IMFORMED CONSENT FORM

Official Title: Generalization and Specificity of Visual Learning During Sleep

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BROWN UNIVERSITY
CONSENT FOR RESEARCH PARTICIPATION

[Generalization and Specificity of Visual Learning During Sleep]
[Version 10; August 7, 2025]

KEY INFORMATION:

You are invited to take part in a Brown University research study. Your participation is voluntary.

- PURPOSE: The purpose of the study is to learn more about what the roles of sleep on learning and memory. Sleep is important to us but its role is not yet clear. The present study aims to measure brain activity and to see which part of the brain is responsible or activated for the consolidation process for memory and learning during sleep.
- PROCEDURES: Before participating our study, you may be asked to show us your photo ID so that we could confirm that you are new subject in perceptual learning. If EEG cap does not fit your head properly, you may be excluded from this study. If you have been trained on the same visual task as will be used in this study, you may be excluded from this study. You may be asked to participate in a session that involves laying in a scanner to image your brain (MRI), having sensors placed on your head (PSG), answering personal questions, doing computer tasks (behavioral testing), keeping a sleep log, wearing an activity monitor on your wrist, stop consuming caffeine, taking a pregnancy test (if you are female) and/or being asked to sleep during the MRI or PSG session. You may be asked to conduct a 15-min session of mindful meditation before the sleep experiment by listening to a recorded mindfulness meditation played from a recorder.
- TIME INVOLVED: The study may take 2-5 weeks of your time and we may ask you to return 2-5 times. Each session may last approximately 2-4 hours for MRI or PSG, and 60-90 min for a behavioral testing session.
- COMPENSATION: You will receive $25/hour for MRI and/or PSG, $15/sleep session for wearing an actigraph and keeping a sleep log, and $10/hour for behavior testing for your time.
- RISKS: You may be uncomfortable laying still in the scanner for a long period of time, removing the gel attached to the sensors on your body (it feels like removing a band-aid), and there is a small risk of the sensors overheating or skin burning with MRI and PSG when used together.
- BENEFITS: There are no direct benefits for participating in this study.

Why is this research study being done?

Sleep may play an important role in learning consolidation. This means that during sleep there is a critical period during which learning and memory is formed and retained. We will test whether this hypothesis is true or not. The present study aims to measure brain activity and to see which

part of the brain is responsible or activated for the consolidation process for memory and learning during sleep.

You have been asked to participate because you are a healthy individual with presumably normal brain function.

How long will I take part in this research study?
It may take you about 2-5 weeks to complete this research study. During this time, we may ask you to make 2-5 study visits.

What will happen in this research study?
Before participating our study, you may be asked to show us your photo ID so that we could confirm that you are new subject in perceptual learning. A copy of the consent form will be given to you to keep.

☐ **Magnetic Resonance Imaging (MRI)**
MRI is a technique that uses magnetic fields to create an image of the brain.

Images of your brain will be taken using Magnetic Resonance Imaging (MRI) during the study. You will lie on a table and your upper body will be placed inside an MRI scanner. You will be asked to remain still during scanning. Small soft cushions will be placed to fit, or you may be asked to use a plastic device which has been form-fitted to your face to help immobilize your head. In order to reduce a loud beeping sound during scanning, you will wear earplugs during imaging.

We will obtain images of your head during the scanning. Also, high-speed images of brain activity ('functional' MRI, or 'fMRI') or magnetic resonance spectroscopy ('MRS') may be obtained. Using a mirror inside the MRI machine, you will see displays on a screen. You will be asked to watch the screen, or asked to move your fingers or hands, or asked to try to fall asleep. You will be able to speak with the study staff at any time. You will be able to stop participation in the study at any time for any reason.

We may ask you to keep regular sleep-wake cycles one week before the experiment starts. We may ask you to keep a sleep log. If you are able to menstruate, we may ask you what phase of the menstrual cycle you are in by a questionnaire. We may ask you to wear a small sensor on your wrist (actigraphy) to monitor your daily activity level for about a week prior to a sleep session. In addition, from one day before the starting of experiments, we may ask you to stop taking caffeine. If you are a woman who might be pregnant, you will have a urine pregnancy test. Please note that pregnancy is an exclusionary criterion.

