

Research Subject Information and Consent Form

Study Title for Participants: Sleep Cohort Study –CognitiveStudy

Formal Study Title: The Role of Impaired Neurobehavioral alertness in Cognitive Decline and Alzheimer’s Disease Pathology

Lead Researcher: David Plante, MD, PhD 608-232-3328

9601 UW Psychiatric Inst & Clinics, 6001 Research Park Blvd. Madison, WI 53719

Institution: University of Wisconsin - Madison

INVITATION: You are invited to participate in a research study which comprises 450 participants. You are invited because you previously participated in our Sleep Cohort Study. Your decision to participate in this research is entirely voluntary. Your participation in this research will help us understand how sleepiness and alertness are related to mental abilities, such as memory, learning, and attention. Each of the tests you take part in is done at no cost to you.

The purpose of this consent form is to give you the information you need to decide whether to be in the study. You may ask questions about anything in this form that is not clear. If you want to talk to your family and friends before making your decision, you can. Once we have answered all your questions, you can decide if you want to be in the study. This process is called “informed consent.”

WHAT IS THE PURPOSE OF THE STUDY? This study investigates how sleepiness and alertness affect cognitive functioning.

WHAT WILL MY PARTICIPATION INVOLVE? If you decide to participate in this research study, it will consist of a study visit in your home or at the University Hospital Clinics in the Clinical Research Unit that will last about 2-3 hours.

During this visit, you will be invited to participate in the tests listed below. All tests will be fully explained and you can refuse any part of the study.

- Health Questionnaires—including questions on health and sleep (about 40 minutes)
- Memory testing including word recall, trailmaking, symbol identification, oral word fluency, and digit identification, all administered by a technologist (about 35 minutes)
- Basic measurements of height, weight, and girth (about 10 minutes)
- A test of vigilance and sustained attention (about 15 minutes)

- Vision test (about 10 minutes)
- Vital Signs – such as heart rate

The health questionnaire will either be sent as a survey link via email or as a paper questionnaire through the mail. You will have an opportunity to choose your preference during recruitment. We will only use your email for the purpose of this survey.

We may share information that we collect with other researchers at this and other institutions. As with all information from your participation, your name will never be attached to any data that we share with other researchers, and your confidentiality is strictly protected.

What will happen to my data after my participation ends?

We will keep your data for an indefinite period of time, meaning we have no plans of ever destroying your data. Any future use of your data beyond this study will require additional approvals by the University of Wisconsin Institutional Review Board. This is what will happen with your data:

- We may use the data in future research projects about sleep, health, aging, and/or development.
- The data may be shared with other approved researchers at the University of Wisconsin-Madison or outside the University. Outside researchers may be at other universities or other kinds of research organizations.
- The data will be labeled with a code instead of your name. If we give your data to other approved investigators for research projects, they will not be able to use the code to figure out which data are yours. The research team will maintain a link between your data and your identifiable information kept by the study team.
- You can request to have your data removed from the study by contacting the research team at any time.

Because **health information** from this research study can be useful for many different kinds of research, organizations like the National Institutes of Health (NIH) have created large databases that collect **health information** from research studies. We will put **health information from** this study in a federal database or in other public scientific resources to make the information broadly available. We cannot predict how this information will be used in the future. Because it can be used for many kinds of research, your information may be used for research that you disagree with or would not choose to be involved in. We will share the data from this study in a database that requires researchers to request access and receive permission to use the data for a specific research project. This is called “controlled access.”

By signing this form you are giving permission for your health information to be used by and shared as described in this form. Unless you withdraw your permission in writing to stop the

use of your health information, there is no end date for its use for this research study. You may withdraw your permission at any time by writing to the person whose name is listed below:

David T. Plante, MD, PhD
Wisconsin Sleep
6001 Research Park Blvd.
Madison WI 53719

Beginning on the date you withdraw your permission, no new information about you will be used. Any information that was shared before you withdrew your permission will continue to be used. If you withdraw your permission, you can no longer actively take part in this research study.

WHO IS FUNDING THIS STUDY?

This research is being funded by the National Institutes of Health.

