Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

RMIT University

Title	An investigation of electromagnetic field exposure on sleep quality and cognitive function in healthy adults
Short Title	Electromagnetic field sleep study
Protocol Number	*21794*
Project Sponsor	RMIT University
Coordinating Principal Investigator **Principal Investigator**	Dr Russell Conduit Nicole Bijlsma
Associate Investigator(s)	Professor Marc Cohen Dr Adrian Schembri
Location	Eastern suburbs, Melbourne

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project because you are a healthy adult that sleeps normally and lives in a detached home. The research project is testing the impact of radiofrequency electromagnetic fields on sleep quality and brain function.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the process involved. 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 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. You will receive the best possible care whether or not you take part.

If you decide you want 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.

2 What is the purpose of this research?

Since 2010, there has been an increase in the prevalence of sleep difficulties in Australian adults which coincides with the use of digital devices [2]. This is thought to be due to the time spent surfing the internet and/or to exposure to blue light known to impact circadian entrainment, melatonin secretion, alertness, sleep regulation and the pupillary light reflex [15, 16]. There is also a growing body of research investigating the impact of pulse-modulated radiofrequency electromagnetic field exposure on sleep quality, however the majority of these studies involve near head exposures to mobile phones in a sleep laboratory [17-20] which do not represent real world scenarios to wireless devices typically used in the home. In addition, it is unclear whether having a baby monitor close by while sleeping affects the quality of sleep or brain function so the clinical significance to the larger population is essentially unknown. This study aims to investigate the impact of a standard radiofrequency device (baby monitor) on sleep quality and brain function in healthy participants.

This research has been initiated by the researcher, Nicole Bijlsma and forms part of her PhD under the supervision of Dr Russell Conduit, Professor Marc Cohen and Dr Adrian Schembri.

Nicole has a scholarship from the Jacka Foundation and RMIT University that is supporting her candidature. The study is self-funded (by the student) and there is no commercial sponsorship. This study has no other funding.

3 What does participation in this research involve?

34 healthy adult participants will be recruited from the general population to participate in a 4 week double-blind, cross-over study. In a cross-over study, the intervention weeks (weeks 2 and 4) will be double blinded and will involve placing an active or deactivated baby monitor within 1 metre of the participant's bedhead for 7 consecutive nights. Both the participants and researchers will be blinded to the intervention allocation which will be determined by computerised randomisation software.

Participants will be healthy participants without current sleep disturbance, live in a detached home, aged between 18 and 55, non-smoker, English speaking and able to provide written informed consent. They will be willing to avoid digital devices at least one hour before bed (or use devices with a blue light filter), able to go to bed and get up at approximately the same time over the study period and willing to avoid stimulants late in the day (caffeine and alcohol) during the intervention period (two weeks) as these factors may adversely affect sleep.

Participants will be excluded if the levels of electromagnetic fields in their bedroom are elevated (ie above 2 mG AC magnetic fields or 10 uW/m2), if they need to use a cell phone during the night, if their body mass index is greater than 30, if they have any medical condition that affects their sleep or any other condition for which the subject is currently taking medications or in the opinion of the investigators would impede competence, compliance, or participation in the study, recent hospitalisation, surgery or antibiotic therapy, taking any medications or supplements that may interfere with sleep, pregnant or expect/attempting to become pregnant, peri-menopausal women with menopausal symptoms and irregular menstrual periods, are unable to give informed consent, need to travel across time zones two weeks before or during the study period or are a night shift worker or have a history of night shift work for more than 2 years.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids researchers and participants jumping to conclusions.

Prior to entering the study, we will require written consent from you. Information will be given in both oral and written form and you will be given the opportunity to inquire about the details of the study. You will be given a copy of the signed consent form and the original will be maintained with the records of the participant. The consent form has been approved by HREC.

There are no costs associated with participating in this research project, nor will you be paid.

There will be no out of pocket expenses incurred from you to participate in this study. However possible benefits may include having an assessment of the electromagnetic field and air quality of your bedroom and an assessment of the quality of your sleep.

