WOOLCOCK
LEADERS IN BREATHING & SLEEP RESEARCH

Participant Information Sheet

Title: The effects of 3 days of simulated wind farm infrasound, sham infrasound and traffic noise on health: A laboratory based randomised, 3 way cross-over study

Short title: Laboratory based effects of infrasound

Co-Principal Investigators: A/Prof Nathaniel Marshall (Epidemiologist at the Woolcock Institute and University of Sydney)

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Introduction

You are invited to take part in a research study aiming to determine the effects of noise on various health outcomes.

The drive to develop renewable energies to reduce fossil fuel consumption has resulted in increasing efforts to harvest wind power as a source of renewable energy delivery. This need has resulted in the construction of multiple wind turbine clusters or "wind farms" in rural areas in Australia to generate power.

Wind power programs have been opposed by a number of communities, in part due to claims that wind farms pose a risk to health. There is currently a lack of research exploring the effects of wind farms, in particular, inaudible levels of noise (called "infrasound") on various health outcomes. Some individuals are more sensitive to noise than others, and we will be looking for these individuals to participate in this research study.

This study will measure the impact of exposure to noise, including infrasound, on multiple dimensions of human health in individuals who report increased noise sensitivity.

Your participation is voluntary

Participation in this study is entirely voluntary. You do not have to take part in it. If you do take part, you can withdraw at any time without having to give a reason. Whatever your decision, please be assured that it will not affect your relationship with the staff who are caring for you. It will also not affect any clinical care you may receive in the future from anybody associated with the Woolcock Institute.

Who is organising and funding the research?

The Woolcock Institute of Medical Research is organising this research. This project is funded by the National Health and Medical Research Council using tax payer funds with the authority of the Parliament of Australia. No energy producing company (either renewable or non-renewable) or any other external entity with any conflict of interest has any role in this project. Chief investigator Dr. Renzo Tonin has had previous appointments as a consultant for the NSW Department of Planning on several wind farms in New South Wales, Australia.

What are you required to do?

By now you would have completed questionnaires from our website and have agreed to be further screened if our questionnaires suggest that you are a suitable candidate for this study. You will be asked to attend a face to face screening appointment, which will take approximately 4 hours. Leading up to this appointment, you will be sent a watch like device called an actiwatch to wear for 7 days that records movement and provides insight on your sleeping and waking patterns. Results will be assessed after the actiwatch is returned when you arrive for your appointment. You will be asked about your medical history, undertake various hearing tests and a psychological examination with trained clinicians. You will be shown around the facility where the study will take place to ensure you understand the protocol and that you are able to cope being confined in a sleep laboratory for 72 hour periods for each of the 3 study visits. There is a possibility that you may choose not to take

part in this study or we may suggest that this is not suitable for you on the grounds of the hearing tests or the psychological examination.

If you are considered suitable for this study; you will then be invited to participate in the **3 laboratory study visits** at the Sleep Research suite at the Woolcock Institute. During each study visit, which will run continuously for 4 days and 3 nights, you will be exposed to continuous background noise for the 72 hours. The 3 types of noise we will play in the background are:

a. Loud audible traffic noise – Such as you would experience living next to a major road in Sydney.

b. Infrasound – Generated from custom made speaker boxes to mimic the sound that wind farms produce. You will not be able to consciously hear this sound.

c. Quiet – Which you will not be able to differentiate consciously from the infrasound (simulated wind farm noise).

Laboratory Study Visits

For each of the 4 day visits, you will be required to attend the Woolcock Institute on Friday at approximately 10am. You will stay in our sleep laboratory for 3 nights and leave at approximately 12pm on Monday. You will stay on your own in our purpose built sleep laboratory, which is similar to a small studio apartment with internet access. We will estimate your usual sleep and wake time using the wrist actigraph you have been wearing. Based on this information we will allow you to go to sleep 30 minutes before your usual sleep time. You will be woken up 30 minutes after your usual wake up time but no later than 7:30am.