POSSIBLE FUTURE RESEARCH: We would like permission to look at your medical records so that we may investigate whether certain medical conditions are related to information about sleep that we have collected from you. We may look in your medical record for diagnoses related to cardiovascular disease, cancer, injuries, neurocognitive conditions, and metabolic/endocrine conditions. We will look at your past records, as far back as your first visit with the Wisconsin Sleep Cohort. Because this is an ongoing study, we will also look at your records periodically in the future. If you should die before we complete the Wisconsin Sleep Cohort Study, we also might look at the medical records to see if you had any of the conditions mentioned above prior to your passing.

You may indicate whether you are willing to let us look at your medical records by checking below:

_____ Yes, I am willing to let researchers from the Wisconsin Sleep Cohort Study look at my medical records.

ARE THERE ANY RISKS?

There is a risk that your information could become known to someone not involved in this study.

Home visits may occur as part of this study. If child or elder abuse or neglect is observed during a visit, members of the study team may be required by state law to report this to the appropriate authorities. This may include reporting to the local law enforcement or protective service agencies, resulting in legal or social risks to you or other members of your household. Your confidentiality cannot be guaranteed in cases of child or elder abuse.

WHAT IF I AM INJURED? In the event that you are physically injured as a result of participating in this research, emergency care will be available. You will, however, be responsible for the charges for the emergency care. There is no commitment to provide any compensation for research-related injury. You should realize, however, that you have not

released this institution from liability for negligence. Please contact the investigator, Dr. David Plante at (608)265-3296 if you are injured or for further information.

ARE THERE ANY BENEFITS? No direct benefit is expected from participating in this study. Your participation in this research may benefit other people in the future by helping us learn how sleepiness and alertness affect cognitive functioning.

WILL I BE PAID FOR MY PARTICIPATING IN THE STUDY? You will receive \$120 for your participation in this study.

IF I DECIDE TO START THE STUDY, CAN I CHANGE MY MIND? Your decision to participate in this research is entirely voluntary. You may choose not to participate. If you do decide to participate, you may change your mind at any time without penalty or loss of benefits that you had prior to the study. You will be told of any new and significant findings which may affect your willingness to continue. Your decision of whether or not to participate in this study will not affect any relationship you might have with the University of Wisconsin or the quality of your medical care at this institution.

WILL MY CONFIDENTIALITY BE PROTECTED? Researchers might use information learned from this study in scientific journal articles or in presentations. None of this information will identify you personally. All data are identified by code number only. Your file will be confidential and maintained in locked files and a firewall protected database.

WHAT IF I HAVE QUESTIONS? If you have questions about this research, please contact the lab manager, Amanda Rasmuson, at (608)265-5548. If you have any questions about your rights as a research participant or have complaints about the research study or study team, call the confidential research compliance line at 1-833-652-2506. Staff will work with you to address concerns about research participation and assist in resolving problems.

CONSENT

Before signing this form, please ask questions about any aspect of this study that remains unclear. We will attempt to fully answer all questions you may have prior to, during, or following these study questions.

- Would you say that your participation in this study is voluntary or mandatory?
-

- What would you do if you decided that you no longer wanted to participate?
-

- Tell me any of the possible risks associated with being in this study.
-

- Do you want to participate in the research study that has just been described to you?
-

Authorization to participate in the research study:

I have read the information in this consent form, reviewed any questions, and I voluntarily agree to participate in this study. I have received a copy of this consent form.

Signature of Subject

Date

Signature of Person Obtaining Consent

Date

Agent Consent– only required in the event that the participant has lost capacity to consent.

If you are a Legally Authorized Representative (LAR) or the Agent for the person being invited to take part in this study, you are deciding whether the person can be in this research study. You do not have to sign this form. If you refuse to sign, however, the person cannot take part in this research study.

If you sign the line below, it means that:

- You believe the person wants, or would want, to be in the study;

- OR, if you cannot find out if the person wants to take part, you believe that participating in the study is in the person's best interest;

- You give authorization for the person's protected health information to be used and shared as described in this form.

Printed Name of Study Participant

Signature of Agent

Date

Name of Agent (please print)

Signature of Person Obtaining Consent

Date