WOOLCOCK
LEADERS IN BREATHING & SLEEP RESEARCH

Participant Information Sheet

Project: Circadian Misalignment Shiftwork Study

Principal Investigator: Associate Prof. Clare Anderson (Monash University)
Email: clare.anderson@monash.edu
Phone: (03) 9905 1714

Co-Investigators: **Dr. Christopher Gordon (Woolcock Institute of Medical Research, University of Sydney)**
Email: **Christopher.gordon@sydney.edu.au**

Prof. Ron Grunstein (Woolcock Institute of Medical Research, University of Sydney)
Email: **ron.grunstein@sydney.edu.au**
Phone: (02) 9114 0438

Introduction

You are invited to take part in this study. Please read this Participant Information Sheet in full before deciding whether or not you wish to participate in this research. If you would like further information regarding any aspect of this project, you are encouraged to contact the researchers.

What does the research involve?

Sleep difficulties are prominent throughout society and increase in prevalence as people undertake shiftwork where circadian misalignment occurs. Slow Wave Sleep (SWS) is the restorative stage of sleep. There is a reduction in the duration and depth of SWS in shiftworkers who may be sleep-deprived, which is likely to affect their next day cognitive performance. Due to the prevalence of sleep difficulties in shiftworkers and the number of individuals in the future that will undertake shiftwork, ways to improve sleep and promote cognitive function are of high importance.

We are studying the effects of an auditory stimuli (PowerSleep device) during sleep on SWS quality in shiftworkers. This research study will test overnight cognitive performance during a simulated night shift.

Who is organising and funding the research?

This project is funded by the Cooperative Research Centre (CRC) for Alertness, Safety and Productivity. This is an Australian Government Initiative that brings together industry, government and university sectors in a co-ordinated program. The major aim of the CRC is to reduce the burden of impaired alertness on the safety, productivity and health of Australians. The Alertness CRC will develop and deploy the next generation of shift scheduling and workplace design techniques; alertness assessment devices; individualised programs for better sleep health and a range of innovative strategies to reduce fatigue.

Screening:

If you decide that you would like to participate in this study, your involvement in this research will include the following:

You will be required to register your interest via a website. You will be sent a link to complete an online questionnaire which will ask you questions regarding your sleep, lifestyle, family history,

health and medical history to determine your further eligibility for the study. If you are eligible, a researcher will contact you to take part in an initial telephone screen which may take up to 20 minutes. Questions regarding your gender, date of birth, sleep habits, medication use (including herbal prescriptions), medical history and shift work status will be asked during this screening interview. If you are eligible after completing the telephone screen, you will then attend an information and consent meeting.

Information and Consent Meeting:

You will be asked to visit the Sleep and Circadian Medicine Laboratory at the Woolcock Institute of Medical Research in Glebe to provide written consent to participate in the study. You will undergo a test for colour blindness, have your height and weight measured and auditory tones will be individually calibrated (on the PowerSleep device) to you.

The study consists of four consecutive phases:

1. at-home monitoring (1 week)
2. in-laboratory assessment (3 consecutive nights)
3. at-home monitoring (1 week)
4. in-laboratory assessment (3 consecutive nights)

Your participation in this study will involve 1 week of at-home monitoring immediately followed by a 3 night stay at the laboratory. You will then repeat this process the following week, with another 1 week of at-home monitoring followed by another 3 night stay. You will be required to spend a total of 6 nights in the laboratory.

At-home Monitoring:

There are two at-home monitoring periods. The first occurs one week prior to the first laboratory visit. The second at-home period will occur between your first and second laboratory visits. You will be required to maintain a consistent sleep schedule during these periods. This sleep schedule is to ensure consistent pre-sleep conditions prior to the in-laboratory testing. Adherence to this schedule will be assessed via a wrist-like activity monitoring device (Actiwatch) and paper-based sleep diaries. The Actiwatch will be worn at all times during the study. You will be asked to abstain from alcohol and caffeine for 48 hours prior to coming into the laboratory.

Laboratory Assessment Visits:

There are two laboratory assessment visits. During both visits, you will be admitted to the laboratory at 9 AM and you will be discharged approximately 72 hours later. You will remain in the laboratory for the entire 72 hours. This consecutive three-night stay in the laboratory will be repeated approximately one week after the first. On both laboratory assessment visits, you will be required to wear an auditory stimulation device (PowerSleep device) for enhancing your slow wave sleep. For the first stay, you will be randomly exposed to one of two conditions: (i) the active mode where the device is fully operational, or (ii) a dummy mode where the device is on, but does not provide active auditory stimulation. You will then complete the other condition on the second stay.

