

Participant Information Sheet/Consent Form

Title	Establishing the physiological and sleep disruption characteristics of noise disturbances in sleep
Short Title	The effects of noise disruption on sleep disturbance
Protocol Number	
Project Sponsor	Investigator led NHMRC funded project
Coordinating Principal Investigator/ Principal Investigator	Prof. Peter Catcheside
Location	Adelaide Institute for Sleep Health, Mark Oliphant Building, Flinders University

Part 1 What does participation involve?

1 Introduction

Wind farms are continually being constructed throughout the world to increase sustainable energy production. There has been speculation that wind farm noise could cause adverse health outcomes including sleep disturbance. However there is no conclusive evidence to support or refute that windfarm noise is any more or less disturbing to sleep than other noise types. This study aims to investigate the sleep disturbance effects of wind farm noise compared to traffic noise by assessing sleep in a controlled laboratory environment.

You have been invited to take part in this research project, which is called “Establishing the physiological and sleep disruption characteristics of wind farm versus traffic noise disturbances in sleep”. You have been invited because you live either close to a wind farm, a quiet rural area or a busy road. Your contact details were obtained by the Survey Research Centre, Edith Cowan University, Western Australia, or you have directly contacted our research team to volunteer for the study.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the processes involved with taking part. 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 you can take part, you might want to talk about it with a relative, friend or local health worker.

Participation in this research is voluntary. If you do not wish the participant to take part, you do not have to.

If you decide you want the participant 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 taking part in the research project
- Consent to being involved in the research 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.

2 What is the purpose of this research?

Negative effects of sleep disorders and noise on sleep quality, quality of life and health outcomes are well established, supporting the importance of good sleep for normal daytime functioning and for good physical and mental health.

The expansion of wind farm facilities nationally and internationally has been associated with widespread community complaints regarding sleep disturbance and adverse health effects. Theoretically, noise from wind farms has the potential to adversely affect sleep, health and wellbeing through two possible main mechanisms; longstanding sleep disturbance from frequent brief arousals and biological activation responses to environmental noise, and/or chronic insomnia that could develop from ongoing difficulty falling and maintaining sleep in response to noise disruption or annoyance. However, high quality evidence from well-designed studies using direct measures of sleep and noise are remarkably lacking, so further studies are needed to better understand the sleep disruption characteristics of wind farm noise compared to other noise types already known to disturb sleep.

The aim of this project is to use the best available measurements of sleep and physiological activation responses to a range of noises to systematically evaluate noise impacts on overall sleep quality and more subtle features of sleep disturbance (brief arousals and physiological activation responses to environmental disturbances).

This research has been funded by the National Health and Medical Research Council and will be one of the first studies to evaluate wind farm noise impacts on direct measurements of sleep.

3 What does participation in this research involve?

You have been invited to participate in this study because you live within the vicinity of a wind farm, in an area with high exposure to urban traffic noise or a quiet rural area.

If you decide to take part in this research project, you will be asked to attend the sleep laboratory for 7 consecutive sleep study nights. Each bedroom is similar to a hotel room, with a king-size single bed, ensuite and shower facilities, and shared lounge, kitchen and washing facilities you would be welcome to use.

You will be invited to attend the Sleep Laboratory for 7 consecutive overnights and booked for your stay subject to your, the facility and experimenter availability. We recommend that you stay an additional 1-2 nights after the 7 experimental nights, to help recover from any potential sleep disturbance you may feel from previous nights. Whilst you are not obligated to stay, it is very important that you understand the potential for this study to disturb sleep and cause sleepiness, and that you feel sufficiently rested before you leave the laboratory at the end of the study. Prior to your scheduled laboratory overnights, you will be given the opportunity to discuss the project in more detail and have any questions you might have answered via phone, email or in person as is most practical. You will then be asked to complete a consent form to confirm your willingness to participate, and provided with a sleep monitoring device (similar to a FitBit) and a sleep diary, which you will be asked to wear and complete in the 2 weeks leading up to the commencement of the laboratory protocol. These materials will be posted to you, along with a range of psychological questionnaires to assess handedness, noise sensitivity, spatial hearing, fatigue, your habits and beliefs about sleep, depression, anxiety and stress. You will be asked to complete these questionnaires in your own time before attending the laboratory study.

