Research Subject Information and Consent Form

Title of Study: Sleep Cohort Study – In-home Study

Study Investigator: Erika W. Hagen, PhD

INVITATION: You are invited to participate in a research study which comprises 640 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 various aspects of sleep throughout adulthood is related to cognitive and physical functioning in later life. 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 sleep quality and sleep duration throughout midlife may be related to mental and physical health and functioning in later adulthood.

WHAT WILL MY PARTICIPATION INVOLVE? If you decide to participate in this research study, it will consist of an evening study visit in your home that will last about 2-3 hours.

During this visit in your home, 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 series of tests of walking and balance. This includes a test of standing up from a chair, walking 10 feet, and returning to the chair. The walking test will be repeated while you step over small objects (about the size of a shoe box) and while you count backwards out loud (about 15 minutes)
- A test of vigilance and sustained attention (about 15 minutes)
- Vision test (about 10 minutes)
- A test of your grip strength (about 2 minutes)

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 one of the lines below:

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

_____No, I do not want researchers from the Wisconsin Sleep Cohort Study to look at my medical records.

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.

ARE THERE ANY RISKS?
There is a risk that your information could become known to someone not involved in this study.

During the test of balance, there is a risk that you could lose your balance and fall.

Home visits will 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. Erika Hagen 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 more about the long-term effects of sleep on the health of older adults.

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 subject, contact UWHC Patient Relations Representative at (608)263-8009.

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

IRB Approval Date: 7/9/2019
University of Wisconsin – Madison