Participant Information and Consent Form

Individualised targeted therapy for sleep disorders: Australia's sleep revolution

Short Title	Australia's Sleep Revolution
Protocol Number	1
Project Sponsor	Flinders University with funding support from Artemis Media via grants from various sources including Screen Australia, Screenwest, the South Australian Film Corporation and SBS.
Principal Investigator	Professor Danny Eckert
Associate Investigators	Associate Professor Sutapa Mukherjee, Associate Professor Ching Li Chai-Coetzer, Prof Robert Adams, Dr Thomas Altree, Dr Simon Proctor, Professor Leon Lack, Dr Gorica Micic, Dr Nicole Lovato, Dr Amy Reynolds, Dr Hannah Scott, Dr Alex Sweetman, Dr Amal Osman, Associate Professor Andrew Vakulin, Dr Bastien Lechat, Professor Peter Catcheside, Dr Kelly Loffler, Mr Jack Manners and Dr Ganesh Naik.
Others involved in the Project	Ms Carolin Tran, Ms Charmaine O'Reilly, Ms Alison Teare, Ms Alison Leviton, Ms Susanne Taylor, Ms Barbara Toson and Ms Alison Pinczel.
Location	Nick Antic Sleep Laboratory, Adelaide Institute for Sleep Health, Flinders University Level 2, Mark Oliphant Building, 5 Laffer Drive, Bedford Park SA 5042

Part 1. What does my participation involve?

You are invited to take part in this research project because you are an adult aged 18 years or above and have either:

1) been diagnosed with one or more sleep disorders (obstructive sleep apnoea (OSA) or insomnia) and are currently either not treated or inadequately treated or

2) you or your general practitioner (GP) suspect that you may have OSA, insomnia or both conditions.

AND you are willing to have your sleep disorder treatment journey filmed and televised as part of a 3-part series on sleep health.

The goal of this research project is to use the latest approaches to diagnose and understand your specific sleep disorder and its causes to help you and your doctor select the most appropriate treatment option for your sleep problem.

This will include the use of monitoring technology in your home and using this information to help decide which therapy or therapies are most appropriate to treat your specific sleep condition. This will include cutting-edge treatments for insomnia and OSA that are available for clinical use, as well as new and emerging treatments and treatment approaches that are in development. The requirements for the study, including the number of visits and treatment and monitoring approaches, will vary depending on your specific circumstances and condition. Elements of this research project will also form part of a 3-part television series titled "Australia's Sleep Revolution with Dr Michael Mosley". If you are eligible for this study, there are separate media consent and release forms and requirements that you will be asked to review and consider. These seek your written permission for elements of your diagnostic and treatment journey to be televised.

This Participant Information Sheet and Consent Form tells you about the research project. It explains the tests and treatment options involved. Understanding 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 to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

If you decide 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 and treatments 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. Consent does not automatically indicate your eligibility for the study. A series of screening steps will determine if you are ultimately enrolled in the study.

Why are we doing this research?

Current approaches to diagnose and treat common sleep disorders are often imprecise and can be difficult to access. For example, treatment for OSA typically involves a one-size-fits-all, trial-and-error approach where most people diagnosed are first prescribed continuous positive airway pressure (CPAP) therapy. CPAP involves wearing a mask attached to a device that blows pressurised air to help keep the airway open during sleep. If tolerated and used, it works very well at controlling OSA and can reduce key symptoms such as daytime sleepiness.

However, more than half the people prescribed CPAP therapy either cannot tolerate it, do not use it, or only use it sometimes. This leaves many people with OSA either untreated or undertreated and at risk of harm. Access to alternate potentially effective treatment solutions is challenging in the current system which often requires a time-consuming trial-and-error approach until a well-tolerated and effective treatment option is established. We and others have developed new techniques to determine the different underlying causes of OSA, which include problems with the upper airway itself and quite complex interactions with breathing, the muscles around the airway and instability of the systems that control sleep. Our aim is to use this information to provide targeted treatment solutions so that individuals can ultimately receive the most appropriate treatment or treatments for their specific needs upfront, including non-CPAP options for the >50% of people who cannot tolerate CPAP. Non-CPAP options include specialised dental devices to help move the jaw forward and keep the airway open, devices to prevent people from sleeping on their back where OSA is most common, and the use of emerging medications.