For the laboratory study, you will be asked to travel to the Sleep Laboratory to arrive at approximately 4pm on the scheduled day of arrival. Upon arrival, you will be familiarised with the laboratory environment, equipment and procedures, and given the opportunity to have any further questions you might have addressed. You will then be given a chance to settle into the

private, self-contained bedroom that you will occupy for the rest of the time. After you have had dinner, we will ask you to change into personal sleep attire ready for the first night. You will be set-up by a trained sleep technician for a full sleep or polysomnography (PSG) study. This is the same test used for diagnosing a range of sleep problems and involves applying harmless non-invasive electrodes to the scalp, face, torso and legs to measure brain activity, eye movements, muscle activity, leg movements, breathing signals and a pulse oximeter (a probe that clips to the finger to measure blood oxygen levels via light transmission through the finger). You will be asked to remain in your bedroom until lights out time, undertaking a quiet activity of your choice in bed. Lights out time will be determined from your average sleep diary bedtime and you can choose when you would like to wake-up. During the night, the sleep technician will monitor your sleep signals to ensure data quality, and your safety and welfare. The first night will be an adaptation night to help you get used to the different sleep environment and equipment. On successive nights, a range of wind farm and traffic noises will be played at different levels during sleep through a large loudspeaker positioned near the foot of the bed. There is no risk of hearing damage given noise amplifier and speaker limitations restrict noise reproduction within sound pressure levels relevant to real-world wind farm noise, which are well below levels associated with hearing damage. Noises and quiet periods will be randomly distributed within and between nights in a computer-generated random order, and neither you nor the overnight sleep technician will know what type or level of noise is being played. Apart from different noises and levels, the evening and overnight sleep procedures will otherwise be the same across nights for all study participants.

Each morning, immediately after you awaken, you will be asked to provide a series of 5 saliva samples (4 at 15-minute intervals immediately after waking and one 12 hours later), using a small cotton swab placed into a tube. These provide a measure of the sharp rise in cortisol levels after waking (cortisol awakening response) and gradual decline across the day, which are markers of the hormonal regulation of sleep and stress. On a single occasion, a very small hair sample will also be taken as a measure of longer-term cortisol levels and stress. Each morning, you will also be asked to complete a laboratory sleep diary that asks specific questions regarding your perceived quality and quantity of sleep, and the number and type of noises that you heard during the night. You will then be provided with breakfast and given an opportunity to relax whilst still wearing the PSG recording equipment before some simple daytime performance and hearing tests. These will take approximately one to two hours and include a reaction time (Psychomotor Vigilance Task), sleepiness (sleepiness scale), mood (questionnaire), balance (balance board), and concentration (digit-symbol substitution) tasks.

After the daytime tests, you will be free to relax in the lab (i.e., your bedroom or participant lounge room) or leave the laboratory for the remainder of the afternoon and asked to return to the lab by 6pm for dinner, if departing for the day. If you decide to leave the laboratory and drive a vehicle, you will be asked to consider your alertness levels and ability to drive. If you elect to drive a vehicle during your laboratory protocol, we will ask you to sign a driving disclaimer to indicate that you understand the risks and feel safe to drive.

We will provide you with all main meals and snacks that you may help yourself to at any time and pack to take with you if departing from the laboratory following morning testing procedures. Provided foods will be mostly based on self-reported food preferences that we will collect from you once informed consent to participate in the study is given. We cannot guarantee that we can cater to all dietary requirements, however we will do our best to accommodate your preferences.

Each evening after dinner, we will conduct one of seven listening tests that are designed to assess your levels of annoyance, disturbance and acceptability for sleep toward road traffic and wind farm noise. These tests will be spread out during each evening of your visit, and will be

between 25-60 minutes long, depending on the test. You will be informed of the duration of each test prior to starting. During each test, you will be exposed to a range of pre-recorded noises, similar or the same as those played during the overnight sleep tests. Following the presentation of each noise, you will be asked to rate noise features such as loudness, your level of annoyance and how acceptable you think the noise would be if you were trying to sleep. In other parts of the listening tests, you will be provided with a hand-held device with a volume adjustment knob, which you will be asked to use to control the volume of the noise. Your physiological responses to noise including brain activity and heart rate changes will also be measured. We will also use these measures to ensure you remain awake and attentive to the noise samples during the test, and to detect if you fall asleep.

