

Participant Information Sheet & Consent Form

Project: Chronic fatigue syndrome: Leptin, interleukin 6 and clinical symptoms

Researchers:

- 1) Professor Julio Licinio, South Australian Health and Medical Research Institute (SAHMRI)/ Flinders University
- 2) Professor Ma-Li Wong, South Australian Health and Medical Research Institute (SAHMRI)/ Flinders University
- 3) Dr Michael Musker, South Australian Health and Medical Research Institute (SAHMRI)

Brief Summary:

You have been contacted because you have expressed an interest in our study "Chronic fatigue syndrome: Leptin, interleukin 6 and clinical symptoms". This study is assessing the relationship between Chronic Fatigue Syndrome and cytokine measures (these are proteins / hormones produced by cells that affect other cells and systemic bodily functions). To participate in the study, your GP will have given you a diagnosis of Chronic Fatigue Syndrome (CFS) or Myalgic Encephalomyelitis (ME) (other names include systemic exertion intolerance disease SEID). We will use the acronym CFS to cover all versions of this diagnosis. You will require a letter from your GP confirming this diagnosis of CFS. You must be aged between 18 years and 65 years. We are looking for 30 volunteers who will have a current diagnosis of CFS from their GP, and 15 controls who do not have this diagnosis, but will match the group in Body Mass Index.

About Chronic Fatigue Syndrome and Cytokines:

Chronic fatigue syndrome (CFS) is characterised by a constellation of symptoms in previously healthy and active individuals. Because of these symptoms, the quality of life of people with CFS can be extremely compromised. While the search for a clear-cut cause remains elusive, we believe that we can make a major contribution to a participant's quality of life by finding the biological basis of their clinical symptoms. If the proximal biology underlying the disabling symptoms of CFS is found, we may be able to target treatments aimed at symptomatic improvement.

It has been demonstrated that in CFS there are decreased levels of physical activity, which can contribute to weight gain. CFS participants who are overweight or obese have significantly worse physical and mental functioning, more severe fatigue, greater disability, and more symptoms than similarly weighted controls. Furthermore, these hormones (leptin) drive and affect other body hormone levels in CFS, and can affect fatigue severity. The fat cells (adipocytes) synthesises both the hormones leptin and interleukin-6 (IL-6). The interaction of these hormones may cause symptoms of fatigue and exhaustion. It has been shown that injections of these hormones exacerbate symptoms, more in CFS subjects than in healthy controls. In our preliminary studies, we have shown a close temporal association of fluctuations in hormone levels (leptin) and daily changes in subjective responses. Other groups have shown a close association between these hormone levels and feelings of fatigue.

We have included specific hormones or cytokine measures as they relate to symptoms, and we have previously shown that they fluctuate substantially throughout the day. Clinical symptoms likewise fluctuate from hour to hour. Single time point measurements are therefore very limited, as they cannot be related to hourly fluctuations in fatigue symptoms.

Our Hypothesis:

We hypothesise that the clinical symptoms of chronic fatigue syndrome fluctuate during the day as a function of diurnal changes in the levels of plasma hormones (leptin and IL-6). Our aim is to study participants with chronic fatigue syndrome compared to healthy controls, collect blood over a normal day and correlate fluctuations of plasma hormones (leptin and IL-6) to clinical symptoms.

CFS increases low activity (sedentarism), resulting in the “metabolic syndrome” a key feature of this is weight gain. Excess weight (Adiposity) increases the levels of these hormones (leptin and IL-6). The Chief Investigator Professor Julio Licinio discovered and published in Nature Medicine (1997) that hormone levels (leptin) have very significant short cycle (ultradian) and changes throughout the day (circadian or 24 hour cycle). He subsequently showed strong associations between fluctuations in these levels and those of feelings of social withdrawal and sadness throughout the day. Professor Licinio also showed that inflammatory marker proteins (IL-6 levels) fluctuate during the day. These inflammatory marker proteins (IL-6 levels) have been associated with fatigue. We will determine whether frequently sampled hormone and inflammatory marker protein levels (leptin and IL-6) match up with changes in CFS symptoms and mood changes throughout the day by using visual analogue questionnaires on an hourly basis.