Similarly, the causes of insomnia vary between people and an individualised approach is required to get the best outcomes for all. The preferred treatment approach for insomnia is cognitive behavioural therapy for insomnia (CBTi). However, access to skilled sleep psychologists who are best placed to treat the different types of insomnia is limited.

Additionally, the one-size-fits-all CBTi approach assumes similar underlying causes of insomnia. Hence, it may not be optimal for insomnia caused by different reasons such as shift work which can be more challenging to treat with standard approaches due to sleep problems arising from disruption of the body-clock. We have developed in-home technologies to target key underlying reasons for insomnia, including bright light therapy devices to treat body clock disruption and another device which retrains people to fall asleep more quickly. Our aim is to use these emerging techniques, and others, to tailor treatment programs to specific individual needs.

Accordingly, this research study will investigate the use of new approaches to more comprehensively identify the different causes of sleep disorders including the use of new technologies that can be used in the home and the potential to use this information to tailor treatment for each person. This includes the latest treatments that are being used clinically and new cutting-edge treatments currently in research development.

This research is being conducted by the Adelaide Institute for Sleep Health, Flinders University.

What does participation in this research involve?

If you agree to participate in this study, this Consent Form will need to be signed prior to any study assessments being performed.

The goal of this project is to provide targeted treatment solutions for sleep disorders based on individual needs and requirements. Hence, the specific diagnostic and monitoring tests and treatment solutions will vary and will be determined in consultation with you, the study clinician, and the research team. Certain components will be common to all enrolled participants regardless of your specific diagnosis. These include:

1). **Pre-screening (online ~30 minutes):** Initially, if you haven't already done so, you will be asked to complete our Volunteer Pre-screening Survey: https://researchsurvey.flinders.edu.au/surveys/?s=T4K4WRFEWF

2). **Study information and pre-screening (telephone or teleconference call ~30 minutes):** Following completion of the Volunteer Pre-screening Survey, a member of the research team will provide you with the information sheet and arrange a convenient time for a telephone or teleconference call to briefly describe the study goals and requirements. If the study sounds of interest and you are available during the designated study times, you will be asked some study specific questions to determine if you are eligible for the current study. In some cases, additional clinical tests may be required prior to your potential enrolment in the study. For example, a clinical sleep study to determine your sleep apnoea severity. We may also ask you to share any of your previous sleep study reports to help determine your eligibility for the current study if available. If eligible, you will be booked for an in-person screening visit.

3). **Screening visit (~2-3 hours):** The screening visit will be conducted at the Adelaide Institute for Sleep Health at Flinders University (or in your home if you are unable to attend in person). Initially, you will be asked to confirm that you have read and understood this information sheet and the study requirements and if so, to sign the consent form. During this visit, a comprehensive screening assessment will be performed as outlined in the sections below to determine your specific diagnostic testing requirements.

4) **Clinical review and treatment plan development (~1-2 hours):** This visit will be conducted at the Adelaide Institute for Sleep Health at Flinders University (or in your home or via videocall if you are unable to attend in person). During this visit, the clinical team will review your diagnostic testing findings and discuss your treatment plan.

5) **Pre- and post-treatment testing (evening and morning questionnaires and overnight sleep studies):** You will be asked to perform a minimum of one pre-treatment and one post-treatment sleep study. You will find extra information about what a sleep study involves on page 5. The sleep studies will either be conducted in your home or at the sleep laboratory at the Adelaide Institute for Sleep Health, Flinders University. In addition, you will be asked to complete a range of questionnaires prior to sleep and the following morning plus some simple morning alertness, performance and reaction time tests as outlined below. The sleep study testing will be conducted with a break of at least 2 nights and up to 8 weeks apart before and after treatment.

6) **Post-treatment review (~1-2 hours):** This visit will be conducted at the Adelaide Institute for Sleep Health at Flinders University (or in your home or via videocall if you are unable to attend in person). During this visit, the clinical team will review your post-treatment findings and discuss possible next steps if required.

Reimbursement

To compensate you for the additional time, cost and inconvenience associated with study visits, you will be offered $50 reimbursement for the screening assessment, $30 for the clinical review, $150 for the pre-treatment overnight sleep study and $150 for each overnight treatment study conducted as part of this research project, as well as $30 for the post treatment review. You will not be reimbursed for clinical studies conducted outside the study prior to enrolment. The total reimbursement ($410 if you complete the screening, clinical review, 2 study nights and 1 post treatment review), is typically transacted after completion of your final post treatment review. However, if you are unable to complete all study visits, you will be reimbursed for the time that you completed. You will also be offered reimbursement for public transport or a taxi voucher to get home after the overnight sleep studies if conducted in the sleep laboratory.

