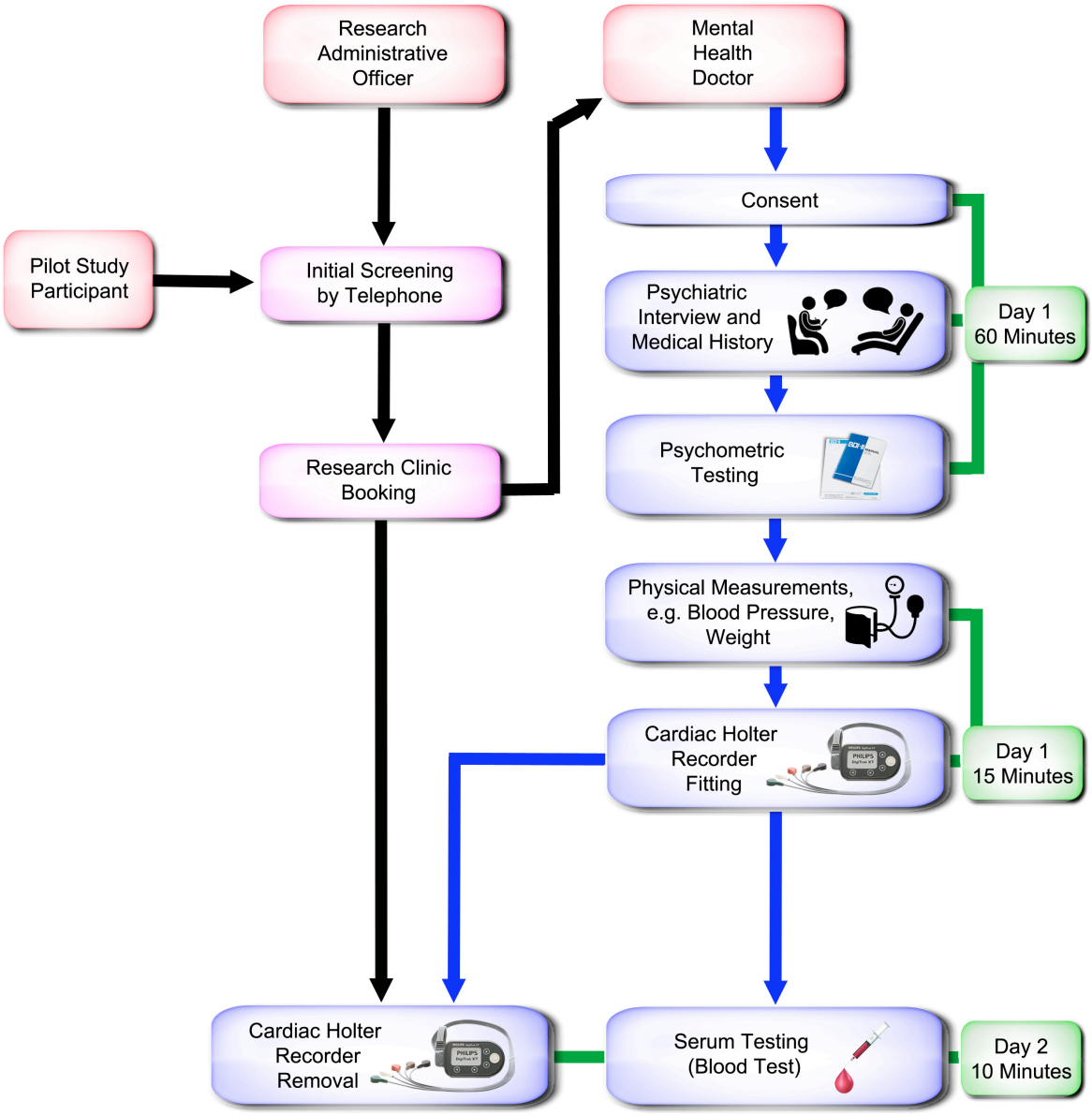

Figure 1. How a Participant Would Proceed Through the Pilot Study

Holter Monitoring

For this study you will be asked to undergo a 24 hour Holter monitor assessment. This will involve carrying a pager-sized device, with leads, which are attached to the chest above the heart, for one day. Electrodes (small, plastic patches) are placed at certain locations on the chest and abdomen.

The monitor is lightweight and is fitted to be worn comfortably with a belt or shoulder strap. The Holter monitor is a non-invasive method of recording heart activity. If you have any concerns generally about your heart health, you are advised to independently consult your regular doctor

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The Holter device will be fitted at the Lakeside Rooms and then you will be free to return home and engage in normal activities. You will be asked to record in general terms your activity, including sleep and wake times. You will also not be able to shower or bath during the 24 hours while wearing the device. The next day the device will be removed at the Gold Coast Hospital... Risks associated with the Holter monitor are rare. Rarely, the adhesive electrode patches may cause skin irritation at the application site. The participant may have to have small areas of skin on the chest shaved so that the electrodes can securely adhere.