How we will test Leptin and Interleukin 6 levels: (plus information on genetic sample)

Assessment part 1 (total 3 hours): We will ask you to attend for an initial baseline assessment, where we will complete a mental and physical assessment (including Body Mass Index), ask you some questions about your physical and mental health in relation to CFS/ME and other disorders. It will be necessary to do some initial blood sampling to rule out other major disorders that mimic CFS/ME or may interfere with the results. Your identity will be protected and will only be accessible through a secure key code held by the head of the Mind & Brain research theme leader Julio Licinio. Here is a list of tests in assessment (part 1), which require 3 tubes of blood, totalling 19 ml (white top 10mls, purple top 4mls, and a grey top 5mls).

Baseline Bloods: (These are the specific blood tests that we will be completing)

- MBA -20 (includes LFT and EUC) and minerals & glucose (this includes a multiple biochemical analysis, a Liver Function Test, and Electrolyte, Urea, Creatinine test, and minerals and glucose profile)
- CBE (Complete Blood Examination)
- ESR (Erythrocyte Sedimentation Rate)
- Hepatitis B Antibody (checking for current Hepatitis Antibodies) – these will be exclusion criterion.
- HIV antibody (checking for current HIV Antibodies) – these will be exclusion criterion.
- Thyroid Function Test, Thyroid Stimulating Hormone T3 T4; Interleukin-6 & Leptin
- Vitamin D3
- Cortisol
- Body Mass Index <35 – obesity level ii (World Health Organisation) and above are exclusion criterion

You can check your BMI at this website: <http://www.heartfoundation.org.au/healthy-eating/Pages/bmi-calculator.aspx>
(To work out your BMI: divide your weight in kilograms (kg) by your height in metres (m) then divide the answer by your height again to get your BMI.)

Any detection of HIV or Hepatitis B will also be given to your G.P and you will be asked to speak to your G.P about your results so that you can be provided with the appropriate counselling and support. The relevant health authority for notifiable diseases will also be informed if a positive HIV or hepatitis serology is detected.

Questionnaires: i) Chronic Fatigue Syndrome / Myalgic Encephalomyelitis and other important medical conditions ii) medical history, such as any previous hospital admissions and disorders iii) Mental Health questionnaires. To complete some detailed

questionnaires that will assess iii) mood and anxiety levels, Becks Depression Inventory, the Hamilton Depression Rating Scale and the Hamilton Anxiety Rating Scale. iv) a detailed questionnaire on CFS symptoms.

Assessment part 2 (9.5 hours from 8.00am to 17.30hrs): We will assess total body fat (adiposity) in all subjects who enter part 2. Measurement of whole-body composition, including bone mineral content, lean body mass (muscle), and total body fat will be obtained with a dual-energy X-ray absorptiometer (DEXA). The DEXA scan will occur prior to the blood sampling, at around 8.15am at SAHMRI. We propose to characterise the rapidly sampled profiles of blood plasma concentrations of leptin and IL-6 in 30 participants with CFS and 15 healthy controls. Blood samples for the determination of leptin and IL-6 will be drawn via a cannula (small blood taking device inserted using a needle) in your arm from each subject at 7-minute intervals for 8 hours starting at 09:00 hrs. and ending at 17:00 hrs. Blood leptin and IL-6 concentrations will be measured by a laboratory test. Symptom ratings will be obtained from questionnaire type scale for 10 emotional and physical states: sadness, social withdrawal, appetite, concentration, fatigue, self-esteem, physical discomfort, headache, muscle pain, and weakness. Each subject will complete the self-ratings hourly from 09:00 until 17:00 hr, simultaneously with the blood collection. The hormone and inflammatory marker changes will be calculated and their relationship and variability will be analysed.