Additional costs

There are no additional costs associated with participating in this research project. All medication, tests and assessments required as part of the research project will be provided to you free of charge.

Other relevant information about the research project

We aim to include at least 30 and up to 60 people in this research study.

Pre-screening: You will be screened for eligibility to confirm that the study is suitable for you.

Medical History

The study team will ask you a series of questions about your medical history and sleep condition. This is to make sure that you have one or more of the sleep conditions being investigated in the current study and that the treatments being tested are appropriate for you and are not contra-indicated.

Description of study procedures

Screening visit

Here we will discuss the study protocol in detail, address any questions that you may have and if you are willing, we will seek your informed consent to participate. You will be introduced to the television casting team during this visit who will discuss the potential filming requirements and seek additional permissions.

We will then ask you a series of questions to learn more about you and your sleep condition. This will include several questionnaires about sleepiness symptoms, insomnia symptoms, alertness, and quality of life as determined by the study clinician and research team. Your general health will also be assessed including measuring your blood pressure, your weight, height, neck and waist circumference and we will ask you to open your mouth widely so that we can check the size of your tonsils and tongue to see whether you have a crowded or narrow airway. We may also ask you to perform some simple reaction time, alertness, and performance tasks during this visit.

At this visit, you will be given an under-mattress sensor to take home with you (see adjacent picture). We will provide you information on how to set-up this device. The under-mattress sensors will record your sleep timing, breathing patterns, heart rate and possible snoring episodes every night. You will need to install two phone applications. The first app is called Withings Health Mate. This app will enable data collection of the under-mattress sensor and will also allow you to view the results of your nightly sleep recordings throughout the study. The second app, called Lumin-Hoap, will be used to record your feelings about sleep and daily performance throughout the study. In addition, we will provide you with a FitBit device to use throughout the study to record your activity levels and estimate your sleep timing. We will also ask you to complete a 7-day sleep and food diary. You may be asked to swallow one or more special capsules that travel through the digestive tract over a three-day period to allow us to measure your body temperature rhythm. You may also be provided with a special ring worn on the finger, designed to measure your oxygen levels and estimate your skin temperature.

Clinical review and treatment plan

During this visit, the clinical team will review your diagnostic and home testing findings including your 7-day sleep diary and discuss your proposed individualised treatment plan (see possible options on the following pages). We may also ask you to perform some simple reaction time, alertness, and performance tasks during this visit.

Pre and post treatment testing

Sleep recording equipment

During the pre-treatment and post-treatment sleep studies we will apply a range of stick-on recording devices (electrodes) to the surface of your head, face, and chest to monitor when you are awake and when you are asleep. In addition, a probe on your finger will monitor your oxygen levels, bands will be placed around your chest and abdomen along with airflow sensors or a mask over your nose to monitor your breathing. You will also have ECG monitoring the activity of your heart overnight. An infrared camera will also be used to monitor your body position during sleep. These studies will either be performed in your home (most people with insomnia) or in the sleep laboratory (most people with sleep apnoea). Even if your sleep study is performed in your home, if you are able, you may be asked to come into the Adelaide Institute for Sleep Health at Flinders University on the evening prior to your study to be set up with the recording equipment.

Sleep studies

Pre- and post-sleep study testing: On the nights that you perform a sleep study with all the above-mentioned recording equipment (either at home or in the laboratory), we will ask you to complete several online questionnaires about your sleepiness symptoms, insomnia symptoms, alertness, and quality of life prior to sleep. In addition, we will ask you to complete several questionnaires in the morning about your perceived alertness and how well you slept the night prior. For those who complete an in-laboratory sleep study, we will also ask you to perform some simple reaction time, alertness, and performance tasks 30 minutes after awakening. This will include a driving simulation performance task (shift workers and people with sleep apnoea only).

Upper airway collapsibility index (people with OSA only): In the evening prior to each in-laboratory sleep study, a breathing test to assess how easily your throat area narrows in response to brief pulses of suction pressure (like a vacuum) delivered via a nasal breathing mask will be performed to measure the “upper airway collapsibility index”. To perform this test, two thin tubes with pressure sensors attached will be passed through your nose (one to the back of your nose, the other to the base of your tongue). A nasal decongestant and local anaesthetic will be applied to minimise any potential discomfort. The two thin tubes and nasal mask will remain in place during the test.

