easternhealth

Participant Information Sheet and Consent Form

Box Hill Hospital

Title	Chronobiology in Dementia
Short Title	Chronobiology in Dementia
Project Sponsor	Institute for Breathing and Sleep
Coordinating Principal Investigator	Associate Professor Amy Brodtmann
Associate Investigators	Associate Professor Mark Howard Dr Matthew Pase Dr Melinda Jackson Dr Fariha Islam Dr Emilio Werden Dr Marina Cavuoto Dr Danielle Wilson Ms Laura McCambridge Mr Elie Gottlieb
Location	Box Hill Hospital
Project Number	E19/013/53511

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project, *Sleep and Chronobiological Changes in Alzheimer's Disease Dementia and Fronto-Temporal Dementia*. You have been invited to participate because you have a diagnosis of Fronto-Temporal Dementia (FTD) or Alzheimer's Disease (AD) Dementia, and have previously provided consent to be contacted for research. This project aims to examine associations between circadian rhythm disruption (i.e., disruption to daily sleep-wake cycles, and hormone levels) sleep patterns (including brain activity during sleep), blood markers, cognitive function, and brain volume measures to help characterise the features of different types of dementia.

This Participant Information Sheet and Consent Form (PICF) tells you about the research project. It explains the procedures involved. Knowing what is involved will help you decide if you consent to taking part.

Please read this information carefully. Ask questions about anything that you do not understand or want to know more about. Before deciding whether or not to agree, you might want to talk about it with a relative, friend, or your local doctor.

Participation in this research is voluntary. If you do not want to take part, you do not 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 taking part in the research project
- Consent to having the tests and research 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?

The purpose of the study is to understand chronobiological (biological rhythm) changes in different types of dementia. This includes daily rhythms of sleep-wake patterns and hormone cycles (i.e., melatonin) over the day. We would like to understand how these changes are associated with different types of dementia, such as Alzheimer's disease (AD) dementia, and Fronto-Temporal Dementia (FTD).

We would also like to understand how these sleep and chronobiological changes relate to cognitive function, brain structure and function, and genetic markers in people with dementia. Sleep-wake disturbances are common in people with dementia, which can affect their quality of life and that of their family/informal caregiver. We hope the results will contribute to improving diagnosis and intervention for people with dementia.

This research has been funded by Austin Medical Research Foundation and the Institute for Breathing and Sleep. This research is being conducted by researchers from Eastern Health, Austin Health, and the Florey Institute.

3 What does participation in this research study involve?

- Firstly you will be asked questions to make sure you are eligible to take part in the study at an appointment with a researcher at Box Hill Hospital.
- If you are eligible to take part, you will be sent some questionnaires on demographics, health, sleep and mood, to bring in to your appointment at the Austin Hospital.

- You will be asked to attend appointments at the Austin Hospital to have:
    - A <u>brain MRI</u> which will last approximately 1 hour
    - A <u>40 ml blood sample</u> will be taken (this is equivalent to two tablespoons of volume). This sample will be used to check for a gene called 'apolipoprotein E' or 'APOE' for short. The APOE gene determines the levels of a cholesterol-carrying blood protein which delivers cholesterol to the nerve cells which use it for the repair and establishment of new connections. There are 3 common types of the APOE gene in people: APOE2, APOE3 and APOE4. We all have 2 copies of the APOE gene in our blood, one from our mother and one from our father. Your APOE type is determined by your genetics. The APOE4 type is thought to increase the risk of stroke and dementia. This blood will only be identified by a code number to make sure that genetic information remains strictly confidential.
    - <u>Cognitive testing</u> which will involve completing verbal, paper-based and computerized tasks that assess memory and other aspects of thinking. The session will also involve a

short period of wearing special glasses that monitor eye movement and sleepiness. This is a short 7-minute test of drowsiness which will involve wearing special glasses and resting with the eyes open and closed. The session will last approximately 2 hours.

• You will then be visited at home by a researcher to set up for 1-week of in-home monitoring of sleep and circadian rhythms.

- Activity monitoring. You will be given a watch-like activity monitor (called an Actiwatch) to wear on their wrist for 7 days. The Actiwatch will record activity, light and sleeping patterns based on movement – it does not record any audio or visual information. The Actiwatch is water-resistant, it can get wet (e.g. in the shower). However, it will need to be taken off during a bath, or when you go swimming. We will also ask your carer/Person Responsible to complete a sleep diary over the same time to help us understand your sleep during the period that you wear the Actiwatch.
- Urine sample. At the beginning of the week of monitoring, we would like you to provide urine samples over a 24-hour period. You will be provided with a collection kit including containers and instructions. If for some reason this process is interrupted, you can begin again on another day.
- Light measurement – will be checked in your home during the sleep study overnight using a HOBO light data logger.
- Polysomnography (i.e., overnight sleep recording). This will involve wearing electrodes on the head and body to measure brain electrical activity, muscle movement, and breathing.
  • Before applying electrodes, the skin where the electrode is to be attached, will be cleaned with a compound to remove oil, dirt and dead skin.
  • The electrodes will be filled with gel to ensure a good connection with the skin. Facial and leg electrodes will be held in place with surgical tape. EEG electrodes will be held in place using a small piece of gauze and special purpose glue.
  • If you need to get up during the night (e.g. to get a drink or go to the bathroom) you will be able to take the sleep recording equipment with you, as it will be contained in a small unit attached to you.
  • You will also be shown how to remove the electrodes if you wish to stop the study prior to the researcher returning in the morning.
  • This will be an unattended study, i.e., the researcher will not monitor the recording at your home.
  • The researcher will arrive at your home in the late afternoon to set up the equipment. The researcher will return in the morning to collect the equipment.

