Appendix A **PARTICIPANT INFORMATION SHEET**

(Insomnia Pilot Study)

You are being invited to participate in a research study. Before you take part in this research study, the study must be explained to you and you must be given the chance to ask questions. Please read carefully the information provided here. If you agree to participate, please sign the informed consent form. You will be given a copy of this document to take home with you.

STUDY INFORMATION

Protocol Title: Auditory entrainment of sleep spindles and the impact on sleep quality in insomniacs: a pilot study.

Principal Investigator(s):
Dr Michael Chee, Cognitive Neuroscience Laboratory, Duke-NUS Graduate Medical School,
8 College Road, Singapore 169857, michael.chee@duke-nus.edu.sg,
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8 College Road, Singapore 169857, TT.DangVu@concordia.ca

WHAT IS THE PURPOSE OF THIS RESEARCH?

You are being invited to participate in a research study, which seeks to test a novel technique to improve sleep quality. Sounds delivered during specific phases of sleep have been shown to boost a certain type of brain activity during sleep, called sleep spindles. These sleep spindles have been shown important for maintaining adequate sleep quality. We are testing the feasibility of enhancing sleep spindles in people with insomnia with the aim of improving their sleep quality.

WHO CAN PARTICIPATE IN THE RESEARCH? WHAT IS THE EXPECTED DURATION OF MY PARTICIPATION? WHAT IS THE DURATION OF THIS RESEARCH? WHAT ARE THE APPROXIMATE NUMBER OF PARTICIPANTS INVOLVED?

This study will recruit 10 individuals aged 21 and above who meet our study requirements; they will participate in the study over a period of three weeks.

Study participants must fulfill the following criteria:

1. Meet diagnostic criteria for chronic insomnia
2. Have English as a first language
3. Have a minimum of 12 years of formal education
4. Have consistent sleeping habits at least 7 days prior to the study
5. Are not on any long-term medications that could affect sleep
6. Have no known medical conditions that could affect sleep
7. Have no history of psychiatric or neurological disorders
8. Do not do shift work
9. Have not travelled across more than 1 time zone in the past month
10. Consume less than 2 units (200mg) of caffeine a day
11. Consume less than 21 units of alcohol per week
12. Not have important cognitive deficits (score at the Mini-Mental State Examination should be ≥ 26 if ≥ 55 years old)

All study participants must also maintain regular sleeping habits through the approximately three-week duration of the study.

WHAT WILL BE DONE IF I TAKE PART IN THIS RESEARCH?

If you agree to take part in this study, you will be asked to undergo tasks on a desktop computer before and after sleep at our sleep laboratory

During the sleep sessions, electroencephalography (EEG), which is a method of recording electrical

activity arising from the brain will be performed. Electrodes in the form of small conducting disks will be placed on your scalp and face. Up to 16 electrodes will be placed. The skin near each electrode is first cleaned with alcohol, and then a small amount of EEG paste is placed between the disk and skin to improve contact. You will also be given headphones to deliver soft tones while you sleep. The EEG procedure is non-invasive, and is neither painful nor hazardous. The paste is water-soluble and can be washed off easily after the recording.

Your participation in the study will last approximately 3 weeks. You are required to make at least four (4) visits to the lab:

1) **Briefing Session** (Date: _____)
   In this session, you will be briefed on the schedule and requirements of the study and, if you agree to participate, you will be asked to sign the consent form to participate in the study, complete a number of questionnaires and collect an Actiwatch, which is for activity monitoring. This session will take about 45-60 minutes.

2) **Adaptation & Screening Session** (Date: _____)
   This will take place 1 week following the briefing session. You are not permitted to smoke, take any medications or alcohol, or consume substances that contain caffeine (e.g., coffee, tea, chocolate, caffeinated soft drinks) for **24 hours** prior to this session.

   You should arrive at _____(time) for this session. We will then proceed with the EEG setup and apply a pulse oximeter, thoracic band and a nasal airflow sensor, to screen for potential sleep apnea. During your sleep, you will be monitored using video cameras installed in the suite for safety purposes and for movement artifacts. Following this session, if we spot significant sleep disturbances, we may have to exclude you from the study but will compensate you on a pro rata basis. A bell will be provided in case you need to alert the researchers at any point during your sleep session (e.g. if you need to use the bathroom).

3) **Experimental Session 1** (Date: _____)
   This will take place 1 week following the adaptation session.

   You should arrive at _____(time) for this session. We will then proceed with the EEG setup and a computerized test before your sleep. Auditory tones (sounds) may or may not be played while you sleep. After this, you will be given some time to wash up before another computerized test. The duration of the completion of the computerized tests and questionnaires in the evening will be approximately 30 minutes, and in the morning approximately 15 minutes. You will be permitted to leave the lab at approximately 2 hours after your wake time.

4) **Experimental Session 2** (Date: _____)
   This session will take place 1 week following the previous session and will be similar to the previous session.

If you agree to participate in this study, you*:*

- Will have to keep your study appointments. If it is necessary to miss an appointment, please contact the study staff to reschedule as soon as you know you will miss the appointment.
- Will have to sleep over at least three sessions in the laboratory
- Will be administered several behavioral tests and questionnaires.
- Must drink, on average, less than 2 units (200mg) of caffeinated drinks a day. **HOWEVER**, you are not permitted to smoke, take any medications[1] or alcohol, or consume substances that contain caffeine (e.g., coffee, tea, chocolate, caffeinated soft drinks, energy drinks) for **24 hours prior to the experiment.**
- Must maintain regular sleeping hours throughout the entire experimental period. We will verify your sleeping habits at every visit, using the data collected from the Actiwatch.