Each session may last approximately 2-4 hours.

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☐ **Polysomnography (PSG)**

In order for us to tell objectively if you fall a sleep, we may monitor your sleep state (PSG). PSG is a technique that measures people's sleep state. PSG is a combination of electroencephalogram (EEG), electooculogram (EOG), and electromyogram (EMG). EEG measures the small electrical currents produced when cells in the brain are active. EOG measures the small electrical currents produced when eyes are moving. EMG measures the small electrical currents produced when muscles are active.

PSG is measured with small metal disks or electrodes placed on your head. Each disk is about one-quarter inch in diameter, and they are incorporated into a cap that fits snugly on your head. Up to 64 electrodes will be placed. The skin near the disk is first cleaned with a detergent solution or gel, and then a small amount of gel is placed between the disk and the skin to improve the quality of their contact.

The electrodes are connected to a computer that records your vigilance level while you are performing different tasks, or while you are resting. PSG and MRI may be collected in the same sessions. You will be asked to sit still during the entire measurement since movements will interfere with getting accurate information.

We may ask you to keep regular sleep-wake cycles one week before the experiment starts. We may ask you to keep a sleep log. If you are able to menstruate, we may ask you what phase of the menstrual cycle you are in by a questionnaire. We may ask you to wear a small sensor on your wrist (actigraphy) to monitor your daily activity level for about a week prior to a sleep session. In addition, from one day before the starting of experiments, we may ask you to stop taking caffeine. If you are a woman who might be pregnant, you will have a urine pregnancy test. Please note that pregnancy is an exclusionary criterion.

Each session may last approximately 2-4 hours.

☐ **Behavioral Testing**

We may also ask you to participate in behavioral testing sessions outside MRI or PSG testing. In the behavioral sessions, we may ask you to fill out sleep questionnaires. These may take about 10 min. If you are able to menstruate, we may ask you what phase of the menstrual cycle you are in by a questionnaire. We may also randomly assign you to one of multiple groups. You may be asked to see a display, hear a sound and respond by hitting a keyboard.

These may take about 60-90 min/session.

☐ **Meditation**

We may ask you to conduct a 15-min session of mindful meditation before the sleep experiment by listening to a recorded mindfulness medication played from a recorder. While listening to the meditation, we may ask you to wear an EEG cap for PSG recording.

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Will I be paid to take part in this research study?

You will receive $25/hr for participation in MRI or PSG experiments in this study. You may be asked to come back to the MRI Center at Brown University for additional scans or for PSG testing. If you choose to participate in additional studies, you will also be paid $25/hr.

If you are asked to participate in an additional testing session outside the MRI or PSG testing, you will be paid $10/hr for your participation. If you are asked to participate in a behavior-only study, you will be paid $10/hr for your participation.

You will receive $15 per sleep session for wearing the actigraph and keeping the sleep log prior to each sleep session. If you do not complete the study, we will pay you for each hour you completed.

For experiments that require many sessions or a long period of commitment, an extra payment may be offered upon completion of all sessions.

What are the risks and possible discomforts from being in this research study?

MRI
There may be some discomfort from being in the MRI scanner because you will be asked to lie down and be very still for a long time. The research team will try to make you as comfortable as possible before the imaging begins. If you feel claustrophobic or anxiety, let the researcher know immediately. MRI scanning risks and discomforts are discussed in further detail in the fMRI addendum to this consent form.

The flashing pattern that might be displayed by the goggles or television set does not present any health hazards to normal volunteers. If you have a history of epilepsy or other seizure disorder, you should notify the researcher in charge of the scan. It is important in these studies that you remain motionless. The head holder is reasonably comfortable, and designed to keep your head immobilized and in a relaxed position. If the head holder is uncomfortable, you should notify the researcher in charge of the scan. If you are or might be pregnant, it is recommended that you do not participate in this MRI study. The visual displays used are often repeated. If this repetition in the display becomes uncomfortable, you should notify staffs, and the scan may be terminated at any time.