Below is a summary of the tasks and appointments involved in this study.

Task/Appointment	**Place and duration**
Screening interview	Box Hill, 1 hour
Brain MRI	Austin Hospital, 1 hour
Blood test	Austin Hospital or Box Hill Hospital, 30 mins
7 Questionnaires to be completed by you. 3 Questionnaires to be completed by the Person Responsible.	At home, 90 mins (Includes questionnaires on demographics, health, and sleep). At home, 20 mins (Includes questionnaires on mood and behaviour of participant, and carer role).
Cognitive testing	Austin Hospital or at home, 2 hours
Wrist worn activity monitor (actiwatch – worn by participant)	At home, 7 days At home, 7 days, 5 mins per day

Sleep diary (completed by Person Responsible	
Polysomnography set-up	Austin Hospital or at home, 30 mins
Polysomnography	Overnight sleep study at home, 1 night
Urine sample	At home, 24-hours

Involvement of Person Responsible
The Person Responsible will need to accompany you to all your appointments, and assist you with completing questionnaires, and providing urine samples. The Person Responsible will need to monitor any issues that may arise with the in-home sleep monitoring, and provide assistance and/or liaise with the research team. The Person Responsible will also need to complete 3 questionnaires about you, in relation to mood, behaviour, and their caring role; and complete the sleep diary about your sleeping patterns over 7 days.

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

There are no costs associated with participating in this research project.

4 What are the potential benefits?

We cannot guarantee or promise you will receive any benefits from this research. However, you will be making a valuable contribution to understanding sleep difficulties in dementia which may help us in the future to improve diagnosis and treatment of FTD and AD.

5 What are the potential risks of participating?

MRI
MRI stands for magnetic resonance imaging. A MRI scanner is a machine that uses electromagnetic radiation (radio waves) in a strong magnetic field to take clear pictures of the inside of the body. Electromagnetic radiation is not the same as ionising radiation used, for example, in X-rays. The pictures taken by the machine are called MRI scans.
We will ask you to lie on a table inside the MRI scanner. The scanner will record information about their brain. It is very important that you keep very still during the scanning. When you lie on the table, we will make sure that you are in a comfortable position so that you can keep still. The scanner is very noisy and we can give you some earphones to reduce the noise. Some people may experience symptoms of claustrophobia from lying in a confined space. If you experience discomfort at any time during the scan, you will be able to alert staff by pressing on a call button provided.

There are no proven long-term risks related to MRI scans as used in this research project. MRI is considered to be safe when performed at a centre with appropriate procedures. However, the magnetic attraction for some metal objects can pose a safety risk, so it is important that metal objects are not taken into the scanner room.

We will thoroughly examine you to make sure there is no reason for you not to have the scan. You must tell us if you have metal implanted in your body, such as a pacemaker or metal pins.

The scans we are taking are for research purposes. They are not intended to be used like scans taken for a full clinical examination. The scans will not be used to help diagnose, treat or manage a particular condition. A specialist will look at the MRI scans for features relevant to the research project. On rare occasions, the specialist may find an unusual feature that could have a significant risk to your health. If this happens, we will contact you to talk about the findings. We cannot guarantee that we will find any/all unusual features.

Blood Test

A regular blood draw needle will be used to take a blood sample, which may cause some pain and swelling at the insertion site. It is possible that one or more attempts to take a blood sample may be necessary. This may cause some additional pain, swelling or discomfort. There is a possibility that the drawing of blood may make you feel dizzy or cause you to faint. Even though sterile needles will be used, there is a slight chance of infection at the insertion site. You should immediately report any unusual feelings or pain to the staff. In order to minimise these risks, you will be able to lie down during the blood draw. If you have had a previous negative experience while having blood taken, we suggest you do not complete this part of the study.

Cognitive Assessment
During the cognitive assessment, sometimes people may get tired, inattentive, or feel anxious about their performance. In this case, testing will be stopped to allow for breaks and discussion, and, if necessary, testing will be rescheduled for another day.