[1] Please check with staff if you are currently taking any medications

- Must take good care of your Actiwatch **and wear it them at times except when bathing or swimming**. You will be held responsible for any loss or damage to the Actiwatch, which may include cost of repairs/replacement of the watch.

- Must be prepared to visit the lab 4 times and undergo all the procedures that are outlined above.

HOW WILL MY PRIVACY AND THE CONFIDENTIALITY OF MY RESEARCH RECORDS BE PROTECTED?

Only the Principal Investigator and persons conducting the research will have access to your identifiable information (i.e. name, email address and contact number). This information will not be released to any other persons who are not involved in the study. Identifiable information will never be used in a publication or presentation. All your identifiable health information and research data will be coded (i.e. only identified with a code number) at the earliest possible stage of the research.

In view of the Personal Data Protection Act, your data will remain confidential and anonymous and it will not be released in any individually identifiable form. According to NUS Research Data Management Policy, all data will be archived for 10 years. Video-recordings will be disposed after 3 months.

WHAT ARE THE POSSIBLE DISCOMFORTS AND RISKS FOR PARTICIPANTS?

For the EEG component, adhesive tape/paste will be used to attach electrodes. In rare cases, this could cause some minor skin irritation or acne. We will monitor for such discomfort and remove them if necessary.

WHAT IS THE COMPENSATION FOR ANY INJURY?

If you follow the directions of the investigators in charge of this research and you are physically injured in spite of the procedure executed under the plan for this research, Duke-NUS will pay the medical expenses for the treatment of that injury. By signing this consent form, you will not waive any of your legal rights or release the parties involved in this study from liability for negligence.

WILL THERE BE REIMBURSEMENT FOR PARTICIPATION?

At the end of the study, if successfully completed, you will be paid a cumulative total of **$150.**

WHAT ARE THE POSSIBLE BENEFITS TO ME AND TO OTHERS?

There is no direct benefit for you from this study. However, your voluntary participation will contribute to the better understanding of human brain function towards sleep quality and memory consolidation during sleep.

CAN I REFUSE TO PARTICIPATE IN THIS RESEARCH?

Yes, you can. Your decision to participate in this research is voluntary and completely up to you. You are also free to withdraw your consent and discontinue your participation at any time without giving any reasons and without prejudice to you. If you decide to stop taking part in this study for any reason:

- You must immediately inform the study investigator
- You must return the Actiwatch immediately to the laboratory

The Principal Investigator may stop your participation in the study at any time for one or more of the following reasons*:*

- Failure to follow the instructions of the Principal Investigator and/or study staff.
- The Principal Investigator decides that continuing your participation could be harmful.
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

WHOM SHOULD I CALL IF I HAVE ANY QUESTIONS OR PROBLEMS?

Please contact the Principal Investigator, Dr. Michael Chee (michael.chee@duke-nus.edu.sg or 6516 4916) for all research related matters and in the event of research-related injuries.

For an independent opinion regarding the research and the rights of research participants, you may contact a staff member of the National University of Singapore Institutional Review Board (Attn: Dr Chan Tuck Wai, at telephone 6516 1234 or email at irb@nus.edu.sg).

When you sign this document, you are stating that the tests performed have been explained to you, and that you understand that the data obtained from these assessments are to be used for research purposes only. This information is not intended for an evaluation or diagnosis of any disorders. However, the results of all tests, tasks, and procedures entailed by your participation in this project may lead to the detection of previously unknown health problems. This is what we call an incidental finding. Should an abnormality be detected, you can opt to be informed by the Principal Investigator.

CONSENT BY RESEARCH SUBJECT

Protocol Title: Auditory entrainment of sleep spindles and the impact on sleep quality in insomniacs: a pilot study.

Principal Investigator(s): Dr Michael Chee, Cognitive Neuroscience Laboratory, Duke-NUS Graduate Medical School, 8 College Road, Singapore 169857, Tel: 6516 3934.

Subject's Particulars:

Name: _____

Address: _____

_____

Contact number(s): _____ (M) _____ (H)

Date of birth: _____ Weight: _____ Sex: Female/Male

Race: Chinese/ Malay/ Indian /Others (please specify) _____

Part I – to be filled by volunteer

I hereby acknowledge that:

1. My signature is my acknowledgement that I have agreed to take part in the above research.
2. I have received a pamphlet (or a copy of this information sheet) that explains the use of my data in this research. I understand its contents and agree to donate my data for the use of this research.
3. I can withdraw from the research at any point of time by informing the Principal Investigator and all my data will be discarded.
4. I will not have any financial benefits that result from the commercial development of this research.
5. I *consent / do not consent** to have the coded data made available for future research.
6. I *agree / do not agree** to be re-contacted for future related studies. I understand that future studies will be subject to an Institutional Review Board's approval.
7. I *agree / do not agree** to the video-recording of the sleep session for the monitoring of sleep disturbances.
8. I *consent / do not consent** to be informed about any incidental findings the research team may uncover.

_____ _____

[Signature of research subject] (Date of signing)

_____ _____

[Signature of witness] (Date of signing)

Part II – Investigator's Statement

I, the undersigned, certify to the best of my knowledge that the volunteer signing this informed consent form had the study fully explained and clearly understands the nature, risks and benefits of his/her participation in the study.

_____ _____ _____

Name of Investigator Signature Date