In-laboratory sleep studies (most people with OSA): You will be asked to refrain from drinking alcohol on the study days. If you smoke, we will ask that you not smoke while at the sleep laboratory. This might be up to 12 hours. You will also be asked to limit caffeinated beverage intake (coffee, tea, cola, and other soft drinks) to 250 mg/day or less of caffeine (equivalent to ~2 cups of coffee), and not use caffeine within 8 hours of bedtime.

Once the recording equipment is applied and you are ready for bed, you will be given an opportunity to sleep for 8 hours with all the recording equipment in place. Staff will continuously monitor your breathing, heart rate, ECG, and oxygen signals during the night.

Following this, you can use the shower and will be offered breakfast. If required, we can provide a taxi voucher for you to travel home.

Possible treatments

The treatment solutions specific to your needs will be determined in consultation with you and your study clinician with input from the findings of the research team. These will be explained in detail during the clinical review visits. Some people may have both insomnia/body clock disruption and sleep apnoea and may require combination therapy. Equally, one treatment approach may be insufficient to fully resolve OSA and combination therapy with two or more treatments may be required. Possible options may include one or more of the following:

Insomnia or body clock disruption: The clinical team will design a tailored treatment program specific to your needs. This will be a non-drug treatment and will include an initial interview, elements of cognitive behavioural therapy for insomnia (CBTi) such as sleep education, cognitive therapy, stimulus control, sleep restriction, intensive sleep retraining, sleep hygiene and relaxation therapy each of which will be described to you in detial. This will require 4-8 weekly sessions with the sleep psychologist (in person or via videocall) or a similar intervention provided via an online app (e.g., for those located in a rural or remote setting). To deliver a rapid treatment version of stimulus control therapy (intensive sleep retraining), you may be asked to wear a small device on your finger called THIM (image example to the right) during one or more consecutive nights at home. This treatment will involve momentarily getting little sleep overnight, as the device will repeatedly wake you from light sleep. Other potential treatments may include chronotherapy, bright light therapy with ReTimer glasses (image example to the left) or melatonin to help realign potential body clock disruption.

Obstructive sleep apnoea (OSA): In this study we will provide non-CPAP treatments. Possible options as determined by the sleep/respiratory specialist will include a dental device, known as a mandibular advancement device (see adjacent example to the left), to move the jaw forward. This device will be fitted by a dentist. Other potential options include a supine avoidance device such as night shift (see adjacent example to the right). This is a medical device used to discourage people from sleeping on their back where OSA tends to be most severe and, in some cases, only occurs with back sleeping. Other interventions may include oxygen therapy, or a drug called reboxetine. Reboxetine is a medication known as a norepinephrine reuptake inhibitor that has antidepressant properties and has been approved for use in Australia for this purpose for over 20 years. We and others have recently shown that reboxetine can also reduce OSA severity, largely by activating the muscles around the throat area to help prevent the airway from narrowing and closing repetitively during sleep.

Post-treatment review and additional visits: During this visit, the clinical team will review your post-treatment findings. If your sleep disorder or disorders are not adequately resolved, the clinical team will discuss possible next steps if required. This may include additional testing such as overnight sleep studies and/or additional therapeutic interventions as recommended by the treating clinician. We will also seek your feedback on your treatment journey to help us modify and improve potential future individualised sleep disorders care models. Finally, one week after this visit we will call you via telephone to check in and see how your treatment is going.

Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. In this case, alternative pathways to treatment will be discussed with you. If you decide to withdraw from the study the investigators may retain and continue to use any data collected before your withdrawal.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Adelaide Institute for Sleep Health, Flinders University.

What are the possible risks and disadvantages of taking part?

All medical procedures may involve some risk of injury. In addition, there may be risks associated with this study that are presently unknown or unforeseeable. Despite all reasonable precautions, you might develop medical complications from participating in this study. The known risks and discomforts of this study are:

Sleeping in a new environment may cause you to have more disrupted sleep than usual and you may be tired the next day. However, if you sleep in the laboratory and are sleepy the following morning you will be offered the opportunity to resume sleep until you feel rested. You will be offered a taxi voucher to avoid driving while feeling sleepy. Similarly, the insomnia treatment may make you feel sleepy during the day. You should not drive, operate machinery, or make important decisions if you are sleepy, until you feel recovered.