Our team also specialises in looking at the genetic code and a blood sample will be taken from those in the assessment part 2. This sample is for future studies in CFS. As both technology and our understanding of the genetic code develops, we will use this sample as part of a developing CFS genetic database. Any future research on these samples will have been approved by a separate ethics application. It will be held in storage for CFS studies.

Ethics:

This project is carried out under the guidelines set out by the National Statement on Ethical Conduct in Human Research and there is certain information we are required to give you. *If you don't understand this explanation, please talk to the research staff.* You may want to discuss this information and your involvement with family, friends or your usual doctor. Once you understand the research and agree to take part, you will need to sign a Consent Form.

PURPOSE OF STUDY & STUDY PROCEDURE

1. Signing up and the consent process: Before you agree to sign up for the study you will be sent a copy of the participant information sheet and consent form. You should read the consent form carefully before proceeding further. Once you have read the consent form you will be asked to provide a signed copy to show that you are consenting to take part in the study and that you understand the information that has been provided to you. You should also note that at any time you want to withdraw from the study, you can email us, or use the online chat facility to indicate your wish to withdraw. You will be asked to provide a copy of a letter from your GP, stating that you have been diagnosed with CFS.
2. Initial Assessment: You will be invited to SAHMRI to take part in the initial assessment which will involve some basic questions about your physical and mental health. We will confirm that you have read, understood and signed the consent form and see if you have any questions about the study.
3. We will ask you to complete some questionnaires about your physical and mental health. These include questions regarding your medical history (past and present), use of medication, alcohol and tobacco consumption, your own and family history of disease. The total time for questionnaires will be approximately 2 hours, and allow a further 30 minutes for a specific assessment of your physical health, including 3 blood samples (total 19mls, 10+5+4). Please note that the first day of assessment is to rule out other major disorders that may affect the results of the study, and the interviewer will be in touch about whether you will be eligible to continue with the study. Any results we find that we believe to be significant will be made available to you to you and your General Practitioner. You will then be

asked to contact your G.P to discuss the results if required. Any detection of HIV or Hepatitis B will also be given to your G.P and you will be asked to speak to your G.P about your results so that you can be provided with the appropriate counselling and support.

4. The Second Assessment – provided that we haven't discovered any exclusionary disorders in your initial assessment, you will be invited back to SAHMRI for a DEXA scan (dual-energy X-ray absorptiometer). This will occur at 8.15am on an agreed date when you will meet with the researcher. You will then be taken for the DEXA scan, and then on to the clinical rooms on level 4 of the main SAHMRI building where you will be prepared for the day of blood sampling.
5. The blood samples will be taken by initially inserting a cannula (introcan safety IV catheter) into a vein in the middle of your arm. This will remain in your arm for the 8 hours and samples drawn off the tube that comes from it. You will be provided with a comfortable chair, but you can stand up between samples if preferred. Samples will be taken every 7 minutes, which equates to 69 samples (that is a total of 69 x 4mls = 276mls). We use a special attachment called a VAMP which prevents any waste of blood. A bag of Heparin & Saline solution will be attached to a mobile drip stand. This will also be attached to the Vamp system, allowing us to maintain an open line throughout the day. If you have to go to the toilet, you will have to take the stand with you. We will provide you with food, drinks and entertainment (TV, iPad, magazines, and a Lazy boy relaxing recliner chair).
6. The total time commitment is half a day for the initial assessment i.e. approximately 3 hours. The second day will require approximately 9.5 hours. Starting at 8am to prepare for the DEXA and finishing at 5.30pm, allowing you half an hour to relax following your participation before you leave or longer if required.

More about your participation:

Feedback: We will not provide any individual results from the overall study to you nor family members. We recommend that your first course of action would be to contact your general practitioner (G.P) if you want to discuss your CFS diagnosis. If you have concerns about your health here is a website that will provide you with information about some useful services <http://b-bright.org/support-services/>.

POTENTIAL RISKS AND DISCOMFORT

DEXA Scan:

This research study involves exposure to a very small amount of radiation with the two Dual X-ray Absorptiometry (DEXA) scans to measure body composition. This test takes about 10 minutes and is performed routinely to measure bone density. You will need change into a gown, then lie on a bed as the scanner passes over your body. The DEXA scan uses very low energy radiation (50-100 times less than a single chest x-ray).