There are no known foreseeable additional risks or side effects associated with electrodes and MRI, other than a very small risk of electrode heating and skin burning with simultaneous PSG + MRI. No serious or lasting incidents or side effects associated with the use of rapidly varying magnetic gradient fields or strong radio frequency fields and electrodes have ever been reported. Discomfort may occur because of (1) the total length of the session, (2) the many sites of electrode preparation and (3) the tedious cleaning of gel is required after completing the session. There may be other risks that are currently unknown.

PSG

There are no known or foreseeable risks or side effects associated with conventional PSG recordings. However, you may be uncomfortable needing to sit still throughout these recordings. There are no known or foreseeable risks or side effects associated with de-magnetization procedures except to those people who have electrically or magnetically mechanically activated implants (such as cardiac pacemakers) or to those who have clips on blood vessels in their brain. There may be other risks that are currently unknown. Removing gel after PSG recordings may require more than one washing.

What are the possible benefits from being in this research study?

This study will not directly benefit you. The study may help tell us more about the roles of sleep on memory and learning.

Clinical Research: This is not a treatment study or designed to improve your health.

What should I do if I want to stop taking part in this study?

If you take part in this study and want to drop out, you should tell us. We will make sure that you will stop the study safely. We will also talk to you about follow-up care if needed.

What is the screening procedure?

Before entering the study, you have been screened to determine eligibility to this study either by email, phone, or in person. However, after entering the study, you may be excluded from this study based on sleep log and/or actigraph recording. In addition, you may be asked to self-report if you have any eye diseases or impairments such as cataracts, macular degeneration, retinopathies, stigmatism, and partial vision loss. If you have an eye disease or impairment, we will ask you not to participate in the experiment. You will not be responsible for providing doctor's note that you have a specific eye disease or impairment. You can wear contact lenses or glasses during the experiments. If EEG cap does not fit your head properly, you may be excluded from this study. If you have seizures, we will ask you not to participate in the experiment. You may be asked to self-report if you have sensitive, allergic, or dry skin. If you have sensitive, allergic, or dry skin, you may be asked to take a skin test, in which we administer alcohol pad and EEG gel on your skin to check your skin sensitivity to determine eligibility to this study.

Before the brain imaging protocol, you may also participate in a training session to learn thoroughly the procedures that will be used during the brain imaging. You will also fill out a "MRI Safety" form, which entails questions about prior surgical interventions and medical implants to ensure your safety

Clinical Trial: A description of this clinical trial will be available on http://www.Clinical Trials.gov, as required by U.S. Law. This Web site will not include information that can identify

you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What should I do if any problem occurs?

Should any problem arise at any point during the study, Prof. Sasaki may be contacted by calling 401-863-2727 (Psychology Main Office).

How will my confidentiality be maintained?

All information will be held in strict confidence and will not be disclosed unless required by law or regulation. Any reports of publications will not identify individual participants by name or initials. Collected data will be stored and locked in the investigator's file or electronically in password-protected computers.

We may reanalyze the data, and the reanalyzed data may be used for future sleep studies. Your privacy and confidentiality of information will be ensured. Neither your full name nor the initials will be shown in any printed/hand-written document which can be read by any individual who is not a registered investigator of the proposed project or in any conference presentation.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

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What should I do if I have any question about the research?

You may ask a question at any time or you can contact Professor Yuka Sasaki. If you have questions about your rights as a research subject, please contact the Human Research Protection Program, Brown University, at (401) 863-3050 or at IRB@brown.edu.

What will happen if I decided to or not to participate in this study?

The participation in this experiment is voluntary. Your decision whether or not to participate will not affect your future relationship with Brown University. If you decide to participate, you are free to withdraw your consent and to discontinue your participation at anytime without penalty of loss of benefits to which you are otherwise entitled.

What does your signature on this document mean?

Your signature on this document indicates that you have decided to participate having read the information provided.

Check if the conditions below apply. Your participation will involve:
☐ Magnetic Resonance Imaging (MRI)
☐ Polysomnography (PSG)
☐ Behavioral Testing

You have read this Informed Consent Form and agree to participate in the study.

THIS EVIDENCE OF INFORMED CONSENT MUST BE SIGNED BY THE PARTICIPANT.

PARTICIPANT:_____ DATE:_____

PERSON EXPLAINING:_____ DATE:_____
THE STUDY

The Participant must also sign the MRI-related Addendum to this Consent Form if the study involves MRI procedures