All meals during your stay will be provided. Please let the researcher know if you have any specific dietary requirements before you attend your first visit of the study. .

During your stay in the sleep laboratory, you will not be permitted to have any visitors at the Woolcock Institute, however you will be able to make phone calls outside of testing and sleep periods.

What Should I bring to each visit?

Nightwear – Pyjamas or shorts/t-shirt must be worn. Please do not wear polyester.
Daytime Clothes – Enough to last 4 days, including underwear, socks and shoes etc. Please wear comfortable clothes that you don't mind getting dirty as there is a chance of some paste getting on your clothes when applying monitoring equipment.
Toiletries – Please wash your hair and shower before the day of your study, this will improve the quality of the recordings. Avoid using any hair products (hair gels, hair spray etc.) prior to and during your stay. Please bring toiletries including shampoo/conditioner, toothbrush, toothpaste etc.
Medication – Take your usual prescribed medications and bring them with you, unless your doctor advises you otherwise. No medications are kept in the sleep unit or will be provided to patients.
Entertainment – Please bring along laptops, tablets, smartphones, books or work and chargers that you may wish to use during your visit. You will not be able to wear headphones during your study visits.

We encourage that you bring something to do during your weekend visit as there will be time available for you to do work and recreation opportunities where there will be no testing. Internet access will be provided and access to Netflix will also be provided for you to use outside of testing and sleep periods.

Neither alcohol, tobacco nor caffeine consumption is permitted or will be provided during your visits to the Woolcock.

Study testing procedures

Throughout the visit you will be asked to perform various tests and answer questionnaires, which will include the following:

1. **Neurocognitive testing (Four times a day)**

This testing will last approximately 30 minutes. You will have a chance to practise the tasks. The tasks are:

- **Psychomotor Vigilance Task (PVT)** – This is a simple 10 minute reaction time test which uses a hand held device with response buttons. You will be asked to pay attention to a visual target and respond to it as quickly as possible by pressing the button with your dominant hand.

- **N back** – This is a 5 minute working memory task which tests your immediate recall to letters displayed on a screen in a particular order.

- **Tower of London** – This 5 minute task asks you to rearrange certain shapes on the screen to reach a required target using a designated number of moves.

- **Karolinska Drowsiness Test (KDT) –** This is a simple 7.5 minute test involving the recording of your brain wave activity (called electroencephalography – EEG). You will have already been set up with the EEG equipment prior to the tests. Looking at a large black dot on the wall, you will be asked to sit quietly with your eyes open for 2.5 minutes and then closed for 2.5 minutes, and again open for 2.5 minutes. During this time we ask that you sit quietly and not to move. Your resting brain activity (EEG) will be recorded during this time and we will analyse your EEG data to assess your alertness levels.

2. Polysomnography (Sleep study)

- **Electroencephalography (EEG) –** EEG is a non-invasive procedure that measures the electrical activity of your brain. You will have electrodes and EEG conductive gel/paste placed on your face and scalp to measure brain activity (EEG), eye movement (EOG), muscle movements (EMG) and heart rate (ECG). These electrodes will be plugged into a monitoring box which will be portable. The electrodes will be worn during the day and night for approximately 19 hours each day with 3-4 hour breaks in the early morning and the late afternoon. Additional electrodes sensors will be applied measuring breathing patterns, body position and extra electrodes for muscle movement during the overnight sleep recordings (polysomnography).

3. Questionnaires asking about general health, sleep and mood

- **Insomnia Severity Index (ISI)** – You will be asked to respond to 5 questions about your sleep during your visits.
- **Depression Anxiety and Stress Scale (DASS-21)** – You will be asked to respond to 21 questions about your mood at the end of each visit.
- **Warwick Edinburgh Mental Wellbeing Scale (WEMWB)** – You will ask 14 questions about your feelings and thoughts at the end of each visit.
- **Noise Annoyance Scale (NAS)** – You will be asked to plot along a line how annoying you find the sound before every testing period.
- **Visual Analogue Scales (VAS)** – You will be asked to plot along lines in regards to any symptoms you may experience during the noise exposure before every testing period.