This research study involves exposure to a very small amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The effective dose from this study is about 0.002 mSv. At this dose level, no harmful effects of radiation have been demonstrated as any effect is too small to measure. The risk is believed to be very low.

Cannulation:

Having a cannula in your arm for the full day will have some effects on your movement around the area. We will support you to move around when required. If you need to go to the toilet, we can temporarily disconnect the device, or you can use an I.V mobile trolley stand to keep the equipment connected. There will also be limited movement in

your arm due the cannula's location. Additional discomforts may occur if there are some local skin reactions or inflammation. You are likely to feel a slight stinging sensation as the cannula is inserted. Possible side effects include: irritation, inflammation, and possible infection. You are asked to advise if you feel any discomfort throughout the day, so that the clinician can intervene and check the site of the cannula. You will have a clinician with you throughout the day.

Although very uncommon, there is a risk that you may become distressed if asked to recall particular experiences. If that happens, you may wish to access Lifeline (Tel. 13 11 14 or <http://www.lifeline.org.au/>) for counselling, without needing to contact us. At any time during the study you can ask to stop or to withdraw completely.

Your general practitioner (G.P) is able to help and can make referrals to specialist mental health services if required. There is also assistance you can obtain in a mental health emergency, contact the mental health triage service - telephone 13 14 65 available 24 hours, seven days a week. These are some of the highly specialised services in mental health:

Counselling and other useful support services:

- [beyondblue](http://www.beyondblue.org.au/) - telephone 1300 224 636 <http://www.beyondblue.org.au/>
- [Salvo Care Line](http://salvos.org.au/salvocareline/): 1300 36 36 22 <http://salvos.org.au/salvocareline/>
- [Crisis Support Services](http://www.ontheline.org.au/) - on line help <http://www.ontheline.org.au/>
- [Kids Help Line](http://www.kidshelp.com.au/) - telephone 1800 55 1800 <http://www.kidshelp.com.au/>
- [Lifeline](https://www.lifeline.org.au/) - telephone 13 11 14 <https://www.lifeline.org.au/>
- [Mensline](http://www.menslineaus.org.au/) - telephone 1300 789 978 <http://www.menslineaus.org.au/>
- [Relationships Australia](http://www.relationships.org.au/) - telephone 1300 364 277 <http://www.relationships.org.au/>
- [Sane Australia](http://www.sane.org/) - telephone 1800 187 263 <http://www.sane.org/>
- [Veterans and Veterans Families Counselling Service](http://www.dva.gov.au/health_and_wellbeing/health_programs/vvcs/Pages/index.aspx) - telephone 1800 011 046 http://www.dva.gov.au/health_and_wellbeing/health_programs/vvcs/Pages/index.aspx
- [Suicide Call Back Service](https://www.suicidecallbackservice.org.au/) - telephone 1300 659 467 <https://www.suicidecallbackservice.org.au/>

Other Useful Links:

- [Headspace](http://www.headspace.org.au/) <http://www.headspace.org.au/>
- [Blue Pages](http://www.bluepages.anu.edu.au/help_and_resources/state_by_state/sa/) http://www.bluepages.anu.edu.au/help_and_resources/state_by_state/sa/
- [Health Consumers Alliance](http://www.hcasa.asn.au/) <http://www.hcasa.asn.au/>
- [KidsMatter](http://www.kidsmatter.edu.au/) <http://www.kidsmatter.edu.au/>
- [The Mental Health Coalition of SA](http://mhcsa.org.au/) <http://mhcsa.org.au/>
- [Mental Illness Fellowship of SA](http://www.mifellowship.org/) <http://www.mifellowship.org/>
- [Mind Matters](http://www.mindmatters.edu.au/) <http://www.mindmatters.edu.au/>
- [Multicultural Mental Health Australia](http://www.mhima.org.au/) <http://www.mhima.org.au/>
- [One Voice Network](http://www.onevoicenetwork.websyte.com.au/) <http://www.onevoicenetwork.websyte.com.au/>

7. ANTICIPATED BENEFITS

There will be no anticipated benefit to you individually. This research may or may not benefit society; we will be able to identify the relationship between specific cytokines and the participant's perception of health status and fatigue. The results will give us a cumulative picture of a small cohort as compared to a matched control group. We will use the data to shape future studies in CFS/ME and to publish our findings.