Clinical Audiology Assessment. During one afternoon of your laboratory stay, you will be booked for a 60-minute formal hearing assessment conducted by a qualified audiologist at the Flinders Medical Centre Audiology Clinic. The time of this booking will be subject to audiologist and audiology booth availability. The Audiology Clinic is a 15-minute walk from the Sleep Laboratory and it is recommended that you walk to this appointment. In the unlikely event that you feel unable to walk (e.g., due to sleepiness) please advise staff and a taxi will be arranged to take you to your appointment and back to the sleep laboratory. This will be a comprehensive assessment of your hearing within the audible range (125-8000Hz), including an ear tympanometry test (to assess the condition of the middle ear and mobility of the eardrum), otoscopy (i.e., visual examination of the external auditory canal), and acoustic reflexes (i.e., involuntary muscle contraction in the middle ear in response to a high-intensity sound stimuli, but within standardised safe limits). This is a routine test performed in audiology centres and in ear, nose and throat clinics and poses no risk to hearing. This appointment will last 45 min and results of the assessment will be available immediately.

At the conclusion of the protocol, you will be debriefed, any questions answered and reimbursed for your time, including compensation for travel expenses and involvement in the study.

If you live near wind turbines and own a health-tracking device (e.g. a FitBit), you may be asked to volunteer to participate in a follow-up study aiming to examine for potential relationships between health-tracker data, local weather and power output data from the wind farm nearest to your home. If you volunteer to partake in this phase of the study, you will be asked to provide consent for research personnel to access your health-tracker data for matching to wind farm power output data relevant to your residence. You would also be asked to keep a simple diary to report when you are in the area versus away from the wind farm. This will help test for potential relationships between your activity levels, sleep and heart rate with wind farm power output and local weather conditions. All data collected will be fully de-identified and only group data will be reported although research staff will be able to provide you with a report about your own data if you are interested.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way to avoid researchers, participants or people reading the final report jumping to conclusions not backed up by reliable study findings.

If you agree to participate in this study, you will be asked to sign the Participant Consent form to confirm that you understand what is involved in this project, and that you are free to withdraw at any time.

There are no costs associated with participating in this research project. You will be reimbursed \$100 per study night, plus \$200 upon successful completion of all 7 overnights for the time and efforts invested in the project and any out-of-pocket expenses incurred during the study. We will reimburse \$400 for travel expenses from rural areas and \$100 for urban travel to the university.

4 Other relevant information about the research project

This project will be carried out in the homes of those participating in the study, and at the Adelaide Institute for Sleep Health sleep research laboratory at Flinders University and involves researchers across Australia working in collaboration. The project in which you are being invited to participate is one of four concurrent projects being run with the aim of establishing the nature of potential sleep disturbance effects from wind farm noise. A total of 80 people will be invited to participate in this project.

5 Do you 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.

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 you can or cannot take part, or that you can take part and then be withdrawn, will not affect your routine care, relationship with professional staff or relationship with Flinders University.

6 What are the possible benefits of taking part?

There will be no clear benefit to you from your participation in this research. However, any abnormal hearing or sleep study findings will be discussed with you and made available to you to follow-up with your usual doctor.

The overall study findings are designed to help clarify what effects wind farm noise have on sleep, and if current noise guidelines designed around traffic noise remain appropriate for the different noise features of wind farm noise.

7 What are the possible risks and disadvantages of taking part?

All of the procedures that will be used are either routine sleep laboratory methods or low risk procedures (sounds played during sleep). However, given some sleep disturbance you may feel that you have not had a good night's sleep and so you may be more tired than normal in the morning and the next day. It is very important that you are aware of this and avoid driving and other activities where sleepiness could be dangerous to you or others, until you have caught up on sleep.

8 What if you withdraw from this research project?

If you do consent to taking part, you may withdraw at any time. If you decide to withdraw from the project, please notify a member of the research team before withdrawal. A member of the research team will inform you if there are any special requirements linked to withdrawing. If you do withdraw, you will be asked to complete and sign a 'Withdrawal of Consent' form; this will be provided to you by the research team.

If you decide to leave the research project, the researchers will not collect additional personal information from you, although personal information already collected will be retained to ensure the most meaningful results of the research project, and to comply with law. You should be aware that data collected up to the time of withdrawal will form part of the research project results. If you do not want your data to be included, you must tell the researchers when withdrawing from the research project.

9 Could this research project be stopped unexpectedly?

This research project is very unlikely to be stopped unexpectedly due to the low risks involved and the type of funding arrangement.

10 What happens when the research project ends?

If you would like to be informed about the study outcomes, the final project results are anticipated to be available in December 2021 and you are welcome to contact the Adelaide Institute for Sleep Health on (08) 8201 2377 at that time.