4. Pulse wave analysis and blood pressure

This is a test to measure your blood pressure and characteristics of your pulse waveform, which gives information about the blood vessels in the body. It is a simple armband device, like a blood pressure cuff, which you will wear for 24 hours on the Saturday of the study visit. The device will periodically take measurements from you whilst you are awake and asleep. Whilst the cuff is inflated and measuring your blood pressure, you may experience some discomfort, however this will stop when the cuff is released.

5. **Pulse wave velocity**

This is a test to measure blood flow characteristics from your aorta. It is a painless test and will require you to wear a blood pressure cuff around your thigh which will inflate whilst simultaneously a probe like device (tonometer) will be placed on the carotid artery of the neck across the skin.

6. **Blood tests**

On the last morning of each weekend visit (Monday) fasting blood will be taken from a vein in your arm using standard procedure with a needle and syringe to test for markers of inflammation.

7. **Urine test**

For a 24 hour period during the study (Sunday) you will be asked to collect all urine that you pass and it will be sent for testing. It will be tested for stress and inflammation markers in the urine. As part of standard procedure for this test, we require participants to avoid caffeine (coffee, tea, chocolate) and alcohol for 3 days leading up to and during their visits. Some medications may affect the results of this test, please let the study coordinator know during your screening visit if you are taking any medication currently.

8. **Endothelial function test (15 minutes)**

This test will examine the flow of blood in your fingertips. A thimble-like fingertip cover will be placed on the index fingers of each hand and will measure blood flow before and after a blood pressure cuff is placed around your arm and inflated for 5 minutes. This technique is safe and has no long term side effects. You will feel some squeezing around your arm whilst the cuff is inflated which some people describe as a feeling of heaviness and/or pins and needles when the cuff is inflated. This will stop once the cuff is released.

9. **<u>Neurotological examination (2 Hours)</u>**

On Monday of each testing weekend we will undertake a series of tests of your hearing and balance in the following order.

- **Bedside examination -** You will be asked some questions regarding your medical history that may affect the following tests. You will be taken through the matted Romberg test where you will be asked to stand on a mat with your eyes closed for 10 seconds. You will then be asked to complete the Unterberger test where you will be asked to walk along a line marked out by the examiner with your eyes closed. Both of these test will be done to assess your balance and your vestibular function.

i. **Otoscopy** – A quick one minute inspection using an otoscope to check the ear canal that it is clear of wax and there is not any blockage within the ear canal.

ii. **Tympanometry** – A 5 minute test that is required to be done before the OAE to test for middle ear function through measuring the movement of the eardrum in response to pressure changes.

- **Videonystamography (VNG) (10 minutes)** – In this task you will wear a different goggle-like device that will be equipped with a camera that will track your eye pupils. You will then be asked to keep your eyes wide open and stare straight ahead or slightly to each side as instructed by the examiner. Following this, you will be asked to lie on a bed. The examiner will instruct you to roll your entire body to each side for approximately 20 seconds for each side.

- **Audiometry (20 minutes)** – Two tests will be done to measure hearing acuity. The first test you will be asked to wear headphones and be asked to respond by pressing a button every time a tone is played. In the second test, words will be played through the headphones and you will be asked to repeat the word that was played.

- **Otoacoustic Emissions (OAE) (10 minutes)** – This test will measure the function of the cochlea organ in your ear in response to sound being played. A foam earbud tip will be inserted into one ear and a tone or click will be played through the earbud, the response from the outer hair cells of the cochlea will be measured. Prior to this test a tympanometry and otoscopy must be performed.