8. FINANCIAL OBLIGATION

The study doctor, Dr Licinio, and SAHMRI have no financial responsibility for additional treatments that you may need that is not directly involved with this study.

9. POSSIBLE COMMERCIAL PRODUCTS

If a commercial product is developed from this research study, SAHMRI or its designee intends to claim ownership of the commercial product. There are no plans for you to profit financially from such a product.

10. EMERGENCY CARE AND COMPENSATION FOR INJURY

If, as a result of your participation in this study, you become ill or are injured, immediately advise your study contact of your condition. In the first instance your study contact will evaluate your condition and then discuss treatment with both you and your regular treating doctor. Since you are participating in a non-sponsored study/investigation any question about compensation must initially be directed to your study contact who should advise their insurer of the matter.

It is the recommendation of the independent ethics committee responsible for the review of this study/investigation that you seek independent legal advice.

11. PRIVACY AND CONFIDENTIALITY

Any information we collect will be de-identified. There will be no anticipated benefit to you individually and you may withdraw consent at any stage before the “code key” link between your personal information and your research data are removed, and if you withdraw your consent will not affect your rights or the responsibilities of the researchers in any respect. There will be a temporary link between your personal data and your research data after which that link will be removed and data stored will be coded and de-identified; which means that following the research your identity will no longer be linked to your research data. So research data will effectively be anonymous.

The results of this research study may be presented at meetings or in publications. Your identity will not be disclosed in those presentations.

All data will be kept in locked files, and subjects will be identified only by codes when the data gathered in this procedure is presented or published. Only the Principal Investigator, Professor Julio Licinio, will have access to a password-protected file linking the codes to your personal information. Data will be stored for at least 5 years after the study is completed.

Only Professor Licinio will be able to re-identify your information by accessing a password-protected file linking the code to your personal information.

We may provide data to other researchers. Your personal information will be substituted by a code, and we will provide only essential information to the other researchers such as gender, age, weight, height and diagnosis.

12. PARTICIPATION AND WITHDRAWAL

Your participation in this research is **VOLUNTARY**. If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without penalty or loss of benefits to which you are entitled.

The researchers may withdraw you from participating in this research study at any time, without your consent, if circumstances arise which warrant doing so.

13. NEW FINDINGS

During the course of the study, if you choose to, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation that might change your decision to be in the study. If new information is provided to you, your consent to continue participating in this study will be re obtained.

Your treating Doctor/s will be notified of your participation in this study and of any clinically relevant information noted by the trial doctor in the conduct of the study.

14. QUESTIONS

Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone from the study team or with family, friends or your personal physician or other healthcare professionals. Some people have personal, religious or ethical beliefs that may limit the kinds of medical or research studies they would want to be involved with. If you have such beliefs, please discuss them with your study doctors or members of the research team before you agree to the study. You should read all the information above, and ask questions about anything you do not understand, before deciding whether or not to participate.

In the event of a research-related injury or if you experience an adverse reaction, please immediately contact one of the investigators listed below. If you have any questions about the research, please feel free to contact:

Michael Musker, Ph.D.
SAHMRI, North Terrace
Adelaide, SA 5000.
Phone: +61 8 8128 4714 or a member of the Mind & Brain Team on 8128 4000

A list of counselling services and other supports have been listed above.

Do not sign the consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to enrol in this study, you will be given a signed and dated copy of this consent form.

15. RIGHTS OF RESEARCH SUBJECTS

You are not waiving any legal claims, rights or remedies because of your participation in this research study.