Upper airway collapsibility test (people with OSA only):

Insertion of small tubes through the nose may cause some mild discomfort such as a gagging sensation or irritation of the nasal cavity. However, local anaesthetic spray is provided to minimise any potential discomfort during placement. They are well tolerated once in place.

Reboxetine (Edronax)- for certain people with OSA only:

All medications can cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects.

Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your study doctor may need to stop your treatment. Your study doctor will discuss the best way of managing any side effects with you.

There may also be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study doctor immediately about any new or unusual symptoms that you get.

Contraindications (if any of these apply to you, you should not take reboxetine):

- Known hypersensitivity or allergy to reboxetine or any of its other ingredients.
- Use of monoamine oxidase inhibitors (MAOIs) (e.g., certain anti-depressants or medicines used for panic disorders).
- People with the eye disease called narrow angle glaucoma.
- Pregnant or breastfeeding women.

Special warning: Seizures: Since rare cases of seizures have been reported in clinical studies, EDRONAX should be given under close supervision to people with a history of convulsive disorder and it should be discontinued if the patient develops seizures.

Adverse events: Very common: (more than 10% incidence) insomnia, dizziness, dry mouth, constipation, nausea and increased sweating; common (more than 1–10%) adverse effects include loss of appetite, agitation, anxiety, headache, restlessness, tingling sensations, altered sense of taste, difficulty with seeing near or far (problems with visual focus), fast heart beat, heart palpitations, relaxing of blood vessels leading to low blood pressure, high blood pressure, vomiting, rash, sensation of incomplete bladder emptying, urinary tract infection, painful or difficult urination, urinary retention, erectile dysfunction, ejaculatory pain or delay, and chills. Uncommon less than 1% dilated pupils, spinning sensation, Rare (0.01-0.1%) glaucoma.

Other reported side effects: hyponatremia (very low levels of sodium in the blood), aggressive behaviour, hallucinations, suicidal ideation, cold extremities, allergic skin inflammation, testicular pain, irritability, increased pressure in the eye, bleeding or bruising more easily than normal, fever, shortness of breath when exercising.

If you have renal or hepatic impairment (problems with your kidneys or liver) or are elderly, a lower dose of reboxetine may be recommended for you by the study doctor.

Contact us as soon as possible and seek medical attention if you notice any side-effects.

Appearance on television

As components of this study will be filmed and televised, your personal medical journey may be widely visible to others which may have unwanted social consequences. You are reminded that you can voluntarily withdraw from the study at any time should you wish to do so. However, any information collected before your withdrawal may still be used. If you do withdraw from the filming component, it may still be possible to complete the treatment component of the research study or alternative pathways to treatment will be discussed with you by the study doctor.

What are the possible benefits of taking part?

You will learn more about your sleep condition and you may experience therapeutic benefit. However, there may also be no clear benefit to you from your participation in this research. However, your involvement will further medical knowledge and may improve future care of people with sleep disorders.

What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the interventions being studied. If this happens, your study investigators will tell you about it and discuss with you whether you want to continue in the research project.

Also, on receiving new information, the study investigators might consider it to be in your best interests to withdraw you from the research project. If this happens, the reasons for recommending study withdrawal will be explained to you and you will be provided with alternate options.

Can I have other treatments during this research project?

We want to make sure that the study interventions do not interfere or potentially interact adversely with your current medical treatments. We will ask you to tell the study investigators about any treatments or medications you may be taking, including over-the-counter medications, vitamins, or herbal remedies (e.g., ginseng), acupuncture or other alternative treatments. It is also important that you tell the study investigators about any changes to these during your participation in the research project, so that we can assess your eligibility to continue and allow our medical team to assess any safety concerns. It is important that you continue your other medical treatments as prescribed by your GP and other health professionals. If you have any regular medications that you would normally take during the time that you are at the sleep laboratory, please bring them with you on your visit.

What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team as soon as possible. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing, particularly if you wish to withdraw during the night after taking the study drug.

Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

- Unacceptable side effects
- Decisions made by local regulatory or health authorities.

What happens when the research project ends?

After you complete the final post-treatment review visit, you will receive a final phone call within a week to check how you are. Following this, involvement in this research project ends. If you would like to receive a copy of the study findings upon completion or be contacted for future research participation, please complete the optional sections of the consent form.

If you have any concerns or worries following your final visit, please feel free to call the research team or advise your treating doctor. If participation in this study does not satisfactorily address your sleep disorder, we will offer referral to standard treatment.