4 What do I have to do?

You will be required to complete a Participant Screening Questionnaire to determine if you are suitable to partake in the study. If this is successful, you will be required to make an appointment to get your home assessed. This will involve a researcher measuring background electromagnetic field exposure in your bedroom using a gauss meter and high frequency meter to measure AC magnetic fields and radiofrequencies respectively to ensure there are no fields that may interfere with the study. If you and your home are deemed suitable, you will be asked to participate in the 4-week study and the following will occur:

- An indoor air monitoring device will be placed in your bedroom during the first week to measure carbon dioxide, particulate, chemicals, relative humidity and temperature.
- You will be asked to complete an online sleep diary ("Sleep Wake Tracker App) every morning for the duration of the study.
- You will be asked to wear a watch (Actiwatch) each night for the duration of the study that will measure your level of movement during the night. We will show you how to use it.
- On the 6th and 7th night of each week, you will be asked to wear a chest strap in bed to measure heart rate variability (8 nights in total). We will show you how to use it.
- On the 6th and 7th night of each week, you will be asked to wear a device during the night which involves attaching electrodes to the back of your head to record your brain waves (8 nights in total). We will show you how to use it.
- On the 8th morning of each week, you will be asked to complete an online sleep quality survey and a computerised cognitive function test (4 times in total). This will take approximately 15 minutes to complete.
- In weeks 1 and 3, you will be asked to record information (as above) whilst sleeping without a baby monitor. Week 1 is baseline and Week 3 is washout period.
- In weeks 2 and 4, a conventional baby monitor (that is either active or disabled) will be placed within one metre of the bedhead.

5 Other relevant information about the research project

Not applicable

6 Do I have to take part in this research project?

Participation in the 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 to take part or not to take part, or to take part and then withdraw, will not affect your relationship with the researchers or with RMIT University.

7 What are the alternatives to participation?

Not applicable

8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, you may appreciate contributing to knowledge. Possible benefits may include having an assessment of the electromagnetic field and air quality of your bedroom and an assessment of the quality of your sleep.

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

This research project involves exposure to non-ionising radiation emitted from a wireless device commonly found in the home, which complies with the exposure standards established by the Australian Radiation Protection and Nuclear Safety Agency. Unlike ionising forms of radiation like x-rays, radiofrequencies are a form of non-ionising radiation that are considered to be safe. The risk is believed to be minimal as the level of radiation will be similar to a child who has a baby monitor in their room. However there is a growing body of literature that these forms of electromagnetic fields may have biological effects that could affect sleep quality and/or brain function.

The impact of exposure to non-ionising radiation such as a baby monitor on the unborn child are not known. Because of this, it is important that research project participants are not pregnant or breast-feeding and do not become pregnant during the course of the research project.

We do not anticipate that participants will experience stress from their participation with this study. There may be side effects that the researchers do not expect or do not know about so in the event you are worried about them, talk with the researcher. If you become upset or distressed as a result of your participation in the research, please contact Lifeline.

10 What will happen to my test samples?

Not applicable.

11 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your researcher will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your researcher will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your researcher might consider it to be in your best interests to withdraw you from the research project. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

12 Can I have other treatments during this research project?

It is important to tell your researcher about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments that may affect sleep quality. You should also tell your researcher about any changes to these during your participation in the research project.

13 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. You have the right to have any unprocessed data withdrawn and destroyed, providing it can be reliably identified. If you do withdraw your consent during the research project, the researcher will not collect additional personal information from you, although

personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

14 Could this research project be stopped unexpectedly?

It is unlikely that the research project may stop unexpectedly in light of the fact that an off the shelf device will be used whose radiation emitted is well within the Australian exposure standards for radiofrequency exposure.

15 What happens when the research project ends?

You will be informed of your individual results as well as a summary of the overall results of the study. You will also be informed of the results of the electromagnetic filed and air quality measurements taken at your home.

Part 2 How is the research project being conducted?

16 What will happen to information about me?

By signing the consent form you consent to the researcher 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. 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.

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 permission, so that your information will remain confidential at all times. Only de-identified and group results will be reported and at no time will any individual's identified results be published. All these publications will be made available through the RMIT Repository in the reports as an Appropriate Durable Record (ADR), which is a publicly accessible online library of research papers.
In accordance with relevant Australian Privacy Act 1988 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 researchers 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.

17 Who is organising and funding the research?

This research project is being conducted by Nicole Bijlsma as part of her PhD at RMIT University. This study is self-funded by the principal researcher (N Bijlsma) and there are no commercial sponsorships. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

18 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). This research project has been approved by the RMIT 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.

19 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, you can contact the principal researcher Nicole Bijlsma on *0417 310 002* or s9711185@student.rmit.edu.au or any of the following people:

Contact person

For matters relating to research at the site at which you are participating, the details of the principal researcher are:

Name	Russell Conduit
Position	Chief investigator / Senior supervisor
Telephone	9925 6688
Email	russell.conduit@rmit.edu.au

Complaints contact person

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	RMIT University
HREC Secretary	Peter Burke
Telephone	03 9925 2251
Email	human.ethics@rmit.edu.au
Mailing address	Research Ethics Co-ordinator Research Integrity Governance and Systems RMIT University GPO Box 2476 MELBOURNE VIC 3001