16. FUTURE CONTACT

By signing the consent form, you agree to participate only in the study described here. After this study is completed, we may recontact you to participate in other future studies. At the bottom of this consent, we are asking your permission to contact you at any time for follow-up reasons, and you may choose not to give us permission. This will not compromise the present study.

If in the course of those future contacts we discuss the possibility of participation in a new research study, we would provide you with a new consent form.

17. Re-imburement

18. There will be payment of \$100 in the form of a voucher for completion in full participation in the study. The vouchers can be used at Coles, Myers, Kmart and a few other stores. If you are not selected for the second phase of the

study, it means that you are not suitable for this particular study and therefore there will be no payment or reimbursement. You can read more about our research facility at our website: www.SAHMRI.com

If you would like more information about this study, now or later, you can contact Dr Michael Musker on (08) 8128 4714 / or 8128 4000 or email michael.musker@SAHMRI.com

The Bellberry Human Research Ethics Committee has reviewed and approved this study in accordance with the National Statement on Ethical Conduct in Human Research (2007) – incorporating all updates. This Statement has been developed to protect the interests of people who agree to participate in human research studies. Should you wish to discuss the study or view a copy of the Complaint procedure with someone not directly involved, particularly in relation to matters concerning policies, information or complaints about the conduct of the study or your rights as a participant, you may contact the Committee chair, Bellberry Human Research Ethics Committee on 08 8361 3222.

19. Terms of Consent

I acknowledge that the nature, purpose and risks of the research project and alternatives to participation have been provided in the participation information sheet.

Specifically, the details of the procedure(s) proposed and the anticipated length of time it will take, the frequency with which the procedure(s) will be performed and an indication of any discomfort that may be expected have been provided to me.

I freely agree to participate in this research project according to the conditions in the Participant information Sheet which I confirm has been provided to me.

I understand that there will be no anticipated benefit to me individually.

I have been given the opportunity to discuss this with a member of my family or another person.

I have been told that no information regarding my medical history will be divulged to unauthorised third parties and the results of any tests involving me will not be published so as to reveal my identity.

I understand that I am free to withdraw from the study at any stage without prejudice to future treatment. If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed, unless I state otherwise.

I am 18 years of age or over and under 65 years of age.

I consent to participating in the following procedures:

1. To respond to questionnaires to evaluate: i) whether I may meet research criteria for Chronic Fatigue Syndrome / Myalgic Encephalomyelitis or any other important medical conditions, and ii) my medical history, such as any previous hospital admissions and disorders iii) Mental Health questionnaires. To complete some detailed questionnaires that will assess iii) my mood and anxiety levels, Becks Depression Inventory, the Hamilton Depression Rating Scale and the Hamilton Anxiety Rating Scale. iv) a detailed questionnaire on CFS symptoms.
2. To undergo a brief physical examination, showing any scars or previous injuries, and areas of current pain.
3. To provide a set of blood samples (3 tubes at a total = 19mls) to allow for the initial assessment of my various hormones and complete blood examination.
4. To enter into the second phase of the assessment which involves a DEXA scan, and a day of blood sampling. The blood samples will take a whole day (9.5hours including preparation, the DEXA scan, and some relaxation time following the procedures). My bloods will be taken every 7 minutes through a tube system that will be

connected to my arm for the whole day. A total of 69 samples will be taken to measure the proteins in my blood. These include a genetic sample for future studies in the area of CFS. If you want to know more about this, you may ask the researcher.

5. I understand that having a cannula inserted into my arm has some risks of discomfort which are listed in the attached Participant Information Sheet.
6. To complete Visual Analogue Scales every hour for 8 hours to assess 10 areas of wellbeing, such as tiredness and other factors.
7. To be contacted by members of the research team for follow up studies, or to be provided with information about this study.
8. Parking is available to me and if I require this I must make prior arrangements with the contact researcher Dr Mike Musker. Instructions are in the appendix.

