WIND FARMS
AND HEALTH

WOOLCOCK
LEADERS IN BREATHING & SLEEP RESEARCH

Participant Information Sheet

Title: Assessing the health effects of six months of simulated wind farm infrasound: A community-based randomised controlled trial

Short title: Community based study of health effects of infrasound

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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 six months of exposure to 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 research staff and it will also not affect any clinical care you may receive in the future from anyone associated with the Woolcock Institute of Medical Research.

If you share your bedroom with another person please discuss your participation in this study and allow them to read this information statement. Although they will not be included in this study they will be sleeping in the bedroom with the infrasound or sham speakers operating. If they agree, we would like them to acknowledge this by co-signing the consent form.

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 government funds with the authority of the Parliament of Australia. No energy producing company (either renewable or non-renewable) or any other 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 a set of questionnaires on 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 wear an Actiwatch for one week and this measures your movement during the day and at night to look for sleep problems. 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 sleep pattern ormental health reasons.

If you are considered suitable you will then be invited to participate in this 6 months randomized parallel group study to measure the impact of exposure to infrasound on your health.

Participants will be randomly selected to receive speakers for the bedroom that deliver either:

1. Wind farm simulated infrasound at 90dB Pk (test exposure)

2. No added sound (sham exposure)

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.

No added sound – Which you will not be able to differentiate consciously from the infrasound (simulated wind farm noise).

If you agree to take part in this study, it will be conducted in your home where the speakers will be installed in your bedroom and operate continuously during the six month study period.

Four 600mm cube speakers will be installed in your bedroom. For your convenience, these speakers can be placed in variable configurations within the bedroom. The speakers are wired together and are powered by a single cord that plugs into a domestic power point.

In addition to the speakers there will be a microphone stand with two microphones placed in the bedroom. Neither microphone collects sound content or conversation, but the microphones will only collect sound level in decibels of 1) infrasound and 2) audible sound.

The speakers and microphones will operate continuously over the six month period of the study.

With your agreement, the acoustic engineer will schedule weekly visits during the first month then monthly, or as required, over the remaining 5 months of the study to ensure the correct functioning of the equipment. All scheduled visits will be arranged with you by our acoustic engineer.

Items to be placed in the master bedroom

4 x 600mm cube speakers

Microphone stand

Study and Testing Procedures

The speakers will be in place in your bedroom for six months and you will be invited to have some clinical assessments at baseline, three month and six month time points. The assessments will take place in your home by one of our researchers and will include the following:

Screening procedures at home:

Actigraphy and Consensus Sleep Diary:

A device is worn on your wrist (Actiwatch 2 Activity Monitor, Philips Healthcare) to take measurements of activity, light and wrist temperature to enable analysis of activity, sleep and wakefulness patterns. Analysis of actigraphy recordings will be undertaken according to a standardised protocol.

You will be provided with a paper diary and asked to record your sleep and wakefulness patterns over 7 nights.

Audiometry testing

A simple hearing test where sounds of different pitch and intensity are played and you will be asked if you can hear these sounds.

Clinical Assessments at home:

Anthropometric measurements

Height, weight and waist circumference will be taken at baseline, 3 month and 6 month visits.

Neurocognitive testing

This testing will last approximately 15 minutes. You will have a chance to practise the tasks. The tasks are:

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 is another 5 minute task, that asks you to rearrange certain shapes on the screen to reach a required target using a designated number of moves.

Polysomnography (Sleep study)

Home-based polysomnography (PSG) for assessment of your sleep and sleep quality will be undertaken using a small portable recorder (Alice PDx, Philips Respironics). A member of the research team will attach equipment in the late afternoon and retrieve it the next morning. Polysomnography data will be analysed at the Woolcock Institute of Medical Research using standardised analysis and reporting protocols.

Questionnaires asking about general health, sleep and mood

- **Insomnia Severity Index (ISI)** – Seven questions about your sleep over the previous two weeks.
- **Epworth Sleepiness Scale (ESS)** - Eight questions about your daytime sleepiness.
- **Depression Anxiety and Stress Scale (DASS-21)** – 21 questions about your mood.
- **Warwick Edinburgh Mental Wellbeing Scale (WEMWBS)** – 14 questions about your feelings and thoughts.
- **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.
- **Expectancy of Outcome Questionnaire:** You will be asked to respond to questions at the beginning and end of the study.

Blood pressure

You will be asked to sit quietly for 5 mins then a cuff will be placed around your upper arm. The cuff will be inflated and then gradually the pressure released from the cuff. This will provide us with your blood pressure measurement at rest.

Pulse wave velocity

This is a test to measure blood flow characteristics from your aorta (the large blood vessel that comes out from your heart). 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.

Hair Sample

We will cut a small hair sample from you so that we can measure a stress hormone.

Neuro-otological examination (2 Hours)

We will undertake a series of tests of your hearing and balance in the following order.

- **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.

- **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.

- **Tympanometry** – A 5 minute test that tests 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.

- **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)

- **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.

- **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.

- **Matted Romburg Test** - a simple method of testing balance. You will be asked to close your eyes while in a standing position. The researcher will be in attendance to ensure you are safe from imbalance.

- **Unterberger Test –**you will be asked to undertake stationary stepping for one minute with your eyes closed.

Blood tests

Blood will be taken from a vein in your arm using standard procedure with a needle and syringe to test for markers of inflammation.

<u>Are there likely to be any side effects or risks?</u>

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 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.

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.

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 or medication 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 to. 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.

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 to. 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 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.

Will this cost me anything?

Participation in this study will not cost you anything. At 3 months and at 6 months we will offer you $500 reimbursement ($1000 total) for the additional cost of electricity to run the speakers and microphones and also for your time and inconvenience.

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 will 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 name, 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 Professor Guy Marks (guy.marks@woolcock.org.au) if you would like to access your information.

What will happen to my test samples?

Blood 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.

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.

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 Wafaa Ezz (Wafaa.ezz@sydney.edu.au) or the Co-Principal Investigator Professor Guy Marks (guy.marks@woolcock.org.au).

If you have concerns about your involvement in the study

If you have any concerns about your involvement in this study, whether about the infrasound or about your health please contact the Wafaa Ezz (Wafaa.ezz@sydney.edu.au) or the Co-Principal Investigator Professor Guy Marks (guy.marks@woolcock.org.au). We will be able to discuss these issues with you and provide guidance about what will happen next.

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.

Trial Registration

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

Ethics approval and complaints

This study has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney Local Health District Protocol no. X17-0235 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 X17-0235.

THIS INFORMATION SHEET IS FOR YOU TO KEEP

WOOLCOCK
LEADERS IN BREATHING & SLEEP RESEARCH

PARTICIPANT CONSENT FORM

Assessing the health effects of six months of simulated wind farm infrasound:
A community-based randomised controlled trial

I , ...
[name]

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

have read and understood the **Participant Information Sheet Version 3, 23 Nov 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) 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: .....

CONSENT FROM BED PARTNER: I confirm that I have read the information statement and discussed this study with my bed partner. I understand that I am not a participant in this study and that I will be sleeping in our bedroom while the speakers are operating.

SIGNATURE: .....DATE:.....