Part 2 How is the research project being conducted?

11 What will happen to information about the participant?

By signing the consent form you consent to the research team 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 strictly confidential, and will only be accessible to the staff directly involved in this study. All records will be kept confidential and anonymous using a unique study identifier instead of your name on all study records except the consent form, which will be stored separately from study data. Hard copy records will be locked in a filing cabinet in a secure facility at the Adelaide Institute for Sleep Health. Electronic study files will be stored on a secure Flinders University server that requires a Flinders University username and password to access.

You will be assigned an identification number according to your chronological participation in the experiments and will be de-identified from your real name/s. Documents with names will be stored separately to information with participant ID numbers to further ensure anonymity and confidentiality. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. The personal information that the research team collect and use is basic demographic information, such as age, gender, and location of residence.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your express permission.

12 Complaints and compensation

Participation in this study does not impact on your basic legal right to seek compensation; however, if you do suffer harm, you may receive compensation without litigation. Compensation may be available if your injury or complication is caused by the procedures, or by the negligence of any of the parties involved in the study. If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies.

If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for your injury or complication free of charge as a public patient at any Australian public hospital.

13 Who is organising and funding the research?

This research project is being conducted by Flinders University and is funded by the National Health and Medical Research Council (NHMRC). Flinders University may benefit financially

from this research project if, for example, the project assists Flinders University in any commercial enterprise.

You will not benefit financially from your involvement in this research project even if, for example, knowledge acquired from your information proves to be of commercial value to Flinders University. In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to Flinders University, the researchers or their institutions, there will be no financial benefit to you, the participant, or your family from these discoveries.

Flinders University is receiving payments from the National Health and Medical Research Council for undertaking this research project. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

14 Who has reviewed the research project?

The grant funding this project underwent rigorous scientific review by the NHMRC in 2015. All research in Australia involving humans is also 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 Southern Adelaide Clinical Human Research Ethics Committee. Some of the research team are employees of the Southern Adelaide Local Health Network (SALHN) requiring a further process of governance review. This project has also been registered on a publically available trials registry.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research 2007 (updated 2018)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

15 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 problems which may be related to involvement in the project, you can contact any of the following people:

Research contact person

Name	Gorica Micic
Position	Post-Doctoral Research Associate
Telephone	08 8201 2377
Email	gorica.micic@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	Southern Adelaide Local Health Network
Position	Director, Office for Research
Telephone	8204 6453
Email	Health.SALHNOfficeforResearch@sa.gov.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	Southern Adelaide Clinical HREC
Position	Executive Officer

Telephone	8204 6453
Email	Health.SALHNOfficeforResearch@sa.gov.au

Reviewing HREC approving this research and HREC Executive Officer details

Local HREC Office contact

Institution	Southern Adelaide Local Health Network
Position	Research Governance Officer
Telephone	8204 6453
Email	Health.SALHNOfficeforResearch@sa.gov.au

Consent Form – Adult providing own consent

Title Establishing the physiological and sleep disruption characteristics of noise disturbances in sleep

Short Title The effects of noise disruption on sleep disturbance

Protocol Number

Project Sponsor Investigator led NHMRC funded project

Coordinating Principal Investigator/ Principal Investigator Prof. Peter Catcheside

Location Adelaide Institute for Sleep Health, Mark Oliphant Building, Flinders University

Declaration by Person Responsible

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 project 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) _____

Name of Witness (please print) _____

Relationship of Witness to Participant _____

Signature of Participant _____

Signature of Witness _____ Date _____

Declaration by 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 Researcher† (please print) _____

Signature _____ Date _____

† An appropriately qualified 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.

Form for Withdrawal of Participation – Adult providing own consent

Title Establishing the physiological and sleep disruption characteristics of noise disturbances in sleep

Short Title The effects of noise disruption on sleep disturbance

Protocol Number

Project Sponsor Researcher led NHMRC funded project

**Coordinating Principal Investigator/
Principal Investigator** Prof. Peter Catcheside

Location Adelaide Institute for Sleep Health, Mark Oliphant Building, Flinders University

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine health care, or relationships with the researchers or Flinders University.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Senior Researcher must provide a description of the circumstances below.

Declaration by Researcher[†]

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Researcher (please print) _____

Signature _____ Date _____

[†] An appropriately qualified member of the research team must provide information concerning withdrawal from the research project.

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