- **Video Head Impulse Test (VHit) (20 minutes)** – You will be asked to sit on a straight backed chair, wearing a pair of video glasses and asked to focus on a near target on the wall. The examiner will hold your head with both hands and deliver 10-20 degree rapid head rotations to the left or right sides whilst you are focussing on a target on the wall. The movement of your eyes in response to the head movement will be captured by a fast, lightweight camera attached to the glasses. Head rotations will be delivered in the horizontal and vertical planes to test the 3 pairs of semicircular canals.

- **Vestibular Function test (30 minutes)**

  i. **Ocular Vestibular Evoked Myogenic Potentials (oVEMP)** – In this test the balance organs in the ears are stimulated by playing loud sounds through vibrating the forehead with a hand-held device for 30 seconds at a time. The reflex is measured through stick-on electrodes placed beneath the eyes, while you look up (30 degrees) at a fixed target. Looking up activates the eye-muscles and yields a surface recording that we call the OVEMP.

  ii. **Cervical Vestibular Evoked Myogenic Potentials (cVEMP)** – In this test the balance organs in the ears are stimulated by playing loud sounds through headphones. The reflex is measured through stick-on electrodes placed on the neck while you lift or turn your head to activate the muscles. This produces a small contraction of the neck muscles, for 30 seconds at a time. The cVEMP will be measured from several neck muscles at the front and back of the neck.

10. Discharge

Once you have completed the testing on the Monday morning, you will be free to leave the laboratory at approximately noon when the visit is concluded. If you are feeling tired you are advised not to drive or operate machinery or make important decisions until you feel you have recovered. You will be offered taxi vouchers for travel to and from the Woolcock Institute for each visit.

11. Are there likely to be any side effects or risks?

- **Blood collection** – You might experience some discomfort at the site from which the blood will be taken. Approximately 40mL of blood will be taken from your arm each visit. This means that over the 3 weekend visits a total blood volume of 130mL will be taken from your arm. This is less than one routine blood donation (400mL). There is also a risk of some minor bruising or infection at the site, although the latter is rare.

- **Noise during sleep** – You will be exposed to traffic noise during one of your study visits. We expect that this will disrupt your sleep and you may find the experience stressful both during sleep and wakefulness. Therefore it is possible that you may feel tired the following morning. You must be careful not to drive, operate machinery or make important decisions until you feel recovered. If you do feel tired and unfit to drive, let staff know and a taxi voucher can be arranged for you to get home after the visit.

12. What are the benefits of this study?

It is very unlikely that this research will be of direct benefit to you. We intend that this research study will clarify whether there are any measurable adverse health effects from exposure to infrasound as is normally generated by wind farms. This study should therefore help to guide future public policy about the health effects of wind farms and traffic noise.

13. Can I have treatments for health conditions during this research project?

You should not stop any treatments you are receiving for existing medical conditions during this study. You should however inform our staff of any treatments you are taking for any condition. During the study if your health care practitioners recommend changing any of your treatments you should tell the study staff as soon as you are able. Treatments that we need to know about include prescription medication, implantable medical devices or changes to any setting of these, over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments.

14. What if I withdraw from this research project?

If you decide to withdraw from this research project, please notify a member of the research team as soon as you are able. If you do withdraw your consent during the research project, the study co-ordinator and relevant study staff will not collect additional personal information from you, although personal information, data, blood and urine samples already collected will be retained. You should be aware that data collected by the research project up to the time you withdraw will form part of the research project results.

15. Costs and payment

Participation in this study will not cost you anything. You will be offered $1000 reimbursement for your time upon completing the study. You will also be offered taxi vouchers to and from the research institute for each study visit. Reimbursement for travel to and from each study visit for private vehicle use or public transport will be available. We ask you to provide us with a receipt for these expenses. If you have your own vehicle we can offer you free parking in our secure carpark underneath the Woolcock whenever you are scheduled to visit us.

Please call or email the study coordinator to organise payment or parking.