During the laboratory visits, you will be continuously supervised by staff. The laboratory is fitted with cameras and you will be monitored throughout your stay. There are no cameras in the bathrooms. While at the laboratory, all meals will be provided for each visit.

Once you arrive in the laboratory, you will be asked to provide a urine sample for drug testing. You will then be fitted with electrodes on your face and scalp which will monitor brain wave activity. You will then be provided a nap opportunity of up to 90 minutes duration. Following the nap, you will have an opportunity to practice the cognitive tests in this study.

At 7PM following dinner, you will commence the nightshift period of the study. Every two hours you will complete a test battery that measures your alertness and your brain activity will be monitored throughout the simulated nightshift periods. The test battery consists of:

a) **Karolinska Sleepiness Scale (KSS)** – a question (rated 1-9) to gauge your current level of sleepiness immediately prior to and after starting the tasks.

b) **Psychomotor Vigilance Task (PVT)** – this is a 10 minute reaction time test which utilises a hand-held device with two response buttons. You will be asked to pay attention to a visual random stimulus on the device and respond as quickly as possible by pressing one of the response buttons.

c) **Karolinska Drowsiness Test (KDT)** – this is a simple 7.5 minute test of your attention by focusing on a fixed spot on the wall in front of you. Your brain wave activity will be recorded to measure sleepiness.

At the beginning and end of your simulated nightshifts, you will also complete the following tests:

d) **Balance Assessment** – will assess your ability to maintain your balance with your eyes open for 1 minute, and then with closed eyes for 1 minute.

e) **Paired Associates Task** – is a memory task that involves remembering word sets.

f) **Go/NoGo** – is a cognitive function test that determines decision-making.

g) **N-Back 1, 2, 3** – is a recall memory tests that takes 10 minutes requiring you to remember the positions of letters starting with 1 letter back, 2 letters back and 3 letters back.

h) **Tower of London** – examines spatial arrangement skills.

i) **Visual Working Memory Task** –examines your ability to immediately recall coloured shapes.

j) **Verbal fluency test** – this tests how many words you can generate in 10 minutes.

At the end of the simulated night shifts, you will be asked to perform a simulated driving task (**AusEd** for 60 mins). The room will be brightly lit to simulate morning light levels.

At the end of the simulated drive, you will be fitted with the SWS enhancer (PowerSleep device) and go to sleep at approximately 9 AM. You will be allowed to sleep for up to 8 hours.

This testing regime is repeated for the next 2 night shifts.

Your **second visit** will be identical to the first visit. Following this second visit, your participation in the study will be complete. A taxi voucher will be provided for you to get home, or if you are driving without recovery sleep, you are required to sign a driving disclaimer form before leaving the laboratory.

Why were you chosen for this research?

You were selected to participate in this study because you are a healthy individual between 30 and 50 years of age and English is your primary language.

To be eligible to participate in this study it is important that you do not have any medical, neurological or psychiatric disorders. This includes pain disorders, neurological disorders and cardiovascular disorders, as well as traumatic brain injury and concussion. Additionally you must

not have been diagnosed with sleep apnoea, nystagmus, eye tremor, colour-blindness or have a hearing impairment.

To participate in this study you must not be taking any medications that affect the central nervous system, sleep or biological rhythms (e.g. cholinesterase inhibitors). You must not have been taking anti-depressants or benzodiazepines in the last three months. If you currently take sedative hypnotics, you will be asked to stop taking these two weeks prior to the start of the study. It is also important that you are not a regular shift worker and that you have not travelled across time zones of more than 3 hours within the last two months. Furthermore, it is important that you do not consume more than 300mg of caffeine per day, 14 standard alcoholic drinks per week and have not smoked for the past 12 months.

Source of funding

Funding for the study has been obtained from the CRC for Alertness, Safety and Productivity**.**

Consenting to participate in the project and withdrawing from the research

Participation in this study is entirely voluntary and you are under no obligation to consent. If you do consent to participate, you may withdraw from further participation at any stage. Should you wish to withdraw, no further data or personal information will be collected from you, although previously collected data and personal information will be retained by the CRC for Alertness, Safety and Productivity. It is important to note that it may not be possible to destroy some data, e.g. after it has been de-identified. If you would like to request to withdraw your data you must do so in writing to the Principal Investigator. Your choice to withdraw your participation or data will not have any adverse effects on your relationship with any researchers involved in the project. Discontinuation of the study will however impact on reimbursement (See “Reimbursement” on Page 7).

Possible benefits and risks to participants

The researchers estimate that you will experience minimal discomfort from this study. However, possible reasons for discomfort are:

- the topics discussed in general, medical and psychological screening may cause some embarrassment or emotional discomfort. You are encouraged to inform the study researcher,

doctor or psychologist if this is the case. We will emphasise that all personal, medical and psychiatric information provided to us remains confidential.