Figure 2. Fitting a Holter Monitor

Collection of a Blood Sample for Physiological Markers

You will be asked to provide a sample of blood (about 10ml of blood). You will be asked to have fasted for this blood test (not have had anything to eat or drink for 12 hours before the blood sample is taken).

What will happen to my samples?

The blood sample will coded with a bar code assigned to it instead of your name. The number will be linked to your name. The blood samples collected will be sent for testing to Pathology Queensland.

A small amount of the blood sample that you provide will be frozen, as some blood tests will be performed on all samples at the end of the study.

The pilot project will, in total, take about two years to complete. Most of the blood sample you give will be used as part of this study but, if we have some remaining, it will be stored as a frozen sample. If that sample is needed for a future study we will contact you and ask for your consent.

Are there any risks in participating?

The blood draw may cause discomfort or a bruise. Sometimes, the blood vessel may swell, or blood may clot in the blood vessel, or the spot from which tissue is taken could become inflamed. Rarely, there could be a minor infection or bleeding. If this happens, it can be easily treated.

The current genetic research in the pilot study will **not** study genes, including gene characteristics and gene versions that are transmitted by parents to children. In this case, only the genetic instructions given to the body to make certain proteins will be studied as a way of investigating what proteins, for example immune proteins, are being made, and how much is being made.

However, as part of this study we might find a diagnosis of an illness that relates to your blood pressure or from your blood test. If the condition is treatable or preventable, you can specify on the consent form if you want to be informed about such a finding. Learning this information may be upsetting. You should note that consenting to the study is separate from consenting to any medical treatment. Also, just like you have the option to exit out of the study at any time, you also have the option to refuse any further medical testing, medical treatment or medical follow-up

If you are found to suffer from depression or another mental illness from this assessment, options for suitable treatment will be discussed with you.

If you become upset or distressed as a result of your participation in the research, the researcher is able to arrange for counselling or other appropriate support. Any counselling or support will be provided by staff who are not members of the research team. In addition, you may prefer to suspend or end your participation in the research if distress occurs.

Are there any benefits in participating?

We cannot guarantee that you will receive any benefits from this research. However, possible benefits may include the following:

- Receiving confirmation of being in good physical and mental health, insofar as we are able to assess this.

Do I have to take part in this research project?

Participation in this research project is voluntary. If you don't wish to take part then you don't have to. If you decide to take part and later change your mind, you are free to withdraw at any stage.

What if I withdraw from this research project?

You can withdraw at any time by contacting any of the Principal Investigators listed on the back page. We will destroy your records and samples if you so wish. Your decision to take part and then withdraw, will not affect your relationship with those taking care of you.If you would prefer to see a different doctor, this can be arranged, too.

Your confidentiality

All the data for this study will be treated completely confidentially. Your clinical information will be stored in password-protected databases. Your blood samples will be coded so only the principal investigators and study co-ordinators can decode them should results become available. Information about you may be obtained from your health records held at this, and other, health services for the purposes of this research. In any publication and/or presentation, information will be provided in such a way that you cannot be identified. Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

Will I get paid to participate in this study?

You will be given $20.00 for participating in the study, when you return the Holter monitor and have your blood test. This is to compensate you for travel costs.

Feedback to you

Feedback can be provided at the end of the study to inform you of the results obtained. Participants who would like a summary of the findings e-mailed to them upon completion of this project can indicate this on the consent form. (If you would like a summary of the results please indicate this by ticking the box indicated on the consent form). The experimenter will record your e-mail address on a separate sheet so that a summary can be e-mailed to you. The

research results are completely de-identified, which means that no personal details will be published or given out, only the statistical findings of the project.

Questions / further information

Any matter or concern regarding the research can be raised with the chief investigator on the contact details provided above.

The Ethical Conduct of this Research

The Gold Coast Hospital and Health Service conducts research in accordance with the National Statement on Ethical Conduct in Human Research. If you have any concerns or complaints about the ethical conduct of this research project you should contact the Research Directorate, at the Gold Coast University Hospital on (07) 5687 3879 or email GCHEthics@health.qld.gov.au

Privacy statement

The conduct of this research involves the collection, access, and / or use of your identified personal information. The information collected is confidential and will not be disclosed to third parties without your consent, except to meet government, legal, or other regulatory requirements. A de-identified copy of this data may be used for other research purposes. However, you anonymity will at all times be safeguarded. For further information consult http://www.health.qld.gov.au/goldcoasthealth/html/about/privacy.asp.

Thank you for reading this patient information and consent form