16. What will happen to information about me?

By signing the consent form you consent to the study coordinator 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. There is an increasing expectation that public funded research data be made available to other researchers; as a result we may make a non-identifiable dataset available in an open access online data repository to be shared. Any information that could be used to identify you such as your date of birth, address or ethnicity will not be included and therefore will make it impossible for you to be identified within this dataset.

Your data will be identified by a code number that we will allocate to you as soon as you agree and consent to participate in the study. The key linking your identity to your participant code will be stored in a secure electronic format accessible only by the lead researchers. Your participation will therefore remain anonymous. Access to your data will only be granted to designated and qualified research personnel, and your data will be held for a minimum of 15 years.

It is anticipated the results of this research project will be published and/or presented in a variety of forums. In any publication or presentation, information will be provided in such a way that you cannot possibly be identified. Any information obtained for the purpose of this research 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.

In accordance with Australian privacy and other relevant laws, you have the right to request access to the 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. Please contact Associate Professor Nathaniel Marshall (Nathaniel.marshall@sydney.edu.au) if you would like to access your information.

17. What will happen to my test samples?

Blood and urine samples will be collected from you as part of this research, as described above. We would like all participants to provide these, however this is not mandatory and if you do not wish to then we ask that you discuss this with a researcher at your screening appointment.

All samples taken are to be used specifically for research purposes related to the health effects of sound, so will not form part of any subsequent medical care.

Samples may be stored in a freezer within the research institute for up to 10 years after the protocol has completed or they will be sent to a local pathology lab for analysis following each visit. If any future testing is to be performed on the samples for any currently unspecified future research, then further ethical consent would be requested from the appropriate Human Research Ethics Committee and informed consent would be obtained from you. Following this period, the samples would be destroyed. Your samples will not be utilised in the future for any commercial purposes.

Only researchers involved in this protocol will have access to the samples. As described in the section above, your samples will be identified by a code number that is allocated to you once you agree to participate in the study. The key linking this code to you will be securely stored and only accessible by the lead researchers. It is therefore only possible for the lead researchers to identify the samples as belonging to you.

18. Could this research project be stopped unexpectedly?

Although very unlikely, this research project may be stopped unexpectedly 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.

19. Further information

When you have read this information, a member of the research team will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please contact the study coordinator or the Co-Principal Investigator A/Prof Nathaniel Marshall (Nathaniel.marshall@sydney.edu.au).

20. Compensation for injuries or complications

If you suffer any injuries or complications as a result participation in 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.

21. Trial Registration

This study is registered with the Australasian and New Zealand Clinical Trials Registry (ANZCTR) - www.anzctr.org.au (ACTRN12617000001392)

22. Ethics approval and complaints

This study has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney Local Health District Protocol no **X16-0073**. Any person with concerns or complaints about the conduct of this study should contact the Executive Officer on 02 9515 6766 and quote protocol number X16-0073.

THIS INFORMATION SHEET IS FOR YOU TO KEEP

WOOLCOCK
LEADERS IN BREATHING & SLEEP RESEARCH

PARTICIPANT CONSENT FORM

Laboratory based effects of infrasound

I , ... ***[name]***

of..... ***[address]***

have read and understood the **Participant Information Sheet Version 3.2 24th July 2017** for the above named research study

and have discussed the study with

..... (insert name of study investigator)

I have been made aware of the procedures involved in the study, including any known or expected inconveniences, risks, discomforts or potential side effects and of their implications as far as they are currently known by the researchers.

I hereby give consent for my non-identifiable data collected in this research study to be included in a dataset that will be published online and agree that confidential information such as my age and gender will only be used.

I hereby give consent for biological samples (Blood and Urine) to be collected.

I freely choose to participate in all or part of this study and understand that I can withdraw at any time.

I also understand that my participation in the research study is strictly confidential and any information collected about me will be handled as such.

NAME: .....

SIGNATURE: .....

DATE: .....

NAME OF WITNESS: .....

SIGNATURE OF WITNESS: .....