Grant Title: The emergence of abstract structure knowledge across learning and sleep

NCT number: NCT05746299

Date: July 1, 2019

UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT
INFORMED CONSENT FORM

Protocol Title: Learning and consolidating structured information

Principal Investigator: Dr. Anna Schapiro, Ph.D.
Department of Psychology
425 S University Ave
Philadelphia, PA 19104
aschapir@sas.upenn.edu
215-898-0482

Research Study Summary for Potential Subjects

You are being invited to participate in a research study. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

The research study is being conducted to investigate behavioral and/or brain responses to words or pictures, in order to better understand human learning and consolidation.

If you agree to join the study, you will be asked to make judgements using button presses about words or pictures shown on a computer screen. Depending on the study, you may be asked to take a nap while electrical activity from your brain is measured.

Your participation will last for 1 to 5 hours.

The known risks associated with this study are minimal. If you are in a study that uses EEG, the cap may cause slight discomfort due to gel in the hair.

Please note that there are other factors to consider before agreeing to participate, such as additional procedures, use of your personal information, costs, and other possible risks not discussed here. If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

Why am I being asked to volunteer?

You are invited because you are eligible for the study and because your participation will contribute to identifying the mechanisms involved in certain aspects of learning and consolidation.

What is the purpose of this research study?

The goal of this research is to investigate behavioral and/or brain responses to objects, words, letters, or abstract designs, and depending on the study, may investigate the effects of sleep on these responses.

What am I being asked to do?

Pictures of objects, words, letters, or abstract designs may be shown on the computer screen. Responding to these stimuli will involve simple button presses. The specific tasks involved will vary between studies; therefore, the research staff will provide exact information regarding the stimuli used in this particular study. Depending on the study, the brain's electrical activity may be measured using electroencephalogram (EEG) during the task and/or a sleep period. If EEG is measured, either a two-electrode headband will be worn or an elastic cap with 64 electrodes attached. If a cap is used, a gel solution will be applied to each electrode after the cap is placed on the head. It will take approximately

20-40 minutes to fit the electrode cap. The cap has been cleaned and disinfected thoroughly. After the study has been completed, the electrode cap will be removed. Remaining traces of electrode gel can be easily rinsed out with water.

What are the possible risks or discomforts?

If you are in a study that uses EEG, the cap may cause slight discomfort due to gel in the hair. Otherwise, the procedure is harmless.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?

You are not expected to get any benefit from being in this research study. You will contribute to our understanding of brain function, however, which may help patients with various psychiatric and neurological disorders.

Will I be paid for being in this study?

As compensation for your participation, you will receive course credit or $12 in cash for each hour of the testing session. If you are sleeping in the lab or waiting between two tasks, you will receive $5 per hour during those sleeping or waiting times. If you are completing tasks while wearing an EEG cap, you will receive $15 per hour. If you do not perform well on an initial task, you will be paid for your time on that task but may not be able to continue on to subsequent tasks. If you are doing a multi-session study, there will be a $10 bonus for completing the study. Please note: In order to be compensated for your participation in this study, you must provide your Social Security Number. Additionally, please note that the University of Pennsylvania is required to report to the IRS any cumulative payments for participation in research studies that exceed a total of $600 in a calendar year.

Will I have to pay for anything?

There will be no charge to you as the participant in this study.

Will I receive the results of research testing?

The tests done in the study are only for research and have no clear meaning for health care. Research results will not be returned to you because they would not be relevant to your health care.

When is the Study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped at any time by your physician, the study Sponsor, or the Food and Drug Administration (FDA) without your consent because:

- The Primary Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The Sponsor, the study Principal Investigator, or the Food and Drug Administration (FDA) has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Withdrawal will not interfere with your future care or your status as a Penn student, if you are a Penn student.

How will my personal information be protected during the study?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The Institutional Review Board (IRB) at the University of Pennsylvania will have access to your records. If this study is being overseen by the Food and Drug Administration (FDA), they may review your research records.

All collected data is labeled by a code rather than by name or other personal identifier. The master for the code and data are kept separately. Only the experimenter will ever be aware of the name corresponding to each subject number. In addition, demographic information about you will be retained for subsequent reporting to funding agencies; this information will also be stored under a code and not your name. To ensure data security, consent forms are stored in a locked filing cabinet in our laboratory. Only Dr. Schapiro and the study's personnel have access to this cabinet. Your data will be stored on the password-protected computer system. Only authorized members of our laboratory can access these files.

What may happen to my information collected on this study?

Your information will be de-identified. De-identified means that all identifiers have been removed and there is no way to link your data to your identity. The information will be stored in a public database and shared for future research in this de-identified fashion. This can be done without again seeking your consent in the future, as permitted by law.

Some of the experiments run under this protocol may be funded by the National Institutes of Health and classified as a clinical trial. If this is the case for this study: Data will be submitted to the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health (NIH). NDA is a large database where deidentified study data from many NIH studies are stored and managed. Sharing your deidentified study data helps researchers learn new and important things about brain science more quickly than before.

Deidentified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. The study researchers will have to collect your personal information from you in order to make that code number. The code number cannot be used to identify you, and the researchers will not keep the number stored. The study researchers will never send your personal information to NDA. It is possible that you will participate in more than one study that sends data to NDA. NDA can connect your data from different studies by matching the code number on your deidentified data from each study. This data matching helps researchers who use NDA data to count you only one time. It also helps researchers who use NDA to better understand your health and behavior without knowing who you are.

During and after the study, the study researchers will send deidentified study data about your health and behavior to the NDA. Other researchers across the world can then request your deidentified study data for different research projects. Every researcher (and the institution to which they belong) who requests your deidentified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

You may not benefit directly from allowing your study data to be shared with NDA. The study data provided to NDA may help researchers around the world learn more about brain science and how to help others who have problems with brain science. NIMH will also report to Congress and on its website about the different studies using NDA data. You will not be contacted directly about the study data you contributed to NDA.

You may decide now or later that you do not want your study data to be added to NDA. You can still participate in this research study even if you decide that you do not want your data to be added to NDA. If you know now that you do not want your data in NDA, please tell the study researcher before leaving the clinic today. If you decide any time after today that you do not want your data to be added to

NDA, call or email the study staff who conducted this study, and they will tell NDA to stop sharing your study data. Once your data is part of NDA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about NDA, it is available on-line at http://nda.nih.gov.

A description of this clinical trial will be available on http://www.ClinicalTrials.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.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the IRB at the number on page one of this form.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

_____	_____	
Name of Subject (Please Print)	Signature of Subject	Date
_____	_____	
Name of Person Obtaining Consent (Please Print)	Signature	Date