Part 2. How is the research project being conducted?

What will happen to information about me?

By signing the consent form, you consent to the study investigators and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. However, as it is the intention to film components of the treatment journey for a sleep health television series, we will seek separate permission for this purpose. If you provide your permission, you may be filmed and thus, identifiable.

The consent forms, medical history, medication history, and other written documentation are stored in locked filing metal cabinets only accessible by those involved in the research and administrative staff. This is kept for 15 years. The sleep studies are stored on a secured section of Flinders University computer network for Adelaide Institute for Sleep Health. This is password protected and only accessible to authorised personnel. Information for recruitment into studies from surveys that you have filled out is kept in another database called REDCap. This is also stored on the Flinders University servers. Security is managed by Flinders Information and Digital Services (IDS). Dr Kelly Loffler is the data custodian and provides access only to authorised investigators.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any scientific publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. In addition, consistent with data sharing requirements for publicly funded research, the de-identified data from this project may also be used in other research, subject to ethical approval of that future research as appropriate.

In accordance with relevant Australian and South Australian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

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.

Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

Who is organising and funding the research?

This research project is being conducted by Professor Danny Eckert and colleagues at the Adelaide Institute for Sleep Health, Flinders University. It will be supported by Artemis Media via grants from various sources including Screen Australia, Screenwest, the South Australian Film Corporation and SBS.

Professor Eckert is funded by a Research Fellowship from the National Health and Medical Research Council of Australia and employed by Flinders University. Two of the potential treatment options for insomnia/body clock disruption that might be used in this study were developed at the Adelaide Institute for Sleep Health, Flinders University (Re-Timer and THIM). Emeritus Professor Leon Lack is an inventor and shareholder in Re-Timer™ that distributes these products. Professor Eckert was an inventor of the treatment prediction algorithm that will be used to inform targeted treatment selections for people with sleep apnoea (Flinders University holds the pending patent rights). However, this is currently used entirely for research purposes and there are no commercial/financial agreements in place for the use of this algorithm at this time. No other members of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the Flinders University HREC.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact:

Research contact person

Name	Professor Danny Eckert
Position	Principal Investigator
Telephone	08 7421 9780
Email	danny.eckert@flinders.edu.au

Study Chief Investigator

Name	Professor Danny Eckert
Position	Chief Investigator and Director of Adelaide Institute for Sleep Health, Flinders University
Telephone	08 7421 9780
Email	danny.eckert@flinders.edu.au

Study Medical Director

Name	Professor Robert Adams
Position	Co-Investigator and Respiratory Physician, Medical Director, Adelaide Institute for Sleep Health, Flinders University
Telephone	08 7421 9751
Email	robert.adams@flinders.edu.au

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	Manager, Research Ethics and Compliance
Position	Flinders University
Telephone	8201 2543
Email	human.researchethics@flinders.edu.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC name	Flinders University Human Research Ethics Committee
HREC Executive Officer	Mr Hendryk Flaegel; Manager, Research Ethics and Compliance
Telephone	8201 2543
Email	human.researchethics@flinders.edu.au

Consent Form - *Adult providing own consent*

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Project Sponsor	Flinders University
Principal Investigator	Professor Danny Eckert
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Others involved in the Project	Ms Carolin Tran, Ms Charmaine O'Reilly, Ms Alison Teare, Ms Alison Leviton, Ms Susanne Taylor and Ms Barbara Toson.
Location	Nick Antic Sleep Laboratory, Adelaide Institute for Sleep Health, Flinders University Level 2, Mark Oliphant Building, 5 Laffer Drive, Bedford Park SA 5042

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Name of Witness* to Participant's Signature (please print) _____

Signature _____ Date _____

* Witness is <u>not</u> to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may <u>not</u> act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Doctor/Experienced Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/ Experienced Researcher† (please print) _____

Signature _____ Date _____

† An experienced member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

OPTIONAL

1) If you wish to find out about the study findings upon publication, please confirm (tick) here. ☐
A copy of the study findings will be sent to the email contact you provided at the time of enrolment after the study findings are published.

2) If you are happy to be contacted for future sleep research studies at the Adelaide Institute for Sleep Health for which you may be eligible please confirm (tick) here. ☐

3) If you are happy for the data collected in this study to be shared with other researchers and research projects as long as your identity is concealed, please confirm (tick) here. ☐

Name of Participant (please print) _____

Signature _____ Date _____