In-Home Sleep Recording
It is possible that you may find the recording equipment uncomfortable, and hence not sleep as well as normally. However, because the sleep monitoring will be conducted at home, we hope the potential for discomfort will be minimised. You will also be shown how to safely remove the electrodes in case you wish to do so before the experimenter returns in the morning, and you will be left with acetone and gauze in order to do this.

The application of electrodes involves only minimal discomfort. There is a slight risk of small red marks on the earlobes or face as a result of preparing the skin for electrode attachment. These are rare events and only occur if a person has very sensitive skin. If they do occur, they tend to last only a day or so and then completely disappear.

You may withdraw from the study at any time, or discuss any concerns with the researchers. Similarly, if any incidental findings are discovered during the course of participation in the study (e.g., obstructive sleep apnoea, brain aneurysm), the lead investigator will contact you to provide you with more information and possible referrals.

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

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide you can take part and later change your mind, you are free to withdraw them from the project at any stage.

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

If you agree and later change your mind, you are free to withdraw your consent at anytime during the study. If you have completed the study, you can also request that your data is withdrawn as long as you let us know within four weeks of the completion of your participation in the project. If you would like to withdraw you can notify the researchers in person, by email, or by telephone, or you can complete the “Withdrawal of Consent” form.

Your decision whether to agree, or to agree and then change your mind, will not affect your routine treatment, or relationship with those treating you or your relationship with Eastern Health.

7 What will happen to information about me?

Any information that is obtained in connection with this study that can identify you (e.g. personal identification number, gender, health data such as previous disease and study records) will remain confidential and will only be used for the purpose of this study. It will only be disclosed with your permission, except as required by law.

The Investigator and all the study staff will have a duty of confidentiality to you and nothing that could reveal your identity will be disclosed outside the relevant institutions (Eastern Health, Eastern Clinical Research Unit at Box Hill Hospital, Austin Health, or the Florey Institute at Austin, 245 Burgundy Street, Heidelberg, VIC 3084).

In accordance with relevant Australian privacy and other relevant laws, you have the right to see all information collected and stored by the Investigator about you in this study. You also have the right to request the correction of any data that is wrong in accordance with the applicable law in your country of residence. Ask the study doctor for more information in this respect. Eastern Health will use the collected information only for this specific purpose.

Your health records and any information obtained during the study are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorized representatives of Eastern Health or any other person as required by law. By signing the consent section, you authorize the release of, or access to, any confidential information there-in about you to the relevant study staff and the relevant regulatory authorities. This will only take place at Eastern Health under the supervision of the Investigator.

During the study, all the participants' records will be kept strictly confidential. This means that only the Investigator and the study staff directly involved in this study will have access to them and the records will be kept in a secure office at the Florey Institute at Austin Health.

In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

On completion of the study, the data will be transferred to an archiving facility for an indefinite period of time, in compliance with good clinical practice (a minimum of 15 years).

8 Further Information on 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 need to report any medical problems which may be related to involvement in the project (for example, any side effects), you can contact the Principal Investigator A/Prof Amy Brodtmann on 0400-614-922.

Clinical contact person

Name	A/Prof Amy Brodtmann
Position	Associate Investigator
Telephone	0400-614-922
Email	agbrod@unimelb.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	Eastern Health Human Research Ethics Committee
Position	Chairperson
Telephone	03 9895-3398
Email	ethics@easternhealth.org.au

If you have any complaints about any aspect of the project, or the way it is being conducted, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Eastern Health Human Research Ethics Committee
HREC Executive Officer	Chairperson
Telephone	03 9895-3398
Email	ethics@easternhealth.org.au

Local HREC Office contact (Single Site - Research Governance Officer)

Name	Eastern Health Human Research Ethics Committee
Telephone	03 9895-3398
Email	ethics@easternhealth.org.au

Thank you for taking the time to read this information and for your interest in participating in this study!

easternhealth

Participant Information Sheet/Consent Form

Title	Chronobiology in Dementia
Project Sponsor	Institute for Breathing and Sleep
Principal Investigator	A/Prof Amy Brodtmann
Location	Box Hill Hospital, Arnold St, Box Hill 3128 VIC
Participant Name	_____

Consent Agreement

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.

Declaration by Participant – for participants who have read the information

Name of Participant (please print) _____

Signature _____ Date _____

Declaration - for participants unable to read the information and consent form

Witness to the informed consent process
Name (please print) _____
Signature _____ Date _____
*Witness must be 18 years or older.

Declaration by Study Doctor/Senior Researcher†

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

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

Signature _____ Date _____

† A senior 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

easternhealth

Form for Withdrawal of Participation

Title	Chronobiology in Dementia
Project Sponsor	Institute for Breathing and Sleep
Principal Investigator	A/Prof Amy Brodtmann
Location	Box Hill Hospital, Arnold St, Box Hill 3128 VIC
Participant Name	_____

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Boxhill Hospital.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Study Doctor/Senior 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 Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

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