I do understand that in my involvement in this research there will be no anticipated benefit to me individually and that I may withdraw my consent at any stage before the “code key” link between my personal information and my research data is removed, and if I withdraw my consent it will not affect my rights or the responsibilities of the researchers in any respect. There will be a temporary link between my personal data and my research data after which that link will be removed and data stored in a key-coded format; which means that following the research my identity will no longer be linked to my research data. So the research data will effectively be anonymous.

I do understand that I will not be able to receive my individual results in relation to the research findings.

I consent to my treating Doctor/s being notified of my participation in this study and of any clinically relevant information noted by the trial doctor in the conduct of the trial.

I do understand that this study has been reviewed and approved by Bellberry Ltd Human Research Ethics Committee (HREC) and it is my right as a participant, to contact Bellberry Ltd HHREC on (08) 8361 3222/ email: bellberry@bellberry.com.au if I have concerns, complaints or queries about the conduct of this study I wish to discuss with someone not directly involved in the study.

I declare that all my questions have been answered to my satisfaction.

I have read and I understand the Participant Information Sheet & Consent Form. I declare that I am over the age of 18 years.

NAME OF STUDY PARTICIPANT: _____

SIGNATURE OF STUDY PARTICIPANT: _____ DATE: _____

Declaration by Co-Investigator (CI):

A verbal explanation of the research project, its procedures and risks has been given to the participant and I believe that the participant has understood that explanation.

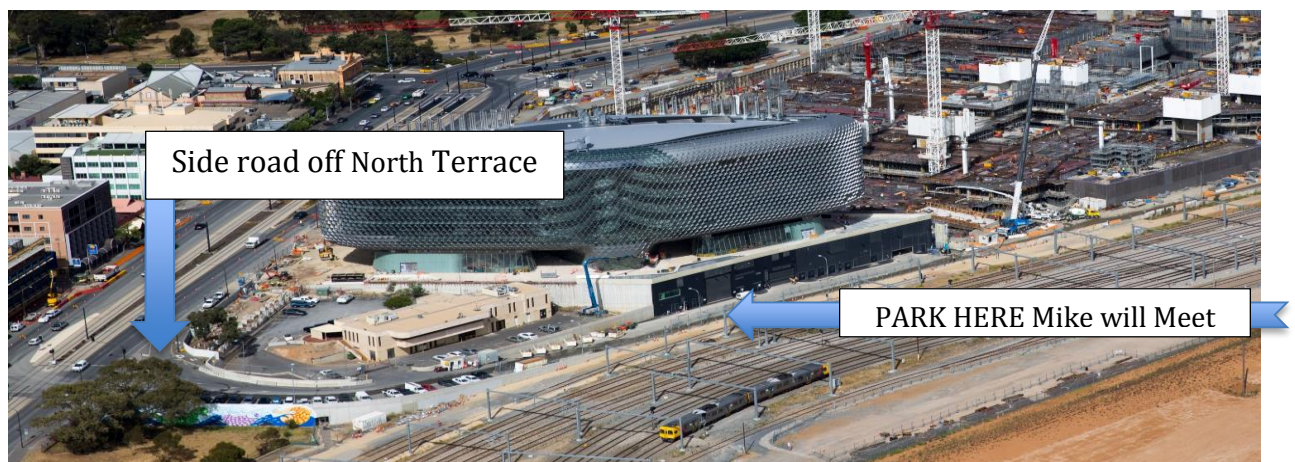
NAME OF CI: Dr Michael Musker

SIGNATURE OF or CI: _____ Date: _____

* The Co-Investigator must provide the explanation and provision of information concerning the research project.

Appendix:

Parking Location - Additional Information



If you are driving along North Terrace toward South Road, then turn right at the lights just before the SAHMRI building.
If you are driving along North Terrace toward the city, then turn left just after the SAHMRI building.

For further information – you can contact Michael on: 08 8128 4714 or 0413915064

The researcher Dr Michael Musker will meet you as agreed by phone prior to the interview, which will usually be a few minutes before the interview. If you are walking or coming by public transport, or parking in the city, then you will be met at your previous appointment location at the CSIRO entrance to SAHMRI.