- you will be asked to abstain from caffeine for 48 hours before the laboratory visit and during your stay in the laboratory.

- the tape and special paste used to attach the EEG electrodes may cause some minor discomfort or skin irritation, and the glue used to hold electrodes to the scalp may leave a flaky residue in the hair for several days. The adhesive electrode pads may cause some skin irritation.

- the altered sleep-wake schedule may cause tiredness. We advise against driving, operating machinery or making any important decisions until they feel fully recovered.

Reimbursement

On completion of the study, you will be eligible for up to $2000 for reimbursement of your time. Reimbursement is based on time required for each of the at-home and in-laboratory periods. Non-compliance to study procedures may result in reduced reimbursement.

Can I have other treatments during this research project?

While you are participating in this research project, it is important to tell the research staff of any treatments or medications you are taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should notify research staff about any changes to these during your participation in the research project.

Confidentiality

By signing the consent form, you consent to the study co-ordinator and relevant research staff collecting and using personal information about you for the research project. All information collected will be confidential, including past and present medication and drug use. You will be provided with an individual participant code and all data will be collected and stored under that code. Identifying information will be maintained in a password protected computer file to which only investigators will have access. Investigators must have been provided access to the folders containing the computer file and also the password to open the file.

Storage of data

De-identified data will be stored on a remote database (CRC Alertness Database) located within Australia. The data within this database will be accessible by a secure connection protocol over the internet to researchers only. De-identified data derived from this study will be available to members of the Project Team within the CRC for Safety, Alertness and Productivity. The data will be backed up to a second storage medium to avoid loss. As this project is part of the Cooperative Research Centre for Alertness, Safety and Productivity, re-identifiable data (i.e. study results from which identifiers have been removed and replaced by a code remains possible to re-identify a specific individual) may be shared with research collaborators including staff from collaborators for other research and development purposes. Data will not be shared without the permission of the Principal Investigator of the current project. This data will be stored in re-identifiable form to avoid transfer of sensitive information. Re-identifiable data may be retained indefinitely within the Cooperative Research Centre Database. Your data may also in future be made available to a third party outwith the CRC, in which case further ethical approval will be sought from both yourself and the Ethics Review Committee.

Use of data for other purposes

In addition to publication, data collected in this study may also be presented at a conference, or in a report to an organisation. In order to uphold your confidentiality, individual data will not be presented and participants will not be identifiable. Any information obtained for the purpose of this research that can identify you will be treated as confidential and securely stored. Coded summary data will be shared with Philips Respironics, who are supplying the SWS enhancer. Data sent to Philips will be de-identified.

In accordance with Australian privacy and other relevant laws, you have the right to request access to the personal or medical information collected and stored by the research team about you. You also have the right to request that any information with which you disagree be corrected.

Could this research project be stopped unexpectedly?

Although very unlikely, the project may be stopped unexpectedly at any time for a variety of reasons. These may include reasons such as:

- if it appears to be medically harmful to you;
- if you fail to follow directions for participating in the study;
- if it is discovered that you do not meet the study requirements;
- if the study is cancelled; or
- for administrative reasons.

In this case, we will explain to you why the study was stopped, ensure that the study was stopped safely and provide follow-up care if necessary.

Additional staff on the study

While participating in this study you will meet a range of research staff, including site investigators, sleep technicians and research assistants.

Further information

A member of the research team will discuss this information with you further and answer any questions you may have. If you would like to know more at any stage, please contact the Study Co-ordinators on (02) 9114 0481 or (02) 9114 0469.

Ethics approval

This study has been approved by the Monash University Human Research Ethics Committee (MUHREC), Protocol No 2017-8329.

Complaints

If you suffer any injuries or complications as a result of participation in this research project, you should contact the study team as soon as possible to be. If you are eligible for Medicare, you can receive medical treatment required to treat the injury or complication as a public patient in any Australian public hospital. Should you have any concerns or complaints about the conduct of the project, you are welcome to contact the Executive Officer, Monash University Human Research Ethics (MUHREC):

Executive Officer Monash University Human Research Ethics Committee (MUHREC) Room 111, Building 3e Research Office Monash University VIC 3800 Tel: +61 3 9905 2052 Email: muhrec@monash.edu Fax: +61 3 9905 3831	Governance Officer The conduct of this study at Woolcock Institute of Medical Research has been authorised by the Governance Officer, any person with concerns or complaints about the conduct of this study may also contact the Research Governance Officer on (02) 9114 0412, email: jelliot@woolcock.org.au and quote project number [2017-8329-10437]